



DIETARY EXPOSURE AND RISK/TOLERANCE PETITIONS

Section 408 of the U.S. Federal Food, Drug, and Cosmetic Act (FFDCA) requires that a residue tolerance or exemption from the requirement of a tolerance must be established for all ingredients of a pesticide product before a food crop use pattern may be registered. Tolerances are based on crop field trials. They are established for enforcement purposes and represent the maximum residue that may be found when the product is applied according to label directions. A dietary risk assessment is conducted to ensure that there is reasonable certainty that no harm will result from consumption of foods from treated crops. An exemption from tolerance may be established when the total quantity of the chemical used on all commodities for which it is useful will involve no hazard to public health. Petitions are evaluated by the U.S. Environmental Protection Agency's (US EPA) Office of Pesticide Programs (OPP).

Tolerances and exemptions from tolerance petitions include information about product chemistry, toxicology, residue field trials, the proposed use pattern, and reasonable grounds for granting the tolerance or exemption. The registrant must also provide a public document summarizing this information for publication in the Federal Register.

toXcel can help you with any or all aspects of tolerance or exemption petitions, including determining whether your data base is adequate, placing studies when required, conducting dietary exposure and risk analyses, preparing the petition (including developing the "reasonable grounds" arguments,) and writing the public document for publication in the Federal Register.

toXcel conducts dietary exposure evaluations to determine whether proposed uses are likely to be accepted by EPA, and performs "what if" analyses to help clients determine what refinements to the risk assessment or changes to use patterns are most likely to result in acceptable exposure and risk. **toXcel** conducts both deterministic and probabilistic risk assessments, and understands how to refine risk assessments using public and company data on the effects of preparation and processing on residues remaining in food and the percent of crop treated.

toXcel is experienced in the use of all three software programs publicly available in the U.S., including:

- CARES® (Cumulative and Aggregated Risk Evaluation System)
- Lifeline™ Aggregate and Cumulative Exposures to Pesticides and Chemicals
- DEEM™ – FCID Software

toXcel staff has decades of experience in dietary exposure and risk assessment and development of tolerance and exemption from tolerance petitions.

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