

use pattern for these emergency exemptions will not result in residues of diflubenzuron in excess of the following levels: Wheat and barley grain at 0.05 ppm, wheat and barley straw at 0.50 ppm, wheat and barley hay at 1.0 ppm, wheat milled byproducts at 0.10 ppm, and aspirated grain fractions at 30 ppm.

Therefore, tolerances are being established for these commodities at these levels. The risk assessment related to incremental addition of these items at this level to dietary exposure is discussed below. Refer also to the September 19, 2002 **Federal Register** document for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies in part upon that risk assessment and the findings made in that **Federal Register** document in support of this action. Below is a brief summary of the aggregate risk assessment.

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. A summary of the toxicological dose and endpoints for diflubenzuron for use in human risk assessment is discussed in the final rule mentioned above, published in the **Federal Register** of September 19, 2002 (67 FR 59017) (FRL-7200-4).

EPA assessed risk scenarios for diflubenzuron under chronic exposures only. Chronic risk estimates were calculated for the residues of toxicological concern, the parent compound of the insecticide diflubenzuron (*N*-[4-chlorophenyl]amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites, CPU and PCA. For the chronic analysis, ARs and PCT information for some commodities were also used. An acute dietary exposure analysis was not performed, because there were no acute toxicological endpoints identified (no effects of concern occurring as a result of a 1 day or single exposure). Short-term aggregate exposure, which takes into account residential exposure plus chronic exposure, was not assessed since diflubenzuron is not registered for use on any sites that would result in substantial residential exposure. Intermediate-term aggregate exposure, which takes into account residential exposure plus chronic exposure to food and water was not assessed, because intermediate-term exposure to diflubenzuron would not be expected from the registered and proposed use

patterns. Aggregate cancer risk for the U.S. population was assessed, since the metabolite, CPU, is of concern for aggregate cancer risk and could be found in drinking water.

A refined, chronic dietary exposure assessment was conducted for the general U.S. population and various population subgroups using the Dietary Exposure Evaluation Model (DEEM™) Version 1.3. software with the Food Commodity Intake Database (FCID). The chronic analysis was performed using ARs and PCT information for several registered plant and livestock commodities, and recommended tolerance-level residues and 100% CT information for all proposed commodities. The chronic dietary exposure estimates are below levels of concern (<100% of the chronic population adjusted dose (cPAD)) for that general U.S. population and all population subgroups. The most highly exposed population subgroups are all infants <1 year old and children 1–2 years old (both at 3% of the cPAD).

A cancer dietary exposure assessment from consumption of PCA and CPU was conducted in the previous risk assessment. Based on the submitted metabolism studies, there are two possible sources for dietary exposure to PCA and CPU: Residues in fungi (mushrooms), and residues in animal commodities (milk and liver). As the wheat and barley uses will not result in additional dietary exposure to PCA and CPU, an updated cancer dietary exposure assessment was not needed to support the current section 18 request. The results of the previous cancer analysis indicated that the estimated cancer dietary risk associated with the use of diflubenzuron is below the Agency's level of concern.

Dietary exposure from drinking water. For the current use on wheat and barley, a chronic aggregate exposure (food + drinking water) assessment was performed. Acute, short-term and intermediate-term aggregate risk assessments were not performed because an acute dietary endpoint was not selected and there are no registered or proposed non-food uses resulting in significant residential exposure, respectively. A cancer aggregate exposure (food + drinking water) assessment was not conducted because, as mentioned above, the current uses will not result in additional dietary exposure to CPU.

Since EPA does not have ground water and surface water monitoring data to calculate a quantitative aggregate exposure, Drinking Water Levels of Concern (DWLOCs) were calculated. A DWLOC is a theoretical upper limit on

a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary depending on the toxic endpoint, drinking water consumption, body weights, and pesticide uses. Different populations will have different DWLOCs. EPA uses DWLOCs in the risk assessment process to assess potential concern for exposure associated with pesticides in drinking water. DWLOC values are not regulatory standards for drinking water. To calculate DWLOCs, the dietary food estimates (from DEEM™-FCID) were subtracted from the population adjusted dose (PAD) value to obtain the maximum water exposure level. DWLOCs were then calculated using the standard body weights and drinking water consumption figures: 70kg/2L (U.S. population and adult male), 60 kg/2L (adult female and youth), and 10kg/1L (infants and children). For chronic dietary exposure, EPA's level of concern is exceeded when estimated dietary risk exceeds 100% of the cPAD.

The chronic drinking water assessment resulted in chronic DWLOCs for the overall U.S. population of 690 parts per billion (ppb), and for all infants (<1 year old) and children (1–2 years) of 190 ppb (the population subgroups with the lowest DWLOC). All chronic DWLOCs were well above the chronic estimated environmental concentration (EEC) for ground water of 0.067 ppb. The chronic DWLOCs were also above the chronic EEC for surface water of 0.32 ppb.

Thus, results of the chronic analysis indicate that the estimated chronic dietary risk associated with the proposed use of diflubenzuron is below levels of concern, and chronic aggregate risk estimates are also below the level of concern.

Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to diflubenzuron residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate methods are available for the analysis of diflubenzuron, PCA, and CPU in crops. Three enforcement methods for diflubenzuron are published in the Pesticide Analytical Method Volume II (PAM II) as Methods I, II, and III.

B. International Residue Limits

There are no Codex proposals, Canadian, or Mexican limits for residues