



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 24 1992

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Amended Registration of Harmony® Extra Herbicide (50% DPX-M6316 and 25% DPX-L5300) on Wheat and Barley. Request to extend the Application timing. (EPA Reg. No. 352-538) (MRID No. 420380-01; CBRS No. 8760; DP Barcode No. D170042)

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TO: J. Miller/M. Ermusele-Matzer, PM-23
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In response to our review of Clyde T. Stanton and Christine L. Olinger (dated 6/17/91), the petitioner, E. I. du Pont de Nemours & Co., Inc. has submitted supplemental labeling data and comments to those deficiencies for Harmony Extra Herbicide associated with the extension of the application timing of the product. After a brief background, the deficiencies are restated below as in the conclusions by C. T. Stanton and C. Olinger, memo dated 6/17/91, followed by du Pont's response and our comments.

Background

Harmony® Extra Herbicide (EPA Reg. No. 352-538) is a registered pesticide of E. I. du Pont de Nemours & Co., Inc. The product contains 50% DPX-M6316 (methyl 3-(((4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino)carbonyl)amino)sulfonyl 2-thiophene carboxylate) and 25% DPX-L5300 (methyl 2-(((N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)methylamino)carbonyl)amino)sulfonyl)benzoate) as its active ingredients.

Tolerances are established for each of the active ingredients, DPX-M6316 (40 CFR 180.439) and DPX-L5300 (40 CFR §180.451), on barley and wheat grain at 0.05 ppm and in or on wheat and barley straw at 0.1 ppm. Both pesticides have application timings restricting their use to between the two-leaf stage and prior to the first node appearing for spring wheat and barley and between the two-leaf stage and third node appearance for winter wheat. The proposed label amendment expands the application timing from the two-leaf stage to before the flag leaf is visible and has a 45-day PHI. The proposed label amendment was not recommended because the submitted data concerning stability of extracts prior to analyses and extraction from one study with fortification data from another study could not be confirmed (C. T. Stanton and C. Olinger, memo dated 6/17/91)

Deficiencies #1 & #2

Du Pont must clarify when extractions, analyses and concurrent fortifications were conducted for MRID No. 417512-03 (Du Pont Report No. AMR-1114-88).

EPA must be able to confirm that sufficient fortifications were conducted and that degradation was not likely to occur during the interval between extraction and analyses.

Du Pont's Response to Deficiencies #1 & #2:

The registrant has provided the date of extraction and analyses of samples that shows all (fortified, control) samples for DPX-M6316 and DPX-L5300 in or on grains and straws were extracted and analyzed within 4 and 6 days (respectively).

All samples were analyzed according to analytical protocol which specified that each set of samples was to be processed with a control and a number of control fortifications equal to at least 20% of the number of treated samples analyzed in that set. All samples were stored at -20 °C after extraction until injection into the clean-up chromatograph; centrifugation was done at -5 °C; samples were collected from clean-up chromatography at 0 °C; and samples were acidified just before injection to HPLC and were not stored after acidification.

CBRS Comments on Du Pont's Response to Deficiencies #1 & #2

Deficiencies #1 & #2 are resolved.

Conclusions and recommendations:

1. The deficiencies (originally, conclusions 2 and 3) cited in our review dated 6/17/91 are resolved.
2. The petitioner has submitted sufficient data in support of this amended registration for Harmony® Extra Herbicide labeling to extend the application timing, which reduces the PHI from 60 days to 45 days.
3. The data submitted previously support this amendment and the residues of DPX-M6316 and DPX-L5300 will not exceed the established tolerances in/on wheat and barley grain or in/on wheat and barley straw.

CBRS has no objection to this amended registration to extend application timing for Harmony® Extra Herbicide (EPA Reg. No. 352-538) on wheat and barley.

cc: Harmony S.F., R.F., Circ., F. Toghrol, C. Furlow (PIB/FOD).
RDI: W.J. Hazel (1/22/92): E. Zager: (1/22/92):
H7509C:DEB:F.Toghrol:F.T.:RM:802:CM#2:703-305-7887:12/6/91.