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Programme décennal d'épandage de phytocides par voie aérienne en milieu forestier sur des terrains privés de Smurfit-Stone inc. sur le territoire de La Tuque et de la MRC du Domaine-du-Roy

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Glyphosate

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for glyphosate.

Use Profile

Glyphosate is a non-selective herbicide registered for use on many food and non-food field crops as well as non-crop areas where total vegetation control is desired. When applied at lower rates, glyphosate also is a plant growth regulator.

Glyphosate is among the most widely used pesticides by volume. It ranked eleventh among conventional pesticides used in the U.S. during 1990-91. In recent years, approximately 13 to 20 million acres were treated with 18.7 million pounds of glyphosate annually. The largest use sites include hay/pasture, soybeans and field corn.

Three salts of glyphosate are used as active ingredients in registered pesticide products. Two of these active ingredients, plus technical grade glyphosate, are contained in the 56 products that are subject to this RED.

The isopropylamine salt, an active ingredient in 53 registered products, is used as a herbicide to control broadleaf weeds and grasses in many food and non-food crops and a variety of other sites including ornamentals, lawns and turf, residential areas, greenhouses, forest plantings and industrial rights-of-way. It is formulated as a liquid, solid or pellet/tablet, and is applied using ground or aerial equipment.

The sodium salt of glyphosate, an active ingredient in two registered pesticide products, is used as a plant growth regulator for peanuts and sugarcane, to modify plant growth and hasten the ripening of fruit. It is applied as a ground spray to peanut fields and as an aerial spray to sugarcane. Preharvest intervals are established for both crops.

The monoammonium salt of glyphosate is an active ingredient in an additional seven herbicide/growth regulator products. This form of glyphosate was initially registered after November 1984, so it is not subject to reregistration or included in this RED. However, in reassessing the existing glyphosate tolerances (maximum residue limits in or on food and feed), EPA included those for the monoammonium salt.

Regulatory History

EPA issued a Registration Standard for glyphosate in June 1986 (NTIS PB87-103214). The Registration Standard required additional phytotoxicity, environmental fate, toxicology, product chemistry and residue chemistry studies. All of the data required have been submitted and reviewed, or were waived.

Human Health Assessment

Toxicity

Glyphosate is of relatively low oral and dermal acute toxicity. It has been placed in Toxicity Category III for these effects (Toxicity Category I indicates the highest degree of acute toxicity, and Category IV the lowest). The acute inhalation toxicity study was waived because glyphosate is non-volatile and because adequate inhalation studies with end-use products exist showing low toxicity.

A subchronic feeding study using rats showed blood and pancreatic effects. A similar study with mice showed reduced body weight gains in both sexes at the highest dose levels. A dermal study with rabbits showed slight reddening and swelling of the skin, decreased food consumption in males and decreased enzyme production, at the highest dose levels.

Several chronic toxicity/carcinogenicity studies using rats, mice and beagle dogs resulted in no effects based on the parameters examined, or resulted in findings that glyphosate was not carcinogenic in the study. In June 1991, EPA classified glyphosate as a Group E oncogen--one that shows evidence of non-carcinogenicity for humans--based on the lack of convincing evidence of carcinogenicity in adequate studies.

In developmental toxicity studies using pregnant rats and rabbits, glyphosate caused treatment-related effects in the high dose groups including diarrhea, decreased body weight gain, nasal discharge and death.

One reproductive toxicity study using rats showed kidney effects in the high dose male pups; another study showed digestive effects and decreased body weight gain. Glyphosate does not cause mutations.

In one metabolism study with rats, most of the glyphosate administered (97.5 percent) was excreted in urine and feces as the parent compound; less than one percent of the absorbed dose remained in tissues and organs, primarily in bone tissue. Aminomethyl phosphonic acid (AMPA) was the only metabolite excreted. A second study using rats showed that very little glyphosate reaches bone marrow, that it is rapidly eliminated from bone marrow, and that it is even more rapidly eliminated from plasma.

Dietary Exposure

The nature of glyphosate residue in plants and animals is adequately understood. Studies with a variety of plants indicate that uptake of glyphosate or AMPA from soil is limited. The material which is taken up is readily translocated throughout the plant and into its fruit. In animals, most glyphosate is eliminated in urine and feces. Enforcement methods are available to detect residues of glyphosate and AMPA in or on plant commodities, in water and in animal commodities.

85 tolerances have been established for residues of glyphosate and its metabolite, AMPA, in or on a wide variety of crops and crop groups, as well as in many processed foods, animal feed and animal tissues (please see 40 CFR 180.364, 40 CFR 185.3500 and 40 CFR 186.3500). EPA has reassessed the existing and proposed tolerances for glyphosate. Though some adjustments will be needed, no major changes in existing tolerances are required. EPA also has compared the U.S. tolerances with international Codex maximum residue limits (MRLs), and is recommending certain adjustments to achieve greater compatibility.

EPA conducted a dietary risk assessment for glyphosate based on a worst-case risk scenario, that is, assuming that 100 percent of all possible commodities/acreage were treated, and assuming that tolerance-level residues remained in/on all treated commodities. The Agency concluded that the chronic dietary risk posed by glyphosate food uses is minimal.

A reference dose (RfD), or estimate of daily exposure that would not cause adverse effects throughout a lifetime, of 2 mg/kg/day has been proposed for glyphosate, based on the developmental toxicity studies described above.

Occupational and Residential Exposure

Occupational and residential exposure to glyphosate can be expected based on its currently registered uses. However, due to glyphosate's low acute toxicity and the absence of other toxicological concerns (especially carcinogenicity), occupational and residential exposure data are not required for reregistration.

Some glyphosate end-use products are in Toxicity Categories I or II for primary eye irritation or skin irritation. In California, glyphosate ranks high among pesticides causing illness or injury to workers, who report numerous incidents of eye and skin irritation from splashes during mixing and loading.

EPA is not adding any personal protective equipment (PPE) requirements at this time, but any existing PPE label requirements must be retained.

The Worker Protection Standard (WPS) for Agricultural Pesticides (please see 40 CFR 156 and 170) established an interim restricted entry interval (REI) of 12 hours for glyphosate. The Agency has decided to retain this REI as a prudent measure to mitigate risks to workers. During the REI, workers may reenter areas treated with glyphosate only in the few, narrow exceptions allowed in the WPS. The REI applies only to glyphosate uses within the scope of the WPS, so homeowner and commercial uses are not included.

Human Risk Assessment

EPA's worst case risk assessment of glyphosate's many registered food uses concludes that human dietary exposure and risk are minimal. Existing and proposed tolerances have been reassessed, and no significant changes are needed to protect the public.

Exposure to workers and other applicators generally is not expected to pose undue risks, due to glyphosate's low acute toxicity. However, splashes during mixing and loading of some products can cause injury, primarily eye and skin irritation. EPA is continuing to recommend PPE, including protective eye wear, for workers using end-use products that are in Toxicity Categories I or II for eye and skin irritation. To mitigate potential risks associated with reentering treated agricultural areas, EPA is retaining the 12 hour REI set by the WPS.

Environmental Assessment

Environmental Fate

Glyphosate adsorbs strongly to soil and is not expected to move vertically below the six inch soil layer; residues are expected to be immobile in soil. Glyphosate is readily degraded by soil microbes to AMPA, which is degraded to carbon dioxide. Glyphosate and AMPA are not likely to move to ground water due to their strong adsorptive characteristics. However, glyphosate does have the potential to contaminate surface waters due to its aquatic use patterns and through erosion, as it adsorbs to soil particles suspended in runoff. If glyphosate reached surface water, it would not be broken down readily by water or sunlight.

Ecological Effects

Glyphosate is no more than slightly toxic to birds and is practically non-toxic to fish, aquatic invertebrates and honeybees. Due to the presence of a toxic inert ingredient, some glyphosate end-use products must be labeled, "Toxic to fish," if they may be applied directly to aquatic environments. Product labeling does not preclude off-target movement of glyphosate by drift. EPA therefore is requiring three additional terrestrial plant studies to assess potential risks to nontarget plants.

EPA does not expect that most endangered terrestrial or aquatic organisms will be affected by the registered uses of glyphosate. However,

many endangered plants as well as the Houston toad (due to its habitat) may be at risk. EPA is deferring any use modifications or labeling amendments until it has published the Endangered Species Protection Plan and has given registrants guidance regarding endangered species precautionary labeling.

Ecological Effects Risk Assessment

Based on current data, EPA has determined that the effects of glyphosate on birds, mammals, fish and invertebrates are minimal. Under certain use conditions, glyphosate may cause adverse effects to nontarget aquatic plants. Additional data are needed to fully evaluate the effects of glyphosate on nontarget terrestrial plants. Risk reduction measures will be developed if needed, once the data from these studies are submitted and evaluated.

Additional Data Required

EPA is requiring three generic studies (Tier II Vegetative Vigor, Droplet Size Spectrum, and Drift Field Evaluation) which are not part of the target data base and do not affect the reregistration eligibility of glyphosate. The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, as well as revised Confidential Statements of Formula and revised labeling.

Product Labeling Changes Required

All end-use glyphosate products must comply with EPA's current pesticide product labeling requirements. In addition:

- **Protection of Aquatic Organisms**

Non-Aquatic Uses - End-use products that are not registered for aquatic uses must bear the following label statement:

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters and rinsate.

Aquatic Uses - End-use products registered for aquatic uses must bear the following label statement:

Do not contaminate water when disposing of equipment washwaters and rinsate. Treatment of aquatic weeds can result in oxygen loss from decomposition for dead plants. This loss can cause fish kills.

- **Worker Protection Standard (WPS) Requirements**

Any product whose labeling permits use in the production of an agricultural plant on any farm, forest, nursery or greenhouse must comply with the labeling requirements of:

• PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and

• PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7."

Unless specifically directed in the RED, all statements required by these two PR Notices must appear on product labeling exactly as instructed in the Notices. Labels must be revised by April 21, 1994, for products distributed or sold by the primary registrant or supplementally registered distributors, and by October 23, 1995, for products distributed or sold by anyone.

- **Personal Protective Equipment (PPE)**

No new PPE requirements must be added to glyphosate labels. However, any existing PPE requirements on labels must be retained.

- **Entry Restrictions**

Products Not Primarily Intended for Home Use:

o Uses Within the Scope of the WPS - A 12-hour restricted entry interval (REI) is required for all products with uses within the scope of the WPS, except products intended primarily for home use. The PPE for early entry should be that required for applicators of glyphosate, except any applicator requirement for an apron or respirator is waived. This REI and PPE should be inserted into the standardized statements required by PR Notice 93-7.

• Sole Active Ingredient End-Use Products - Labels must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on current labeling must be removed.

• Multiple Active Ingredient Products - Registrants must compare the entry restrictions set forth in this section to those on their current labeling and retain the more protective. A specific time period in hours or days is considered more protective than "until sprays have dried" or "dusts have settled."

o Uses Not Within the Scope of the WPS - No new entry restrictions must be added. However, any entry restrictions on current product labeling with these uses must be retained.

Products Primarily Intended for Home Use:

o No new entry restrictions must be added. However, any entry restrictions on current product labeling must be retained.

Regulatory Conclusion

The use of currently registered pesticide products containing the isopropylamine and sodium salts of glyphosate in accordance with the labeling specified in this RED will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

These glyphosate products will be reregistered once the required product-specific data, revised Confidential Statements of Formula and revised labeling are received and accepted by EPA.

Products which contain active ingredients in addition to glyphosate will not be reregistered until all their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for glyphosate during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703- 305-5805.

Following the comment period, the glyphosate RED document will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the glyphosate RED, or reregistration of individual products containing glyphosate, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.