

**Candidate for Listing via the Authoritative Bodies Mechanism
Being Referred to Developmental and Reproductive Toxicant Identification
Committee**

**Office of Environmental Health Hazard Assessment
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The U.S. Environment Protection Agency (U.S. EPA), an authoritative body for purposes of Proposition 65 (Title 22, California Code of Regulations, section 12306 (22 CCR 12306(1))), identifies chemicals as causing developmental or reproductive toxicity in implementing its Toxic Release Inventory (TRI) program (*i.e.*, section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA)). On this basis the U.S. EPA, in 1994, added a number of chemicals to the TRI list and published its findings in the *Federal Register* (**59**:1788-1859, 1994 and **59**:61432-61485, 1994). The Office of Environmental Health Hazard Assessment (OEHHA) has reviewed the bases for these TRI chemical additions in the context of the regulatory criteria governing Proposition 65 listing via the authoritative bodies mechanism (22 CCR 12306).

OEHHA determined for several TRI chemicals that the 22 CCR 12306 regulatory criteria were met and is in the process of placing these chemicals on the Proposition 65 list of chemicals known to cause reproductive toxicity. For metribuzin (CAS No. 21087-64-5), there is significant ambiguity in the record regarding how U.S. EPA characterizes the reproductive toxicity of the chemical. Metribuzin is no longer under consideration for administrative listing, and will be referred to the Developmental and Reproductive Toxicant Identification Committee for consideration.

Metribuzin (CAS No. 21087-64-5)

Two developmental toxicity studies in rabbits were cited by U.S. EPA as the basis for identification under TRI of metribuzin as causing developmental toxicity. In U.S. EPA's 1997 *Reregistration Eligibility Decision (RED): Metribuzin*, U.S. EPA reviewed the same two studies in rabbits that formed the basis for the TRI identification, as well as a developmental toxicity study in rats which showed similar effects, and concluded that "at this time metribuzin is not considered to be a developmental toxicant." This conclusion is accompanied by the statement that "developmental toxicity in these studies occurred at or above doses that induced maternal toxicity." Although the discussion of maternal toxicity in this RED document is more extensive and detailed than that provided in the TRI documentation, maternal toxicity was taken into consideration in the TRI process also. Thus, it appears that the authoritative body has formed two conflicting opinions on the developmental toxicity of metribuzin based on essentially the same information.

Title 22, California Code of Regulations, Section 12306 does not explicitly address the situation posed here, i.e., a contrary conclusion reached on essentially the same data by two different regulatory programs within the same authoritative body. However, there is some guidance in this regard in the controlling regulation and the Statement of Reasons prepared in conjunction with adoption of this regulation. More specifically, subsection (j) of 22 CCR 12306 is somewhat analogous to this situation. That provision specifies that a determination by OEHHA that the authoritative body no longer identifies a chemical added to the Proposition 65 list as causing cancer or reproductive toxicity shall be grounds for reconsideration of the chemical. Reconsideration results in referral of the chemical to the appropriate committee for its review and consideration. In addition, the Statement of Reasons for 22 CCR 12306 makes it clear that merely “procedural” or “ministerial” objections will not result in chemicals that are in the Notice of Intent to List stage being referred to the Committee. In this instance, the ambiguity in the record as to how U.S. EPA views the developmental toxicity of metribuzin, is certainly much more than a mere ministerial or procedural matter. Accordingly, and consistent with the overall spirit of 22 CCR 12306 that the lead agency will not substitute its judgment for that of the authoritative body, metribuzin is being referred to the Developmental and Reproductive Toxicant Identification Committee for its consideration whether the chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause reproductive toxicity.