



NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLCAN sobre Plaguicidas
Le groupe de travail technique de l'ALENA sur les pesticides

PROJECT SHEET

SUBCOMMITTEE: Food Residues Working Group

PROJECT TITLE: **Dietary Exposure Assessment** (Methodologies)

PROJECT TEAM: Ariff Ally (Canada/PMRA),
Bart Suhre (US/EPA)
Rocío Alatorre (Mexico)

INITIATION: XXXXX

UPDATE: Nov 8, 2003

GOAL: **To promote learning exchange between regulators**

Background:

Under the WTO a separate agreement on food safety and animal and plant health standards the Sanitary and Phytosanitary Measures Agreement or SPS refers to the use of risk assessment in determining food health risks. Food safety standards relating to maximum levels of pesticide residues, additives, contaminants (including microbiological contaminants) and standards in the form of guidelines on processes and procedures (e.g. codes of practice). SPS allows countries to set their own standards. These must be based on science and applied only to the extent necessary to protect human, animal or plant life or health. Therefore countries may use measures which result in higher standards if there is scientific justification.

The PMRA has utilized, to the greatest extent possible, the policy and guidance outlined in the United States Environmental Protection Agency (U.S. EPA) document, Available information on assessing exposure from pesticides in food—a user's guide (U.S. EPA 2000), in part, to harmonize dietary risk assessment procedures for determination of the safety of pesticide residues in domestic and imported treated foods.

This endeavor, to harmonize DRA methodologies, is part of the North American Free Trade Agreement (NAFTA) goals within the Pesticides Technical Working Group Subcommittee

The PMRA is responsible for regulating the nature and amount of pesticide residues in food under the Food and Drugs Act and Regulations (FDAR). Section 4(a) and 4(d), of the Food and Drugs Act (FDA), authorizes PMRA to set a maximum residue limit (MRL) within Regulation B.15.002(1) of the Food and Drugs Regulations (FDR) or an exemption from the requirement of a MRL under Regulation B.15.002(2) of the FDR. The U.S. EPA is responsible for regulating pesticide residues in/on food under FFDCA. Under the Act, EPA is authorized to establish tolerances in food.

The United States and Canada performs various types of risk assessments to evaluate the safety of pesticides in food, including analyses to determine the nature and the amounts of pesticides that people might be exposed to over a single day and over a life time. Exposure estimations are determined for general and regional populations, as well as many subpopulations (infants, children, teenagers, adults, seniors, etc.), some of which may require information on specialized foods.

As noted above, the PMRA has harmonized DRA methodologies for the determination of exposure of food residues, with those used by the U.S. EPA.

PROJECT DESCRIPTION (Area of cooperation):

To determine whether any risk can result from either short-term (i.e., acute) or longer term (i.e., chronic) exposure, one considers both the toxicity of the pesticide (which is sometimes referred to as hazard) and the amount of pesticide to which an individual may be exposed. In the actual risk equations, which are discussed later on, toxicity is expressed as: an acute reference dose (ARfD) an acceptable daily intake (ADI) and a potency factor for cancer called the q^* . Which toxicity expression the risk assessor uses depends on the duration of exposure (e.g., acute or chronic) and, in the case of a carcinogen, the method chosen for quantifying risk. The risk posed by carcinogens can be quantified using an equation that assumes the pesticide's toxic effect occurs via a linear response, or it can be calculated using an equation that assumes a nonlinear response.

The amount of pesticide to which an individual is exposed (i.e., exposure) is determined by combining the amount of pesticide that is in or on the food (i.e., residue levels) and the amount and type of foods that people eat (i.e., food consumption).

Risks are estimated using computer models that combine the toxicity, residue, and consumption information.

Several models exist and are used to calculate acute and chronic dietary risk estimates for the general U.S. population and various population subgroups. The food consumption data used in the program are taken from the most recent USDA Continuing Survey of Food Intake by Individuals (CSFII). The software is capable of calculating probabilistic (Monte Carlo) type risk assessments when appropriate residue data (distribution of residues) are available.

MILESTONES (To be determined, area of cooperation)

WORK PLAN

SUBCOMMITTEE: Food Residues Working Group

PROJECT TITLE: Dietary Exposure Assessment (Methodologies)

UPDATE: November 7, 2003

GOAL	ACTIVITIES	TIME FRAME
To promote learning exchange between regulators	TWG (area of cooperation) <ul style="list-style-type: none">to facilitate the intra-NAFTA exchange of scientific knowledge and approaches needed to carry out Dietary Exposure Health Risk Assessments.	2003-2007

Appendix 1

General Description of Duration of Exposure Currently used in Assessments

Acute Exposure

An acute exposure is defined as a single or one day exposure that is estimated using worst-case assumptions for the pesticide residues present in the food. In practice, acute dietary risk assessments are performed for a food-use pesticide only if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure.

Chronic Exposure

A chronic exposure is presumed to occur over a substantial portion of the individual's lifetime. These lifetime or other long-term (i.e., continuous) exposures to pesticides may occur when a chemical is eaten, inhaled, or absorbed through the skin; however, by far, the largest continual exposure for an individual is via the food and water that is consumed each day. A chronic dietary assessment is performed for all food-use pesticides. There are two components to dietary exposure, food source and drinking water.

Thus, total Chronic Dietary Exposure = Chronic Food Exposure + Chronic Drinking Water Exposure

Naturally occupational exposure to a pesticide, if it occurs, need to be accounted for in the acute and chronic assessment and in some instances for subchronic exposure situations.

References For facilitating the Learning Exchange

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