

February 11, 1993

PESTICIDE REGULATION (PR) NOTICE 93-02

NOTICE TO REGISTRANTS, PRODUCERS, AND FORMULATORS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Registration of Pesticides

SUBJECT: **Waiver of Crop Field Trial Data for Aerial Applications**

This notice is to inform all pesticide registrants that the requirement for crop field trials (residue data) reflecting aerial applications may be waived under certain circumstances provided adequate data are available on the same crop following application with ground equipment.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires the registration of all pesticides distributed or sold in the United States. Additionally, if a proposed use of a pesticide may result in residues in or on agricultural commodities used for food or livestock feed, a tolerance or exemption from tolerance must be obtained under the Federal Food, Drug and Cosmetic Act (FFDCA) or the food will be deemed adulterated.

EPA regulations in 40 CFR 180.7, 180.34 and [158.240](#) require that data be submitted establishing the residue that may remain in or on a raw agricultural commodity when the pesticide chemical is applied according to directions registered under [FIFRA](#) or according to directions contained in an application for registration. Such residue data are generated by studies commonly referred to as "crop field trials" and are used to determine the tolerance level for the pesticide.

Since a tolerance is established to cover the maximum residue likely to occur on a raw agricultural commodity, crop field trials involve the maximum application rate, maximum number of applications, and, in most cases, the minimum preharvest interval (PHI; time between last application and harvest) permitted by the label directions. In the absence of data showing otherwise, it has been EPA policy that application of pesticides by aerial equipment could result in higher residues than those obtained from ground applications. Therefore, if registrants desired to allow aerial applications of a pesticide on the product label, crop field trials reflecting such treatments were required to determine what tolerance should be established or to determine if a tolerance established on the basis of ground data is still adequate.

In May 1991 the National Agricultural Chemicals Association (NACA) submitted a study entitled "A Comparison of Pesticide Residues Obtained as a Result of Ground and Aerial Application Techniques". This study was accompanied by a request that the crop field trial requirement be waived for aerial applications provided adequate ground application data are available and a minimum spray volume of 2 gallons per acre (GPA) is specified for the aerial use.

The NACA study included 94 cases or comparisons of residues of a wide variety of pesticides on assorted crops following ground and aerial applications. All but 23 of

these cases involved "side-by-side" plots so that the crops treated by ground and aerial equipment would have the same growing conditions. In other words, factors such as rainfall and temperature could be eliminated as causes of different residue levels. Therefore, if differences in residues were observed between the "side-by-side" plots, they would likely be due to the mode of application. Most of the aerial applications were made using spray volumes of 2-10 gallons per acre. It was not NACA's intent to obtain a data waiver for spray volumes less than 2 GPA (often referred to as ultra-low volume applications).

The NACA cases were reviewed by EPA scientists, who drew the same basic conclusion as NACA. In almost all cases the residues resulting from ground application were comparable to or higher than those obtained from aerial application at the same rate and preharvest interval. Therefore, since tolerances are established to cover the maximum residue likely to be present, the Agency has concluded that crop field trials involving application with ground equipment are adequate to register use of aerial equipment with a few limitations on the gallons per acre and the type of diluent as spelled out below.

Based on the results of the NACA study, the Agency policy regarding residue data requirements for aerial applications for the purposes of establishing tolerances is changed as follows:

Provided that the pesticide product label specifies that aerial applications are to be made in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree or orchard crops), crop field trials reflecting aerial application will be waived in those cases where adequate data are available from use of ground equipment reflecting the same application rate, number of applications, and preharvest interval. This data waiver does not apply to aerial applications using diluents other than water (e.g., vegetable oils). In addition, the Agency reserves the right to require aerial data if special circumstances warrant it.

Examples where the aerial residue data may still be required include instances where ground applications are prohibited due to regulatory actions based on factors other than residues in food or when a more accurate dietary exposure estimate is needed to estimate the risk from a pesticide.

Persons desiring further information on this notice may contact:

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