



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 COMPLETION SHEET

SUBCOMMITTEE: Food Residue

PROJECT TITLE: Analyzing Maximum Residue Levels (MRLs)

PROJECT ID: FR03-03-1005

PROJECT TEAM¹:

Canada:	Henri Bietlot, Monique Thomas, William Mohan, Angela Murray
United States:	Jeff Herndon, Rick Loranger, David J Miller, Steve Funk, Philip Villanueva, James Nguyen
California:	Mike Papathakis

INITIATION: November 2003

COMPLETION: April 2008

GOAL: The goal of this project is to formulate a standard methodology that can be used by the US and Canada as part of our joint review program such that the same or similar datasets will result in the same recommendation for MRL (i.e. tolerance) levels. To the extent that the methodology can or might be accepted by the EU, Codex, or other governmental regulatory bodies, any proposed US/Canada methodology should take into consideration the current methods used by these bodies.

PROJECT DESCRIPTION:

The purpose of this project was to develop and propose a statistically-based methodology which could be used as a standard basis for establishing tolerances; doing so, however, must recognize the “balancing act” that is implicit in setting tolerance levels between the desire to set tolerances at a level high enough so as to avoid seizing crops which were legally treated, on the one hand, but low enough such that residues from illegal use can be detected on the other. Any proposed procedures would function to serve as “benchmarks” or guidance for establishing tolerance/MRL, and not fixed rules. In addition, any developed methodology should be reasonably simple to use by non-statisticians (requiring only calculators or spreadsheets), should aim to be reasonably-well accepted, and should be based – as far as possible – on accepted statistical principles and methods.

BACKGROUND/RATIONALE:

¹ Initially international observers participated in workgroup discussions regarding various methods for calculating MRLs and selecting the most appropriate method. These observers were Anja Friel and Luc Mohimont (EFSA) and Bas Drukker and Luis Martin-Plaza (EC).

Previously, tolerance-setting methodology in the U.S. and Canada was based on identifying the highest residue from series of field trials and then “rounding up”. There was little guidance regarding how much higher the tolerance should be than the highest field trial residue, and different reviewers and different agencies/governments (e.g., California DPR, US EPA, and Canada’s PMRA) can have different viewpoints on the level at which tolerances should be set. There is a general consensus that a tolerance should be established at a level which balance probabilities associated with wrongly seizing a legally treated crop vs. probability of being incapable with a reasonable degree of surety of detecting illegal use.

OUTPUT/RESULTS:

The workgroup’s successful efforts to harmonize the MRL-setting process within NAFTA have served as an impetus for the formation of an OECD workgroup tasked with a similar objective of harmonizing the MRL-setting process of the OECD member states. The OECD workgroup includes members from the NAFTA MRL Harmonization workgroup and other scientists from the international community representing both regulatory bodies (including the European Food Safety Agency, or EFSA) and the regulated community. With the incorporation of NAFTA workgroup members, the OECD workgroup’s efforts and work products are anticipated to supersede those of the NAFTA workgroup. As such, previously scheduled workplan activities to revise and finalize the MRL spreadsheet, SOP, and white paper have been withdrawn, with the expectation that the OECD harmonization activities will fulfill these objectives on a more global scale.

- 1) An Excel spreadsheet to automate calculation, selection, and rounding of statistically-based MRLs based on field trial residue data. The spreadsheet also automatically provides summary statistics and graphical plots of the residue data.
- 2) An accompanying standard operation procedure (SOP) for the MRL spreadsheet, which contains instructions and screen shots for operating the spreadsheet and interpreting the results. The SOP also provides a brief description of the various MRL calculations and rationale for selecting the most appropriate calculations based on various characteristics of the residue data being analyzed.
- 3) A statistical white paper that provides the technical details and rationale supporting the various MRL calculations implemented in the MRL spreadsheet. The white paper also summarizes and documents the various simulations (including the accompanying SAS code) supporting the workgroup’s evaluation of the various MRL calculation methods and how best to select various calculations based on characteristics of the residue data being analyzed.
- 4) Training and technical support for contractors and staff responsible for calculating MRLs. Specifically, training was provided for staff from PMRA and California DPR, and EPA staff and contractors.
- 5) PMRA and EPA websites from which the MRL spreadsheet, SOP, and white paper can be downloaded.
- 6) Stakeholder outreach by means of public comment periods for the MRL spreadsheet, SOP, and white paper.
- 7) Multiple national and international presentations and outreach efforts to various regulatory bodies and the regulated community in both formal and informal settings. These presentations would often include an overview of the workgroup’s effort and the MRL spreadsheet, including a brief demonstration of its use.

WORK PLAN

SUBCOMMITTEE: Food Residue

PROJECT: Analyzing Maximum Residue Levels (MRLs)

ACTIVITY	TIME FRAME
Initial conference call between California, Canada and the United States	November 24, 2003
Develop a list of two or three proposals	Late January–February 2004
Preliminary exploration of various proposals using existing data sets	April 2004
Preliminary report to NAFTA Executive Board	June 2004
Finish testing various proposals using existing data sets (large versus small data sets)	Late October 2004
Decide on a proposal (large versus small data sets)	October–December 2004
Discuss within agencies and preliminary outside discussions	December 2004– January/February 2005
Prepare written Standard Operating Procedure and finalize spreadsheet	March–April 2005
Presentations to stakeholders and logistical considerations regarding implementation ¹	April–May 2005
Discussion on Standard Operating Procedure and spreadsheet. Disseminate/approve plans at NAFTA Executive Board meeting	Early May 2005
Formal dissemination to stakeholders followed by associated presentations	May–August 2005
Pilot implementation at Office of Pesticide Programs and the Pest Management Regulatory Agency	August 2005
Written comments from stakeholders	June–November 2005
Presentation of draft outline of statistical white paper and update on Project to NAFTA Executive Board	December 2006
Preparation and dissemination for comment of draft white paper	May 2007
Revise white paper and reply to comments	February –April 2008 (Withdrawn: supplanted by OECD MRL harmonization activities)
Finalization of SOP and technical white paper	May 2008 (Withdrawn: supplanted by OECD MRL harmonization activities)

¹ Logistical considerations include country-specific contractor and staff training, database development, data storage considerations, etc. These represent the operational steps that need to be taken for the methodology to be implemented.