Department of Pesticide Regulation

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DATE: August 9, 2017

SUBJECT: Discontinuance of Tolerance Assessments in HHAB Risk Characterization Documents

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The Food Safety Act of 1989 requires the Department of Pesticide Regulation (DPR) to evaluate potential health risks resulting from human exposures to pesticides in the diet. (Stat. 1989, c.1200, §8, codified as Food & Agricultural Code, § 13134). Historically, scientists from the Risk Assessment Section (RAS) of DPR's Human Health Assessment (HHA) Branch prepared two types of dietary assessments on targeted pesticides: (1) total dietary exposure assessments, which estimated the risk from exposure to residues on commodities with established tolerances for the pesticide of concern, and (2) tolerance assessments, which evaluated the health protectiveness of pesticide tolerances for individual commodities (DPR, 2009). This memorandum concerns the second of these, the tolerance assessment.

Tolerances are legal maximum residue concentrations on raw agricultural commodities or processed food. U.S. EPA sets tolerances under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). The federal tolerances for pesticides on individual commodities are found in Code of Federal Regulations, Title 40, Part 180. In 1996, the FFDCA was amended by the Food Quality Protection Act to give U.S. EPA the authority to set food tolerances for individual commodities, preempting the authority of any state to do so unless the state goes through a petition process that requires specific data on compelling local conditions that would justify a different tolerance (FFDCA, Section 408). However, in no case can a tolerance be higher than the tolerance established by U.S. EPA.

There are differences in how U.S. EPA and RAS/DPR evaluate the health protectiveness of tolerances for specific pesticides. U.S. EPA evaluates all commodities with registered uses to

establish tolerances for each commodity that are health protective (the "risk cup" analysis). RAS/DPR evaluates tolerances by assessing acute exposures to individual commodities at the tolerance level. RAS/DPR does not include all commodities simultaneously at their respective tolerances because acute exposures at those levels are unlikely. Since the analysis done by RAS/DPR is not providing the information necessary to overcome federal preemption of a legal tolerance, there is no need to continue to perform these assessments. Further, the provisions of the Food & Agricultural Code that reference the establishment of food tolerances give DPR the discretion to review tolerances, but do not mandate such review (sections 12561-12565).
In order to make sure HHA uses resources and staff time wisely, we recommend that RAS/DPR discontinue conducting pesticide tolerance assessments in the context of our risk characterization documents. However, RAS will continue to conduct tiered dietary evaluations, including estimating exposures resulting from pesticide residues at tolerance levels on all commodities combined, using a tiered approach as described in our dietary exposure guidance (DPR, 2009). Ultimately, our focus should be on producing refined total dietary assessments.

Reference:

DPR (2009). DPR MT-3. Guidance for Dietary Exposure Assessment, Version IV. Medical Toxicology Branch, Department of Pesticide Regulation, California Environmental Protection Agency, Sacramento, CA