Process for Allowing Pesticide Use on Food

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The registration of a pesticide for use in the gardens or a farmer's field requires assessment of the potential negative effects of that pesticide on human health. To anticipate how a pesticide might impact human health, laboratory animals such as mice and rats are exposed to varying dosages in their foods --from very minimal to extremely high levels. Toxicologists then evaluate the observable effect(s) of consuming known quantities of that specific pesticide on acute, subchronic, chronic, mutational, reproduction and neurological effects. Information gained from such test is evaluated by toxicologists and medical experts to determine potential human effects.

Dietary risk assessment evaluation process

1. Toxicologists from national authorities, such as United States Environmental Protection Agency (US EPA), and international organizations, such as the United Nations Food and Agriculture Organization (FAO) and World Health Organization (WHO), begin the evaluation process by determining the quality of toxicological studies in terms of compliance to study guidelines and Good Laboratory Practice (GLP).
2. The second step in the evaluation process is the selection of the highest pesticide dose that does not cause any adverse effects to experimental animals. This dose level is

referred to as the No-Observed Adverse Effect Level (NOAEL). The NOAEL value can be established from single or multiple exposure studies.

3. The NOAEL usually is divided by a safety factor of 100 (safety factors range from 10 to 1,000) to take into account individual differences among people and the extrapolation of human health from animal data. This value is known as the Acceptable Daily Intake (ADI). In the United States, the term 'Reference Dose (RfD)' is often used instead of ADI.
4. The ADI generally is expressed in terms of milligram of a pesticide consumed per kilogram of body weight (mg/kg) per day. It is the amount of a pesticide residue that, if ingested daily over a 70-year lifetime, a human could consume without expecting any health-related problems. It is the ADI that is used as the toxicological indicator when pesticide residues are tested on foods designed for human consumption.
5. For pesticides that have been shown to cause cancer in laboratory animals, U.S. EPA uses complex mathematical models to estimate the potential increase in cancer cases extrapolated from laboratory animal data assuming a daily exposure over a 70 year period. The ultimate outcome is to predict the potential increase in cancer cases, from laboratory animals exposed to high concentrations to humans exposed to low level residues in their diet. U.S. EPA will allow the use of a pesticide on a food crop if the estimated risk of its causing cancer is one in a million or less. The likelihood of any person developing cancer from a lifetime exposure range of zero to one in a million has been coined the negligible risk standard, or the de minimis risk.
6. In the next step, regulatory scientists determine how much of a particular pesticide residue the average consumer might ingest over a life expectancy of 70 years. One measure used to calculate lifetime exposures is the Theoretical Maximum Residue Contribution (TMRC). The TMRC assumes that the foods we consume will contain maximum amounts of pesticide residues. These theoretical residue calculations assume that the maximum allowable amount of a pesticide will be applied to 100 percent of the labeled crops, that the number of pesticide applications will be in accordance with the maximum allowed by the product label, and that the food commodities will be consumed daily for a lifetime. The TMRC is calculated by multiplying the MRL (tolerance) on each crop by the average daily consumption of

that crop. The individual TMRCs are then added to derive a single, Theoretical Maximum Residue Contribution which serves as one of the indicators for theoretical exposure.

7. The ultimate objective is the comparison between the total theoretical amount of that specific pesticide residue which we consume daily over a lifetime (TMRC value) and the highest safety level (ADI or RfD value). The pesticide is judged to be harmless to public health when the TMRC value is below the ADI (RfD) safety value. If the TMRC value is above the ADI (RfD), national regulatory authorities, such as US EPA, review actual residue data and other information to ascertain more realistic exposure estimates. This second tier exposure estimate incorporates 'real world' residues into the calculations and is termed the Anticipated Residue Contribution (ARC). The ARC allows for a realistic refinement of the TMRC. Actual pesticide use, anticipated residues as determined in controlled field studies, the effects of processing, peeling, washing, and cooking on residues, regulatory monitoring and market basket study data represent the kinds of information used to evaluate the ARC alongside the ADI (RfD).