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SCIENTIFIC DATA REVIEWS
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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 29-AUG-2002

Subject: PP#0F06130. Glyphosate. Review of Amendment Dated 25-APR-2002 to Modify the Supplemental Label for Roundup UltraMAX Herbicide for Applications to Wheat with the Roundup-Ready Gene.

DP Barcode: D285042

Class: Herbicide

PC Code: 417300, 103601

Submission: S620691

40 CFR: 180.364

EPA Reg. No.: 524-512

From: William H. Donovan, Ph.D., Chemist
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Health Effects Division (HED) (7509C)

Through: G. Jeffrey Herndon, Branch Senior Scientist
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To: Jim Tompkins/Michelle Centra, PM Team 25
Registration Division (RD) (7505C)

In a review of PP#s 0F6130, 0F6195, and 0F6273, HED determined that, based on the proposed use pattern and submitted field trial data, the appropriate tolerance level for wheat grain was 6.0 ppm (D265970, W. Donovan, 31-JAN-2002). The proposed use pattern consisted of 1) preplant/preemergence applications, 2) a postemergence over-the-top application, and 3) a preharvest application. Wheat field trial data were submitted that reflected several different application scenarios. The highest relevant glyphosate residue level in wheat grain (5.6 ppm) was obtained from a use pattern that included the preharvest application.

In response to the HED review, Monsanto submitted a revised Supplemental Label that removed the preharvest use and requested that the wheat, grain tolerance level remain at 5.0 ppm. Monsanto also included the following label modifications requested by HED: 1) the maximum seasonal application rate per acre was added, 2) a 30-day plant back restriction for rotational crops not approved on the label has been added, 3) a restriction against the use of additives, including surfactant and ammonium sulfate has been added, and 4) the application rates have been adjusted to reflect the increased glyphosate concentration in Roundup UltraMAX.

Conclusions/Recommendations

HED concurs that, based on the removal of the preharvest application to wheat, the field trial data now support a tolerance level of 5.0 ppm for "wheat, grain". The modified Supplemental Label is acceptable except for the use instructions included under the heading "Over-the-top". These instructions now read as follows: "Any single over-the-top broadcast application should not exceed 26 fluid ounces per acre. No more than two over-the-top broadcast applications may be made from crop emergence through the fifth leaf stage of development. Sequential over-the-top applications of this product should be at least 10 days apart."

These instructions should make it clear that the maximum total application rate for over-the-top application is 26 ounces per acre per season. Accordingly, HED recommends that the registrant add the following sentence to the end of the "Over-the-top" section of the Supplemental Label: "The combined total application rate from crop emergence through the 5-leaf stage must not exceed 26 fluid ounces per acre per season." **A revised Supplemental Label should be submitted.**

cc: W. Donovan, D. Vogel
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Chemical: Glyphosate; Isopropylamine glyphosate (N-(phosphono

PC Code: 417300; 103601

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