



PROJECT SHEET

SUBCOMMITTEE: Food Residues

PROJECT TITLE: Pilot Project to Validate the Residue Zone Maps

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UPDATE: July 10, 2000

GOALS:

To reexamine the criteria for the Residue Zone Maps in order to:

1. Simplify the residue zone requirements to achieve a North American residue data package.
2. Make recommendations on possible amalgamation of residue trial zones through a review of the actual scientific data (residue reports conducted in the zones).

To support this reexamination through a pilot project which will be used to identify relevant data parameters and develop analytical methodologies for this assessment.

PROJECT DESCRIPTION AND METHODOLOGY:

General/Scope:

This is a pilot project, which will be designed in such a way that it can be easily expanded should this be determined to be scientifically acceptable.

The deliverable document will consider and compare residue results for 3 representative crops from 3 different crop groupings and 3 dissimilar products with measurable residues. There will be a particular focus on zones 1, 5, 7 and 14 including exchange of data between the USA and Canada. Within this project the intent is to include a minor use crop involving the Canadian Horticultural Council and IR-4 with a north-south focus.

Data to be reviewed includes crop, zone, application timing, type of product (e.g. herbicide, fungicide), chemical class or active ingredient, application type (e.g. foliar), number of years of data. The presence of surfactants in the application will also be examined. The GAP will be as close as possible (25-30 %)

An analysis of the data will be conducted by a consultant and will include a recommendation which will be submitted to the Food Residues Working group.

It is planned that the examples chosen will meet the following parameters:

1. Same formulation
2. Same GAP (25-30%)
3. Measurable residue
4. More than one year of data if at all possible

The regulatory agencies are expected to be involved in two major steps following approval of this project:

- 1) Review of the detailed plan (crops, products chosen, data sets) in order to ensure that the parameters chosen will also be of benefit to the agencies; and

2) Review of the data, analysis and recommendation.

Possible Limitations: There are possible limiting factors to completing this project successfully. They are:

- 1) Limited number of new products with measurable residues focused on the target zones.
- 2) Limited residue trials from various zones.
- 3) Financial resources, should the project be delayed.

Methodology:

The pilot phase of the project will consist of 3 crops and 3 products with measurable residues. The first stage of the project will be to examine the residues from crops grown in crop subzones in Canada. The United States eliminated subregions in their crop regions (Zones) definitions in the past. Thus the project will initially focus on crops that span many crop zones allowing for an assessment of these zones. Particular emphasis will be on neighboring crop regions or zones with the following combinations of zones 1/1A, 5/5A/5B and 7/7A/14 being given priority.

The number of crop trials required in the subzones is limited. In Canada, Zone 5A is indicated as including two US states (Michigan and Wisconsin) but the US does not make this distinction for a crop subzone.

The US has also identified two problem areas that may be addressed in the in the pilot project. Data from Zone 14 cannot be used in support of a US registration and data generated on either side of the St Lawrence River (Zone 1 vs. Zone 5/5B) are not transferable for registrations for either country.

This pilot project will be used to determine if there is scientific evidence to support the merging of some residue trial zones. A secondary objective would be to establish that residue trials in neighboring zones are transferable. To ensure that there is no bias in the selection of candidate products, the products will be selected with limited criteria. Only products with detectable residue will be included in the initial phase. These detectable residues may be both food or feed item to ensure that suitable candidate products are available. The residue trial will have been conducted to ensure that applications are made that are a reflection of the proposed good agricultural practices (GAP) within the criteria of each agency.

The pilot project will select crops that fulfill the requirement of being grown in the neighboring zones or regions. The crops selected allow an approach similar to that employed in both agencies (PMRA/EPA) in the assessment of new active ingredients. Representative crops of different crop groups will be selected. This is the approach taken in the assessment of metabolism, freezer stability and rotational crops. The approach will be directly evidence based.

The residue data will be examined in relation to GAP, PHI and application timing (crop growth stage). For the results, the residues will be summarized for range of residues, the mean and the supervised trial median residue. The data will be graphed to allow a visual inspection of the results. The graphing will also include exact trial location to ensure that the trails were located in representative sites (safe zone) within a zone. With detectable residues, variation between residue levels are normal. The data will also be examined to ensure that the results fall within normal parameters.

As the scope of the project is expanded or where possible in the present project, it is envisioned that statistical methods will be applied to the residue results to ensure that the samples are representative. The chemical properties of the products examined will also be included in the assessment.

In the pilot phase the crop selected will cover as many zones as possible. The proposed crops and related crop groups will possibly include the following:

Crop group 1	Potatoes
Crop group 8	Beans
Crop group 10	Apples
Crop group 16	Wheat
Crop group 20	Canola (the EPA has not assigned canola to a crop grouping).

A review of Canada and US trial locations demonstrates the suitability of these choices.

Selected Examples of Crops and Required Trials.

Crop	Agency		Crop Zone																	
			1	1 A	2	3	4	5	5 A	5B	6	7	7 A	8	9	10	11	12	13	14
Potato	PMRA	16	3	4				3	1	1			1					1		2
	EPA	16	2		1	1		4						1	1	6				
Wheat	PMRA	20					2				7	1								10
	EPA	20			1		1	5			1	5		6			1			
Beans, Green	PMRA	5		1			2		2											
	EPA	8	1		1	1	3								1	1				
Canola	PMRA	16					1				1									14
	EPA	8			1		2				2					3				
Apple	PMRA	12	1	1			4		3								3			
	EPA	16	4		2		3							1	1	5				

The selection of potato wheat, green beans and apples will allow the project to demonstrate the nature of residues in the Canadian subzones. Apple residue data will demonstrate that residues on either side of the St. Lawrence River should be transferable and canola that data generated in crop zone 14 would be suitable for residue results for Zone 7 and 5. Additional attention will be given to the concern of the Idaho Barley Association with respect to the current zone maps for exchange of data between Canada and the USA.. The crops selected will be reassessed when candidate products are identified.

The data will be examined to demonstrate whether residues are effected by zone location. It is expected that for recent residue trials conducted at GAP, any variables related to application, timing and rate will be minimized (i.e. same use pattern).

Thus the deliverable document will include tabular results of the residues detected from the supervised trials. The tabular results will include range of residues, mean and median residues. The data will also be presented graphically. An assessment of the results will be included. An overall determination of the evidence to support the proposal to reduce crop zones and expand the pilot project, will be conducted.

MILESTONES:

- August 12, 1999 - initial discussion between NAFTA IWG & PMRA on this project
- August 18, 1999 - initial discussion between NAFTA IWG & EPA on this project
- September 19, 1999 - received from the Crop Protection Institute Board of Directors approval for limited funding (for a consultant)
- October, 1999 - initiated the involvement of ACPA Residue Expert Group
- October 27, 1999 - met with the PMRA to discuss parameters and process.
- November 30, 1999 - Submitted project proposal to NAFTA TWG
- April 12, 2000 - Initial response from NAFTA TWG with requested revisions (see systematization project)
- May 24, 2000 - NAFTA TWG requested a status update on the proposed timeline.
- July 10, 2000 - Final revised project submitted to NAFTA TWG with revised timeline.

BACKGROUND / RATIONALE:

The Canadian and USA residue zone maps have been in use for a number of years. These zone maps were established using an assumption that in most cases, no data were available on the interrelationship between geographical crop location and terminal residue values.

Now that a number of years of data are available, it would be prudent to reexamine the basis for these maps and to validate the original assumptions with actual residue results.

Since the development of these zones, there has been a strong encouragement from the regulatory agencies for the registrants to compile North American registration data packages, to file simultaneous submissions and to participate in harmonization goals. Both countries have been encouraged to find acceptable solutions to resolve the issue of artificial trade barriers particularly as they relate to minor use crops. (Reference: *Record of Understanding between the Governments of Canada and the United States of America Regarding Areas of Agricultural Trade*, Dec 2, 1998). Through the experience gained in various work sharing initiatives of the PMRA and the EPA (e.g. Joint Reviews), it has been recognized that there may be further opportunity for process simplification and harmonization of processes related to residue data and its review.

Important Note: This proposal is intended as a pilot project which is being tested to determine if there is scientific evidence to support the merging of some residue trial zones within and between the United States and Canada.

This project is considered a very important initiative by our industry as well as by the grower associations representing the some of the minor use crops. The industry is faced with difficulties in meeting the current zone requirements for the following reasons:

- 1) There are limited or no government or independent researchers available to conduct residue trials in some of the zones.
- 2) The GLP requirements have substantially increased the cost of conducting residue trials. This is of particular concern to the minor crop area.
- 3) With the increased NAFTAization and rationalization of the industry, resources available are decreasing. Related to this, the need for NAFTA based registrations are increasing.

The industry believes that the expected benefits of this project will serve to further:

- Reduce the total number of residue trials required to obtain registration in North America (Canada, USA).
- Potentially reduce the number of residue zones.
- Develop criteria for determining when crop scenarios require less than the number of trials determined in the Residue Chemistry Guidelines.
- Encourage the development of a North American residue data package by the registrant for products in order to simplify the review process and further advance the mutual harmonization goals.
- Reduce the number of new artificial trade barriers through development of simplified North American based residue data.

TIMELINE:

ACTIVITY	COMPLETION DATE
TWG to confirm interest in proceeding with this project.	March 1, 2000 (Completion May 15, 2000)
IWG to prepare a detailed protocol for project (products, crops, zones)	September 30, 2000
TWG to complete review of the detailed protocol and comment back to the IWG	December 15 , 2000
Consultant analysis, final report, and recommendation written by IWG and submitted to TWG for review.	June 15, 2001