

US EPA ARCHIVE DOCUMENT



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

April 19, 2002

**CERTIFIED MAIL**

Rodney Akers  
Registration Scientist  
BASF Corporation  
P.O. Box 13528  
Research Triangle Park, NC 27709-3528

Dear Mr. Akers:

This is the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for difenzoquat", which was approved on April 19, 2002. A Notice of Availability of this tolerance reassessment decision will be published in the *Federal Register* (FR) shortly.

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the date of the enactment of the FQPA, which was in August of 1996. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. Once a safety finding has been made that aggregate risks are not of concern, the tolerances are considered reassessed. A reregistration eligibility decision (RED) for difenzoquat was completed in September 1994, prior to FQPA enactment. Therefore, the tolerances need to be reassessed to meet the FQPA standard.

The Agency has evaluated the dietary risk associated with difenzoquat and has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to difenzoquat when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, no mitigation measures are needed, and the twenty two (22) tolerances established for residues of difenzoquat in/on raw agricultural commodities are now considered reassessed as safe under section 408(q) of the FFDCA.

FQPA requires that EPA consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” The reason for considering other substances is because of the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect, as would a higher level of exposure to any of the other substances individually. EPA did not perform a cumulative risk assessment as part of this review of difenzoquat, because the Agency has not determined that there are any other chemical substances that have a mechanism of toxicity common with that of difenzoquat. If EPA identifies other substances that share a common mechanism of toxicity with difenzoquat, then a cumulative risk assessment will be conducted that includes difenzoquat once the final framework EPA will use for conducting cumulative risk assessments is available. Further, EPA is in the process of developing criteria for characterizing and testing endocrine disrupting chemicals and plans to implement an Endocrine Disruptor Screening Program. Difenzoquat will be reevaluated at that time and additional studies may be required.

The Agency’s human health findings for the pesticide difenzoquat, were discussed in a closure conference call, and are summarized in the enclosed chemical overview and summary of the risk assessments. The risk assessments and other documents pertaining to the difenzoquat tolerance reassessment decision are listed at the end of this document and are available on the Internet at <http://www.epa.gov/pesticides/reregistration/status.htm> and the public docket for viewing.

Tolerances are established for residues of difenzoquat, derived from application of the methyl sulfate salt and calculated, in/on barley, wheat, and animal commodities [Source: 40 CFR §180.369]. Current tolerances range from 0.05 to 20 ppm for residues in/on barley and wheat commodities, and are 0.05 ppm for residues in livestock commodities. Adequate enforcement methods are available for the determination of difenzoquat residues in/on plant and animal commodities.

The Agency has recommended establishing tolerances in processed commodities, barley bran, wheat bran and wheat shorts at 0.25 ppm and has reassessed the tolerances for wheat straw, barley straw, and barley grain at 5.0, 5.0 and 0.05 ppm, respectively. Fat, meat, and meat byproducts of poultry are being reassessed each at 0.05 ppm. (See Table I)

The available livestock feeding data suggest that the established tolerances for residues of difenzoquat in ruminant meat are adequate. However, actual reassessment of ruminant meat tolerances will be made when the requested residue data for all major livestock feed (wheat forage and hay; and barley hay) items have been submitted and a re-calculation of maximum dietary burden has been performed. Meanwhile, the label restriction against the grazing of livestock on treated fields and the cutting of treated forage for silage/hay should remain on the label until forage and hay data are submitted and evaluated.

The Codex Commission has not established or proposed maximum residue limits (MRLs) for residues of difenzoquat in/on various raw agricultural and processed commodities. Therefore, there are no inquiries with respect to compatibility of U.S. tolerances with Codex MRLs.

**Table I. Tolerance Reassessment Summary for Difenzoquat**

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment
<i>Tolerances listed under 40 CFR §180.369</i>			
Barley, grain	0.2	0.05	
Barley, straw	20	5.0	
Cattle, fat	0.05	TBD	
Cattle (mbyp)	0.05	TBD	<i>[Cattle, meat byproducts]</i>
Cattle, meat	0.05	TBD	
Goats, fat	0.05	TBD	<i>[Goat, fat]</i>
Goats (mbyp)	0.05	TBD	<i>[Goat, meat byproducts]</i>
Goats, meat	0.05	TBD	<i>[Goat, meat]</i>
Hogs, fat	0.05	TBD	<i>[Hog, fat]</i>
Hogs (mbyp)	0.05	TBD	<i>[Goat, meat byproducts]</i>
Hogs, meat	0.05	TBD	<i>[Hog, meat]</i>
Horses, fat	0.05	TBD	<i>[Horse, fat]</i>
Horses (mbyp)	0.05	TBD	<i>[Horse, meat byproducts]</i>
Horses, meat	0.05	TBD	
Poultry, fat	0.05	0.05	
Poultry (mbyp)	0.05	0.05	<i>[Poultry, meat byproducts]</i>
Poultry, meat	0.05	0.05	
Sheep, fat	0.05	TBD	
Sheep (mbyp)	0.05	TBD	<i>[Sheep, meat byproducts]</i>
Sheep, meat	0.05	TBD	
Wheat, grain	0.05	0.05	
Wheat, straw	20	5.0	

<i>Tolerances That Need To be Proposed Under 40 CFR §180.369</i>			
Wheat, bran	None	0.25	
Barley, bran	None	0.25	
Wheat, shorts	None	0.25	

Note that technical registrants will be sent a Section 3(c)(2)(B) Data-Call-In (DCI) letter under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) in a separate mailing. If you have questions on this document, please contact the Chemical Review Manager, Tawanda Spears, at (703) 308-8050.

Sincerely,

Lois A. Rossi, Director  
Special Review and  
Reregistration Division

Enclosures: "Difenzoquat Overview" and "Difenzoquat Summary"