# Pesticide Residues in Food

# Canada‘s Regulatory Framework

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## Basis for Maximum Residue Limits

- Maximum Residue Limits  are recommended on the basis of appropriate residue data obtained from supervised residue trials; and
- The residue data must reflect proposed or approved usage of the pesticide in accordance with GAP.
- MRLs are set for each pesticide/crop combination.
- MRLs apply to both domestic and imported food.

## Good Agricultural Practice (GAP)

- GAP conditions include public and occupational health and environmental considerations;
- GAP encompasses pesticide applications up to the highest authorised use rate, applied in a manner which leaves the smallest residue; and
- GAP may include any stage in the production, storage, transport, distribution and processing of food commodities and animal feed.

## Residue Chemistry Studies

- Residue Chemistry Guidelines (DIR98-02; http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802a-e.pdf) outline the residue chemistry data requirements which form the basis for setting pesticide MRLs; and
- Canada's residue chemistry requirements are consistent with the U.S. EPA residue chemistry requirements (OPPTS 860.1000).
- Continue to participate in OECD Test Guidelines and guidance Document Development on Pesticide Residue Chemistry

# Food Residue Chemistry Studies

- Product chemistry
- Label (GAP)
- Plant and livestock metabolism studies
- Confined rotational crops
- Analytical methods – plant and animal matrices
- Storage Stability - plant and animal matrices
- Crop Field Trials - Primary crops
- Field Accumulation - Secondary crops
- Processing studies
- Livestock feeding studies

## Product Chemistry

- Identifies the physical/chemical properties of the technical grade active ingredient;
- Identifies the manufacturing process (Confidential Business Information) and any impurities resulting from the process; and
- Identifies the formulants, adjuvants and all other solvents used to produce the pesticide formulation.

# Label

- Identifies petitioned uses (i.e., crops/crop groups)
- Identifies use directions
  - Rate of application
  - # of applications/season
  - Re-treatment interval
  - Pre-harvest interval (PHI)
  - Plant-back intervals
  - Type of application (ground or aerial)

# Livestock Metabolism Studies

- Determines the metabolic profile of a pesticide in livestock animals (ruminant and poultry);
- Identifies the metabolites and degradates which may occur after livestock animals (ruminants and/or poultry) are exposed, either directly or indirectly, to a pesticide; and
- Used as a basis for the determination of the residue definition for animal matrices (e.g., meat, milk, eggs)
  - Which metabolites must be included in the residue definition for dietary exposure assessment and MRL setting.

## Plant Metabolism Studies

- Determines the metabolic profile in plant commodities (e.g., cereals, root vegetables, leafy vegetables);
- Identifies the metabolites and degradates which may occur in a food as a result of pesticide use; and
- Used as a basis for the determination of the residue definition for plant matrices (e.g., cereal grain, carrot, lettuce)
  - Which metabolites must be included in the residue definition for dietary exposure assessment and MRL setting.

## Determination of the Residue Definition (RD)

Challenges faced:

- Lack of information on the toxicity of major (>10%TRRs) metabolites and/or degradates; in the absence of such data, the toxicity of these compounds is considered equivalent to that of the parent and must be included in the RD for risk assessment;
- Analytical methodology does not include the analysis of the major metabolites; and
- Parent compound is extensively metabolized and is not expected to be present in any human foods.

## Residue Analytical Methods

- Quantify the pesticide and any associated metabolites/degradates which must be included in the residue definition for plant and animal commodities.
- Can be used as an enforcement method if it:
  - is specific to the analytes of interest;
  - is validated by an independent laboratory; and
  - demonstrates acceptable extraction efficiency.

# Freezer Storage Stability Studies

- Determines whether the residues of the pesticide and the metabolites/degradates are stable in plant and animal commodities stored under frozen conditions.
- Measures the degree of loss or degradation during frozen storage.
- Ensures the integrity of the residues reported in many of the food residue  chemistry studies (e.g., metabolism, crop field trials, field crop rotation).
- If acceptable freezer storage stability data is provided for five diverse crops (e.g., oilseed, nonoily grain, leafy vegetable, root crop, fruit or fruiting vegetable), additional storage stability studies may be waived.

## Supervised Crop Field Trials

- Determine the magnitude of the residue in/on raw agricultural commodities (RACs) after treatment with the pesticide according to approved label directions.
- Conducted in representative growing regions to account for different soil types and climate.
- Number of trials may vary according to the crop based on dietary share and production data (acreage).
- Results from the crop field trials form the basis for the establishment of the MRLs.

# Calculation of Maximum Residue Limits (MRLs)

Statistical Spreadsheet

- Developed by the NAFTA MRL/Tolerance Harmonization Working Group;
- Used to calculate statistically based pesticide MRLs using field trial data;
- First version of the spreadsheet was posted on the PMRA website in September 2005 (Guidance for Setting Pesticide Maximum Residue Limits Based on Field Trial Data (http://www.pmra-arla.gc.ca/english/pdf/pro/pro2005-04-e.pdf))
- Revised version, incorporating minor modifications, are posted on the PMRA website.

## Residue Decline Studies

- Determine the rate of decline of residues at time periods before and after the proposed pre-harvest interval;
- Determine if residues are higher at longer preharvest intervals (PHIs) than requested; and
- Determine the approximate half life of the pesticide.

# Rotational Crop Studies

- A rotational crop is a crop which is planted in a field following harvest of the primary crop that has been treated with a pesticide;
- Rotational crops may contain residues resulting from pesticide applications made to the primary crop; and
- Confined rotational crop studies:
  - determine the metabolic profile of a pesticide in rotational crops; and
  - used to assess whether the metabolic profile in primary crops is similar or different from the metabolism in rotational crops.
- Field rotational crop studies:
  - determine the level of pesticide residue uptake into rotational crops; and
  - used a basis to determine whether MRLs must be set to cover the potential uptake of residues in rotational crops.

## Food Processing Studies

- Determines whether the pesticide residues reduce or concentrate when the raw agricultural commodity is processed (e.g., apples to juice);and
- Results are used to determine the processing factor.
- If residues in the processed foods are expected to be higher than those in the raw commodity, a separate MRL will be established for this processed commodity.

## Livestock Feeding Studies

- Quantify the magnitude of the residues in meat, milk and eggs resulting from livestock consumption of treated feed, or direct application to livestock.
- The residue levels form the basis for the establishment of the MRLs for animal matrices.

## Import MRLs

- For the establishment of import MRLs, the same residue chemistry studies listed above are required (with the exception of the rotational crop studies and feeding studies), however,
- Trials must be conducted in the representative growing regions and according to the approved label of the exporting country.
- NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities in the United States and Canada (http://pmra-arla.gc.ca/english/pdf/nafta/TWGImport_Tolerance-e.pdf)

## Components of Dietary Exposure Assessment

- Residue – Level of the pesticide in foods.
- Consumption - Amount and types of foods consumed in a given period of time.
- Toxicology endpoints – Acceptable Daily Intake (ADI), Acute Reference Dose (ARD), Cancer risk.

# Residue Inputs

Canada conducts dietary exposure assessments in a tiered manner

Basic Level:

- Canadian MRLs and US tolerances to account for a large percentage of imported foods from the US
- Default processing factors

Intermediate/Refined Level:

- Median residue values
- Experimental processing factors (reduction / concentration factors)
- Cooking studies (when available)
- % Crop treated - market share
- Monitoring data provided by the Canadian Food Inspection Agency (CFIA)
- Market Basket Surveys—purchased foods

## Consumption Information

- Dietary Exposure Evaluation Model – Food Commodity Intake Database (DEEM-FCID Version 2.03)
- The source of consumption data used in the DEEM-FCID software is the USDA Continuing Survey of Food Intakes by Individuals (CSFII): 1994–1996, 1998 (children specific) - 2 days.
- This survey represents the North American diet of all ethnic groups, all age groups, both sexes; monitoring across all seasons and includes a large number of respondents.

## Exposure Scenarios

- **Chronic exposure** = average amount of pesticide residue a person might consume every day over extended periods.
- **Acute exposure** = amount that might be ingested on a single day.

## Dietary Risk Assessment

Potential Daily Intake (PDI) = Residue X Consumption

$$\text{Dietary Risk} = \frac{\text{Potential Daily Intake}}{\text{Toxicology Endpoint}}$$

# Potential Daily Intake (PDI)

- Estimated for various subpopulations and age groups, including infants, toddlers, children, adolescents and adults.
- Accounts for residues in food from both domestic and imported sources.

**Acceptable Risk**

- If PDI does not exceed the toxicology endpoint, risk is acceptable, MRLs may be established.

**Unacceptable Risk**

- If PDI exceeds the toxicology endpoint, risk management options must be implemented to permit the safe use of the product.

# Data Associated Risk Management Options

Residues

- Restrict uses: remove selected crops, selected pests;
- Do not authorize the feeding of treated crops or its by-products to animals;
- If residues are known to decline with time, increase the pre-harvest interval to reduce residues present at harvest;
- If foreign residue data were used o support initial Canadian registration, obtain definitive residue data for crops based on actual use in Canada; and
- If supported by efficacy assessment, reduce label rates and/or application frequency.

# Risk Management Outcomes Options

- If the assessment is acceptable after implementing the risk management options
  - recommend the MRL(s)

**or**

- If the assessment is not acceptable after implementing the risk management options
  - do not recommend the MRL(s)

## Setting Maximum Residue Limits in Law

- Under the *Pest Control Products Act* (PCPA), MRLs are recommended based on an acceptable daily intake with special consideration given to children, pregnant women, seniors, etc.
- Proposed MRLs are consulted externally.
- MRLs become law through a routine amendment of the *Food and Drug Regulations* (FDR) and in the future will be established under the PCPA.

## Maximum Residue Limit Enforcement

- The Canadian Food Inspection Agency (CFIA) uses MRLs as the benchmark residue level. Therefore when CFIA finds residues at levels greater than the established MRLs, there is “reasonably certainty” that the pesticide was not used according to GAP.

## Canadian Regulatory Framework

- Unless a specific MRL is established, there is a provision in the Canadian *Food and Drugs Act* which allows for a default MRL of 0.1 ppm for any pesticide/crop combination.
- Health Canada is considering revoking this default MRL and replacing it with specific MRLs.
- As part of this project, Health Canada is exploring ways of exempting residues of low risk pesticides in food by working with EPA to identify opportunities to harmonize actions.

# Thank you…



Canada