PEST MANAGEMENT REGULATORY AGENCY

RESIDUE CHEMISTRY GUIDELINES

SECTION 9

CROP FIELD TRIALS

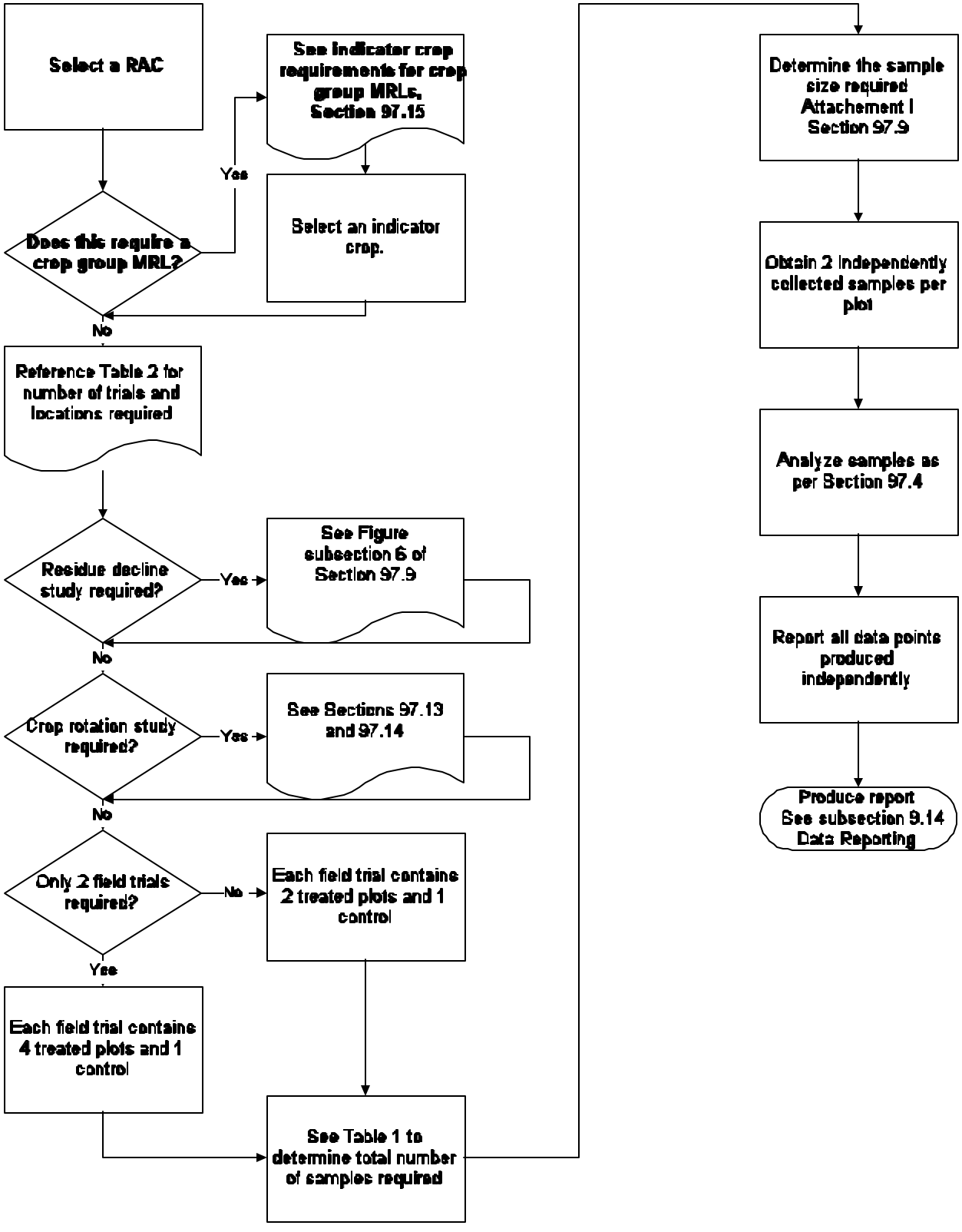
9.1 Preface

This document was produced by the Agriculture Division of Statistics Canada for the Pest Management Regulatory Agency (PMRA) of Health Canada under the terms of a memorandum of understanding between the two departments. The Agriculture Division agreed to produce a Canadian draft document comparable to the U.S. Environmental Protection Agency (EPA) document, *Pesticide Reregistration Rejection Rate Analysis Residue Chemistry*, (June 1994). See Reference 16. Section 9, *Crop Field Trials,* is provided to assist petitioners in the preparation of scientific data from supervised crop residue trials and residue decline studies.

Included in the development of this report were the following:

- the delineation of crop regions,
- the determination of the number of field trials required for national and provincial registration of agricultural chemicals for all significant crops grown in Canada,
- the allocation of field trials among the crop regions, and
- the elaboration of guidelines for conducting field trials.

An overview of the crop field trial data requirements is presented in the following schematic shown:


Select a RAC
See Indicater crop requirements for crop group MRLs, Section 97.15
Yes
Does this require a crop group MRL?
Select an indicator crop.
No
Reference Table 2 for number of trials and locations required
Residue decline study required?
Yes
See Figure subsection 6 of Section 97.9
No
Crop rotation study required?
Yes
See Sections 97.13 and 97.14
No
Only 2 field trials required?
No
Each field trial contains 2 treated plots and 1 control
Yes
Each field trial contains 4 treated plots and 1 control
See Table 1 to determine total number of samples required
Determine the sample size required Attachement I Section 97.9
Obtain 2 independently collected samples per plot
Analyze samples as per Section 97.4
Report all data points produced independently
Produce report See subsection 9.14 Data Reporting

9.2 Definitions

The following are definitions of terms used in Section 9, *Crop Field Trials*.

- A **plot** is defined as an area of ground with defined boundaries on which a crop is grown. Replicate plots can be established within the same treated area. For guidance on plot sizes, and related information concerning the design of field trials, the petitioner may consult Reference 21, Section 9; in addition, the PMRA is assisting in the development of a North American Free Trade Agreement (NAFTA) guidance document on this topic.

- A **site** is a geographically defined field trial at an address/location within a country/region/province. The site is generally a field, a space, a water body or another area in, or on which, an agricultural chemical field trial is conducted. In most cases, this definition applies to a site being one farm. A site typically consists of several plots, each of which receives a specified agricultural chemical application regimen.

- A **field trial** entails one or more proposed applications per growing season of a formulated agricultural chemical product to a specified crop or the soil, at one site, following actual or simulated cultural practices. Such applications are usually in accordance with registered or proposed label directions, or a fraction or multiple thereof in some cases, to provide treated commodity samples for estimating proposed maximum residue limits (MRLs) and/or dietary exposure to agricultural chemicals. A field trial always consists of one or two treated plots and one control plot. Each plot receives a treatment of a formulated pesticide that has been prepared as separate batches and applied separately.

- A **zone or region** is a geographically defined area of arable land where various crops are predominantly grown for use as human food or livestock feed. Field trials are conducted in zones as specified in Appendix III, Table 2 of Section 9, *Crop Field Trials*.

- A **sample** is a defined amount of individual agricultural commodity units, e.g., a specific number of fruits or tubers, or a set weight of grain, etc., randomly selected from a plot that may be composited for agricultural chemical analysis. Note that, as discussed in the next section, MRLs are normally based on analyses of composite samples. In the future, the PMRA may also require analyses of individual servings, e.g., one apple or one potato, to assess the dietary risk from acutely toxic agricultural chemicals. This requirement is not discussed further in the present document.

9.2.1 Good Agricultural Practice (GAP) in the Use of Agricultural Chemicals

includes the nationally authorized, safe uses of agricultural chemicals under the actual conditions necessary for effective and reliable pest control, as defined on the approved label, i.e., use pattern: rate(single and maximum per season), timing, preharvest interval (PHI), etc. They

encompass a range of levels of agricultural chemical applications up to the highest authorized use, applied in a manner that leaves a residue that is the smallest amount practicable. Authorized safe uses are determined at the national level and include nationally registered uses, that take into account public and occupational health and environmental safety considerations. Actual conditions include any stage in the production, storage, transport, distribution and processing of food commodities and animal feed. Lower case **gap** applies to the proposed or recommended, safe use of agricultural chemicals, as described above, and as defined on the proposed label, i.e., use pattern: rate (single and maximum per season), timing, PHI, etc.

- A **study** is a report of a research project involving field and laboratory work conducted at one or more trial site(s).

9.3 Introduction

A petition for the registration of an agricultural chemical for use on crops grown in Canada is the responsibility of the PMRA. One of the Agency's concerns when evaluating data that are submitted in support of a petition is the amount and type of agricultural chemical residue left on/in the plant material as a result of the chemical's use. The Agency requires petitioners to measure the type and amount of residue in a number of field trials where the agricultural chemical is applied according to the label directions for a particular crop that is growing in a number of different locations.

The purpose of this document is to provide guidance to assist petitioners in the preparation of scientific data requirements concerning supervised crop residue trials and residue decline studies. While the Agency believes that the number and location of trials are adequate in most cases, there is a risk that the results may be inconclusive. The field trials attempt to account for the variability in results among field trials by selecting more than one test site. This will measure the combined effects of such factors as soil type, weather, and regional cultural practices. As well, variation within the field trial is measured by collecting more than one treated sample at each site. This accounts for such factors as local drainage patterns, and mixing and spraying practices.

It is not necessary to conduct field trials in more than one growing season except when the weather/climatic conditions for the trials deviate from normal conditions, or in the case of petitioning a provincial registration where eight or more field trials are required nationally, as per schematic at Attachment II.

The information in this document was developed using the concepts and methods set out in the U.S. EPA document, *EPA Guidance on Number and Location of Domestic Field Crop Trials for Establishment of Pesticide Residue Tolerances,* June 1994. See Reference No. 16.

9.4 Number of Field Trials for Individual Crops

Selection of Crops

All crops with a production area of 250 hectares (620 acres) or more in the 1991, Census of Agriculture, were considered.

Leeks and nectarines were added because the 1995 Fruit and Vegetable Survey indicated that the areas exceeded 250 hectares. Rhubarb was included because the production area approaches the lower limit of 207 hectares.

Mushrooms and greenhouse production of tomatoes, cucumbers, lettuce and peppers were included, due to the importance of seasonal production and consumption, even though the areas are less than 250 hectares. Areas are reported in square feet.

Individual items from the census questionnaire were selected with the following exceptions:

- tame hay includes all grasses and legumes grown for forage or seed purposes, i.e., the sum of alfalfa and alfalfa mixtures, other tame hay, forage seed and sod.

- wheat includes spring, winter and durum varieties.

- rye includes spring and fall varieties.

- dry field beans include dry white beans, fababeans and other dry beans, but exclude soybeans.

- mixed grains and nursery products were excluded since the specific crops in these categories are unclear.

- cherries include both sweet and sour varieties.

The list of crops for which a minimum number of field trials is assigned is presented in Table 1 (Appendix II). The primary sources used for hectareage/acreage information were the following Statistics Canada publications:

1991 acreage:
Agricultural Profile of Canada - Part 1, (Catalogue no. 93-350). Information on some low acreage crops that are not included in the aforementioned publication was obtained from Statistics Canada, Census of Agriculture. See Reference numbers 9 and 10.

1995 acreage:
Field Crop Reporting Series, (Catalogue no. 22-002), *Fruit and Vegetable Production*, (Catalogue no. 22-003), and *Greenhouse Industry*, (Catalogue no. 22-202). See Reference numbers 11, 12 and 13, respectively.

Determination of Number of Field Trials

Step 1

Assign a base number of field trials to each crop as follows:

1995 Area		Base Number of Field Trials
Hectares	Acres	
> 4,046,860	> 10,000,000	16
> 404,690 # 4,046,860	> 1,000,000 # 10,000,000	12
>121,410 # 404,690	> 300,000 # 1,000,000	8
> 12,140 # 121,410	> 30,000 # 300,000	5
> 810 # 12,140	> 2,000 # 30,000	3
> 81 # 810	> 200 # 2,000	2
# 81	# 200	1

Step 2

Increase the base number one level, i.e., 8 to 12 or 12 to 16, etc., if the area exceeds 121,410 hectares (300,000 acres) and the dietary share[1] is 0.40% or more.

(wheat, oats, potatoes)

[1] Dietary Share, See Estimation of Dietary Share, p. 9 of this document, and Attachment III (Appendix VI).

Step 3

Decrease the base number one level if the area exceeds 121,410 hectares (300,000 acres) and the dietary share is less than 0.10%.

(tame hay, flaxseed, dry field peas, lentils, mustard seed, corn for silage, canary seed)

Step 4

Increase the base number one level if the area is 121,410 hectares (300,000 acres) or less and the dietary share is 0.02% or more.

(All fruits and vegetables are affected except cranberries, saskatoon berries, green onions and shallots, Brussels sprouts, radishes, Chinese cabbage and other ethnic leafy vegetables, leeks and, hazelnuts and filberts.)

Step 5

A minimum of 16 field trials is required for crops of more than 121,410 hectares (300,000 acres) and a dietary share of more than 1.00%.

(wheat, oats*, potatoes)

*Oats was found to exceed the 1.00% diet criterion when using the infant diet, but not when using the diet of the general population. See, *Estimation of Dietary Share*, below.

Step 6

A minimum of 12 field trials is required for crops 121,410 hectares (300,000 acres) or less and a dietary share of more than 1.00%.

(apples, tomatoes)

Afternote

The U.S. methodology includes a step where the base number is reduced by one level if 90% of the crop is grown in one region. This step was omitted from the Canadian Guideline because only one crop, soybeans, would be affected.

Crop Group[2] MRLs

When a petition is made for a crop group, the number of field trials required is equal to the sum of the number of field trials for each crop in the group, with the following qualification when the number of trials required for an individual crop is eight or more. The number of trials is reduced by one level (Base Number, see Step 1, *Determination of Number of Field Trials*) if it is a member of the group for which a MRL is requested.

Example: an application is made for beans as a group, i.e., soybeans, dry field beans and, green and wax beans. The number of trials required for the individual crops would be 12, 5 and 5, respectively, from Table 1, Appendix II, for a total of 22. Using the qualification, the number of trials for soybeans could be reduced to 8, thus lowering the total trials required to 18.

Estimation of Dietary Share

Data measuring the importance of the various crops in the diet of Canadians are derived from the *Nutrition Canada Food Consumption Patterns Report*, (1975, see Reference No. 3) and are expressed as a percentage of the total diet for the general population. See Table 1, Appendix II.

This information was used to adjust the number of field trials up or down, depending on the percentage share of the particular crop in the diet. The critical levels were adopted from the U.S. methodology (1.00%, 0.40%, 0.10%, 0.02%).

The data were examined, as in the U.S. methodology, to determine if any particular crops represented significantly greater proportions in the diets of nonnursing infants compared to the general population. No significant differences were found, except for oats.

Data were not available for a number of crops. Estimates were made to fill in some of the gaps as follows:

- the nutrition survey estimate of 0.17% for plums, prunes and apricots was allocated 0.13% to plums and prunes and 0.04% to apricots, according to the relative areas.

- the nutrition survey estimate of 0.43% for peaches and nectarines was allocated 0.40% to peaches and 0.03% to nectarines, according to the relative areas.

- the nutrition survey estimate of 0.18% for turnips and parsnips was allocated 0.16% to turnips and 0.02% to parsnips, according to the relative areas.

[2] For crop groups and crops representative of a group, refer to Section 15, *Crop Groups*, (Reference No. 18); for crop food codes refer to *Codex Alimentarius, Pesticide Residues in Food, Volume 2*, 2nd Ed., 1993 or later (Reference No. 1).

- the percentage indicated for squash, zucchini and pumpkins of 0.06% represents only squash.

- using the human food requirements data from the Grain Marketing Unit of Statistics Canada, it is estimated that the dietary percentage for barley is approximately 0.10%.

- according to the nutrition survey, vegetable oils in cooking oil, salad dressing and margarine represent 0.47% of the diet. Canadian produced crops of corn, canola, soybeans, sunflower and safflower are the source of this oil, with the bulk of the oil coming from canola, corn and soybeans. It seems unlikely that either canola or soybeans could approach or exceed 0.40% of the diet, but they are probably above 0.10%.

- it is assumed that the dietary share of tame hay, corn for silage, flaxseed, lentils, mustard seed, canary seed and dry field peas is less than 0.10% for purposes of applying Step 3.

- it is assumed that the dietary share of dry field beans, sunflowers, tobacco, sugar beets, buckwheat, millet, triticale, safflower, caraway seed and ginseng is less than 0.02% for purposes of applying steps 4 and 6.

- it is assumed that the dietary share of cranberries and saskatoon berries is less than 0.02% for purposes of applying steps 4 and 6.

- considering that the dietary share of all nuts other than peanuts is 0.03% in the nutrition survey, it is assumed that the dietary share of hazelnuts and filberts is less than 0.02%.

- data were not available from the nutrition survey for a number of minor vegetables, i.e., radishes, Brussels sprouts, green onions and shallots, Chinese cabbage, leeks and spinach. By comparing the areas and dietary share of these crops with other vegetables and the equivalent U.S. dietary share data, it is estimated that the dietary share of spinach would reach 0.02% and fall short of 1.00% for purposes of applying steps 4 and 6. The dietary share of the others is assumed to be less than 0.02%.

Additional/Fewer Trials

For the purposes of standardizing the number of required field trials, it should be emphasized that in most cases (see next paragraph) the number of trials, based on the above criteria and listed in Table 1 (Appendix II), represents the minimum number of trials that is acceptable, with the exception of crop group MRLs. See Section 15, *Crop Groups*, subsection 15.4, *MRLs for Crop Groups*, or the uses resulting in no quantifiable residues as described later in this document. Additional trials are always welcome and, in fact, encouraged because more data points provide greater certainty of expected residue levels.

As discussed above, the PMRA has taken into consideration several major factors to determine the necessary numbers of trials, and believes that these numbers are applicable in most cases. However, in limited circumstances, the Agency may require additional trials or accept fewer trials than specified in Table 1 (Appendix II). It should be noted that where the required residue data is highly variable and/or inconclusive, additional residue data may be required/requested. Any petitioner believing that fewer trials are adequate for a given crop should provide a convincing scientific rationale. In such cases, the Agency strongly advises petitioners that before initiating such trials, they submit a protocol outlining number and locations of trials, and the rationale.

The numbers of trials in Table 1 (Appendix II) represent how many acceptable trials are required, reflecting the label use pattern producing the highest residue. In most cases, such trials are performed at the maximum rate per application and per season, the maximum number of applications, the minimum interval between applications, and the minimum preharvest interval. Trials that reflect other use patterns are not counted unless the difference in use is insignificant (± 20% of gap, [e.g., rate and PHI], i.e., 20% of any one component of gap, unless the component has a significant effect on residues). In those cases where multiple use patterns are desired and it is not clear which would result in the highest residue, e.g., different PHIs as a function of application rate, the full number of trials is needed for each use unless side-by-side studies consistently show higher residues from one use pattern. Additional guidance on this subject for early season uses appears in subsection 8 of this section. Petitioners must also be aware that trials are not counted that for some other reason do not generate viable samples reflecting the proposed use. Possible causes of the absence of such samples include the following: crop failure, mislabelling of samples, contamination, misapplication and/or insufficient documentation of sample integrity from collection to analysis. For these reasons, it would be prudent for petitioners to conduct at least the field portions of a greater number of trials than the minimum listed in Table 1 (Appendix II).

As already mentioned, the Agency has determined that one or two trials are adequate for very low acreage crops (81-810 hectares/200-2,000 acres). In such scenarios, petitioners have the option of conducting additional field trials to attempt to define clearly the residue pattern as a result of application. In fact, petitioners always have the option of conducting three or more field trials at the 1x rate, with two treated samples per trial, instead of the two trials with at least four treated samples per trial and plots reflecting 1x rate, (or 2 plots at 1X rate plus 2 plots at 2X rate when residues are less than the limit of quantitation (LOQ) as discussed above).

Additional Points

Additional points need to be made with regard to the numbers of trials listed in Table 1 (Appendix II):

1. Residue decline studies are often required for many uses on crops needing $5 trials. Refer to subsection 6, *Residue Decline Studies*, of this section for details.

2. These numbers are based upon each crop being the only one within its crop group for which a MRL is requested. Refer to Section 15, *Crop Groups*, subsection 15.4, *MRLs for Crop Groups*, for how many trials are needed for uses on crop groups.

3. Fewer trials may be accepted for uses that do not yield quantifiable residues. Refer to subsection 7, *Uses Resulting in No Quantifiable Residues,* of this section for details.

4. The numbers reflect the use of only one formulation type being requested for use on each crop. Refer to subsection 9.10, *Formulations*, regarding data requirements for additional types of formulations.

5. The spray volumes specified for certain uses, especially ultra-low volume (ULV) and orchard uses, can affect the number of required trials. This is discussed in subsection 9.11, *Spray Volumes - Ground versus Aerial Equipment*, of this section.

6. Fewer trials are needed for an amended registration provided that the existing MRL is shown to be adequate. Refer to subsection 9.12, *Amended Registrations,* of this section for more details.

7. Table 1 (Appendix II) addresses only national registration of terrestrial uses on domestic crops. Data requirements for import MRLs are the same as those for domestic.

8. The numbers represent trials required for permanent MRLs. In the future, it may be possible to establish temporary MRLs. The Agency is considering requesting one-half of the total number of trials required for national registration, to a minimum of two trials.

9. Validated analytical methodology, appropriate storage stability data, and documentation on sample handling, shipping, and storage intervals and conditions from sampling to analysis are needed to support all field trials. Refer to Sections 3, *Residue Analytical Method,* 5, *Storage Stability Data*, and Regulatory Directives, Dir98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, and Dir98-03, *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products.* See References 5, 6 and 8, respectively.

10. Sampling and analysis of treated and control samples for each raw agricultural commodity (RAC) of a crop as specified in Attachment I, Appendix I, e.g., corn grain and silage, must be included in all field trials.

11. Commercially important varieties of a crop, as well as seasonal variations, e.g., winter

wheat versus spring wheat, must be covered by the field trials. Data on different varieties are especially important if there are significant differences in size and/or length of growing season.

12. For national registration, it is not necessary to conduct field trials in more than one growing season, i.e., in more than one year, although it would be considered advisable, especially when the weather/climatic conditions deviate significantly from the normal conditions. Where a registration is being sought for a geographically restricted area, e.g., a province, field trials in more than one growing season are required for crops requiring eight or more field trials nationally as detailed in Attachment II (Appendix V).

13. The numbers of trials are intended to cover terrestrial food uses on growing crops. They do not address postharvest applications to commodities, such as fruit or stored grain, or commodities grown in greenhouses. Due to controlled climatic conditions or specific uses, including postharvest dips of fruits, postharvet treatment of grains and greenhouse crops, two trials and eight treated samples are sufficient. Other applications will continue to be handled on a case-by-case basis.

14. Where radiolabeled data for a crop grown from treated seed show no uptake of residues, i.e., total radioactive residue (TRRs) in all plant tissues are less than 5 parts per billion (ppb), no further data are required. If TRRs are greater than 5 ppb, then it is not treated differently than any other food use and all data requirements are in effect. However, in many cases, such uses may be eligible for the 25% reduction in the number of trials due to residues being below the method's LOQ.

9.5 Sample Requirements

With respect to how samples must be collected, the Agency normally bases its assessment of MRLs on composite samples.

Number/Weight of Crop Samples

The number or weight of agricultural commodity that must be collected for each composite sample is specified in the Codex, *Guidelines on Minimum Sample Sizes for Agricultural Commodities from Supervised Field Trials for Residue Analysis*. See Attachment I, Appendix I, the PMRA revised ALINORM 87/24A, 1987, Reference 2; this guidance document has been revised by the PMRA, as shown by the shading of changes made to elucidate sampling requirements for all RACs listed. Petitioners should follow these revised Guidelines.

In each field trial report, the petitioners must indicate whether or not these Guidelines have been followed. If they have not, an explanation must be provided along with details on how the sampling deviates from the Codex recommendations. Petitioners must also include in the field

trial report, the number of agricultural commodity units making a composite sample as well as the weight of the composite sample.

Number of Samples Per Plot

With regard to the number of samples per plot, the Agency has determined that two composited, treated samples are needed to provide some estimate of variability, but that three or more samples are unlikely to result in significant additional information.

Number of Field Trials

The numbers of field trials for each crop listed in Tables of Appendix II (pages 9-71 to 9-73) represent the minimum number of acceptable trials reflecting the label use pattern producing the highest residues. Trials reflecting other use patterns or which for some reason do not generate viable samples will not be counted. In addition, these numbers of trials are predicted upon only one formulation type being requested for use on the crop. If additional types or formulations are desired, additional data may be needed as discussed in the subsection 9.10, ***Formulations***.

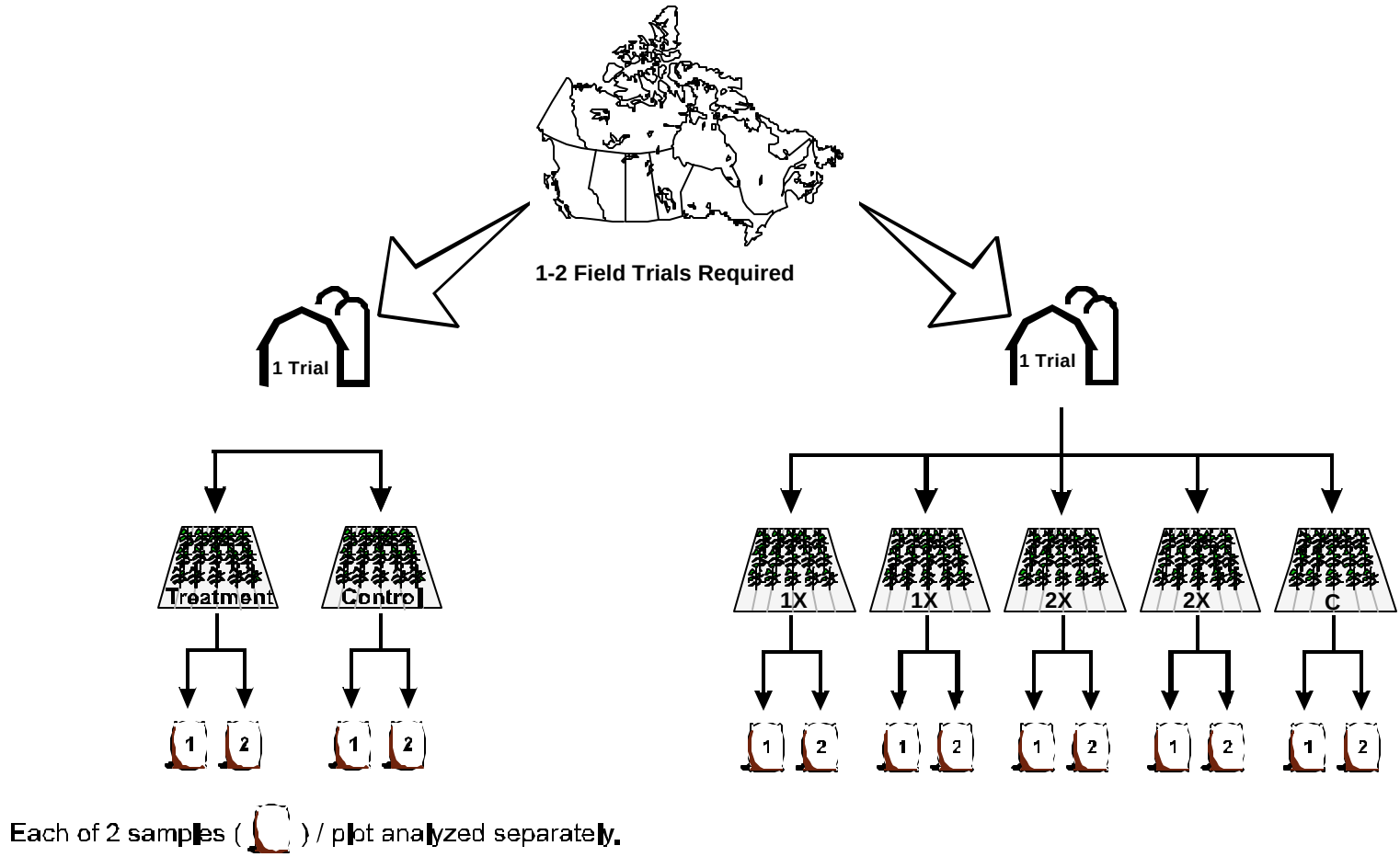
A) Crops Requiring One to Two Field Trials

For crops that require only one to two field trials (81-810 hectares/200-2,000 acres; see page 9-7, ***Determination of Numbers of Field Trials,*** **Step 1**), two composite samples at the proposed or registered application (1x rate) from each plot may be adequate if the LOQ is sufficiently low (0.01 - 0.05 ppm). If the LOQ is above 0.05 ppm, then two plots at 1X and two plots at 2X gap rate should be treated.

Furthermore, each plot must receive independently prepared applications of the agricultural chemical to allow assessment of variability. In other words, the same tank mixture, i.e., pesticide treatment, spray solution, preparation, batch, etc., must not be used to treat more than one plot.

Note that as discussed in subsection 9.4 of this section, petitioners always have the option of conducting three or more field trials at the 1x rate with two treated plots per trial, instead of the two trials with at least four treated samples per trial and plots reflecting the 1x rate.

A schematic overview for crops requiring two trials is shown below:



Each of 2 samples ( ) / plot analyzed separately.

*If the LOQ is sufficiently low (0.01 - 0.05 ppm) then one-two plots must be treated at the proposed or registered application rate (1x rate); if the LOQ is above 0.05 ppm then two plots at 1x and two plots at 2x gap rate should be treated.

B) Crops Requiring Three Field Trials or More

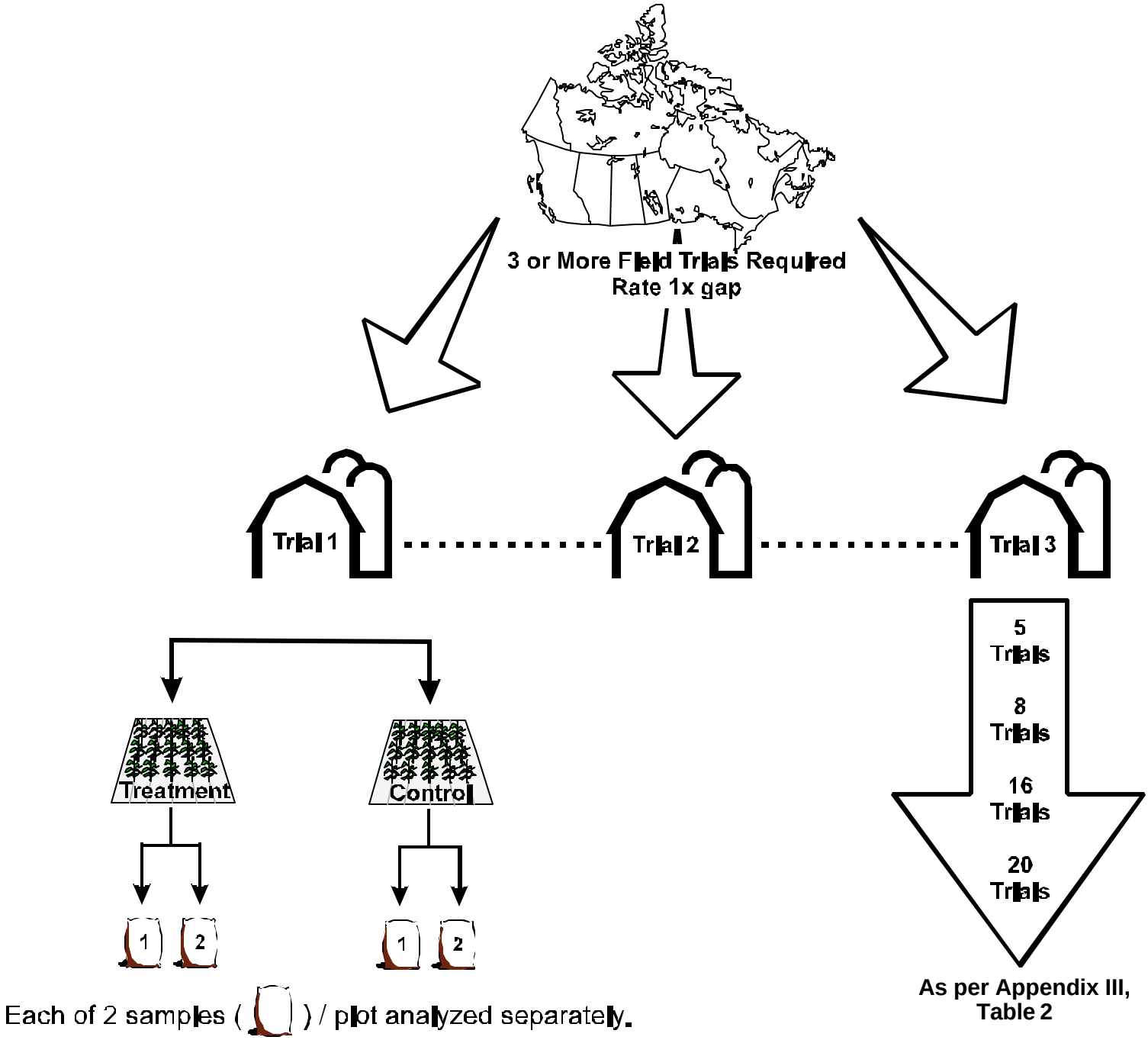
The Agency has concluded that two independently composited samples of a treated commodity must be collected at each plot for each trial site, i.e., for each field trial with the exception of crops needing only two trials as described later in this section. In addition, at least one control, i.e., untreated, sample must be collected and analyzed at each site.

In those cases where the two treated composite samples are obtained from the same plot, it needs to be emphasized that the samples should be collected in two separate sampling operations in the plots, following the aforementioned Codex Guidelines. See Attachment I. Splitting one sample from a plot or conducting two analyses on one sample is not an acceptable alternative to separately collecting and analyzing two samples.

In other words, multiple analyses of a single sample or of subsamples constitute the equivalent of only one data point. However, as explained below, if such multiple analyses are conducted,

each value must be reported and clearly indicated as to which sample it represents.
In the future, the petitioner may be required to assess and report whether the dataset produced for the field trials in a zone are normally distributed, i.e., statistically the data follow a normal distribution.

A schematic overview for crops requiring 3, 5, 8, 12, 16 and 20 trials is shown below:



Handling of Samples

With regard to the handling of samples at the residue analysis stage, petitioners must follow the guidance in Section 102 of the U.S. Food and Drug Administration (FDA), *Pesticide Analytical Manual*, Volume I (PAM I, see Reference No. 19) on sample compositing and comminuting, except for advice concerning the washing of RACs prior to analysis. In this case, petitioners must follow advice given in the Health Canada, *Analytical Methods for Pesticide Residues in Foods*, Section 4.1(a)(i)(A), *Samples Ready for Sale* (Reference 22), to not wash samples; this advice is supported by the Food and Agriculture Organization (FAO) Guideline (Reference 23). Multiple analyses of a sample are not required, but are advised as a check in those cases where the residue values from the two composite samples are significantly different.

In all field trial reports, petitioners need to indicate clearly whether each reported residue refers to a separate sample or a second analysis of the same sample. In either case, all analyses must be reported; petitioners must report multiple analyses of a single sample, as well as all of the results of multiple samples in a trial.

Data Reporting

Individual values and average values for each site should be reported to allow proper assessment.

9.6 Field Trial Regions

Method of Delineating Crop Field Trial Regions

The Canadian major and minor crop field trial regions were delineated, using the geographic information system (GIS) data processing hardware and software facilities in Spatial Analysis and Geomatics Applications (SAGA), Agriculture Division, Statistics Canada. In general, the delineation process involved integration, evaluation and reference to numerous geographic data sources in a GIS to determine the best sources for the delineation.

As a first step prior to the delineation of the Canadian regions, the geographic descriptions provided in the EPA document, *Pesticide Reregistration Rejection Rate Analysis Residue Chemistry*, (Reference 16), were used to digitize the U.S. crop field trial regions. This work was completed in order to ascertain problems that might be associated with the delineation of the Canadian regions at the U.S./Canada border.

The delineation of the Canadian field trial regions required the development of coverages that depict current crop growing regions, and also where crops could be grown (arable land). Current crop maps, i.e., crop area dot maps and cropland of Canada, were derived using the 1991, Agricultural Ecumene, and statistical data from the 1991, Census of Agriculture, (Statistics Canada). Arable land in Canada was derived by intersecting the Agricultural Ecumene with the *Canada Land Inventory* (CLI) for agriculture coverages. A more detailed

description of the methodology and delineation criteria used to define arable land and cropland regions of Canada is found in an earlier document, *Methodology and Delineation Criteria Used for the Delineation of Canadian Crop Area and Arable Land Regions,* SAGA/PMRA, 1996. See Reference No. 15. Lands outside the arable regions were considered agriculturally unimportant and therefore were not included in the field trial region delineation.

Numerous maps, available in both digital and hard copy format, were acquired, manipulated and assimilated into a GIS. The first task involved the assessment of the strengths and limitations of the various datasets. This process evaluated supporting documentation to thoroughly understand the content and information used to produce a particular dataset. Next, the GIS was used to conduct a spatial evaluation of the various datasets in digital format. This evaluation noted commonalities and discrepancies between the various data sources, and evaluated those differences, using the information from the supporting documentation.

This overlap of information was useful to verify boundary locations and also to eliminate less important and redundant coverages. The Ecoregions of Canada database provided a useful base map for the delineation process as it is derived from the Soil Landscape of Canada database and presents climate, soil and topographical data in a single coverage. An intersection of the Agricultural Ecumene with the Ecoregions of Canada indicated ecological variations within Canada's agricultural regions. Soil and climate data from the Soils of Canada, and the Climatic Characteristics of Canada databases respectively, provided further detail within the ecological regions. From this analysis, eight data sources were selected as primary sources of information for the delineation process. These sources included:

- Agricultural Ecumene of Canada (SAGA, Agriculture Division, Statistics Canada);
- Arable Land in Canada (SAGA, Agriculture Division, Statistics Canada);
- Terrestrial Ecozones and Ecoregions of Canada (Environment Canada);
- Ecoclimatic Regions of Canada (Environment Canada);
- Soils of Canada Map (Agriculture and Agri-Food Canada);
- Canada Land Inventory for Agriculture (Environment Canada);
- Crop Area Dot Maps (SAGA, Agriculture Division, Statistics Canada); and
- Climatic Characteristics of Canada (Natural Resources Canada).

In addition, supplemental data sources were also used, where appropriate.

The next step involved systematically displaying the digital maps and overlays of map combinations using GIS software. Each of the map coverages was assessed alone and integrated with other available coverages to identify key biophysical conditions and relationships with cropping practices. An excellent example of these relationships would be the change in biophysical conditions within the Fraser Valley of British Columbia and the emergence of fruit crops.

After identifying the key biophysical and crop relationships, the next step assigned boundaries to those regions of similar crops and biophysical conditions. From this process, SAGA found that the boundaries fell into two categories: hard and soft lines. Hard lines are boundaries where all or most of the source information indicated a dramatic change. An excellent example is the Southern Ontario border between Zones 5 and 5A, extending from the St. Lawrence River to Georgian Bay. Here the Canadian Shield extends southwards with dramatic changes in biophysical conditions that directly impact on the nature of agriculture. Soft lines refers to the more gradual changes in biophysical conditions and crop practice. An example of this can be seen across the prairies, extending from dryland conditions in the Swift Current, Saskatchewan region to cold temperate conditions in the Peace River region.

The crop area dot maps assisted in the placement of the delineation boundaries. Crop and ecological maps reflect variations in soils and climate, but contain some anomalies associated with modification of the landscape or unnatural processes, such as irrigation. These anomalies were considered when generating the field trial region boundaries. An example of such an anomaly is the irrigation district of Alberta that has similar biophysical conditions to Zone 7. Because of the irrigation, this region contains a very different crop mix to Zones 7 and 14. Many irrigation areas can be found in Zone 7, but because of the size of the Alberta anomaly, this became its own subregion. This process allows for specific identification of field trial regions and acknowledges the close relationship of crops with biophysical conditions.

Several preliminary versions of the field trial regions were generated and evaluated by SAGA. These versions placed different emphasis on the various data sources used in the definition of boundaries. In consultation with the PMRA, a preliminary final version was chosen that accommodated delineation of the Canadian regions to match the U.S. regions.

The final version involved modifying the above version to match with appropriate features. In the U.S. version, highways, rivers and political borders as boundaries were chosen. In many parts of Canada, there is a lack of appropriate and identifiable features to adequately define Canadian regions. The final delineation was derived by clipping the boundaries by soil zones; this recognizes the close relationship between soils, climate and crops. This approach also has the added advantage of easily verifying a test site to determine if it falls within one of the broad soil zones.

The PMRA distributed copies of the proposed crop field trial delineation to its major stakeholders. Based on the feedback received, a minor modification was made and the regions were considered final as of February 9, 1996.

Map Outputs

Five maps showing the final *Canadian Major and Minor Crop Field Trial Regions* have been produced in digital and hard copy colour format (see Appendix VI or VII). The five maps

depict the field trial regions throughout Canada, the Northern U.S. and North America.

These maps are identified as follows:

- *Canadian and U.S. Major and Minor Crop Field Trial Regions*
- *Major and Minor Crop Field Trial Regions for Canada and the Northern U.S.*
- *Major and Minor Crop Field Trial Regions within Canadian Arable Lands*
- *Canadian Major and Minor Crop Field Trial Regions*
- *Canadian Major and Minor Crop Field Trial Regions - Safe Zones*

Description of Crop Field Trial Regions

This subsection describes the seven major and the four minor field trial regions. Each of these regions recognizes physical characteristics, such as soils, and crops and climate, that make the region unique within the Canadian agricultural landscape. The subzones address differences within a region, generally reflected in the types of crops grown in that region.

The Canadian regions, as much as possible, correspond to the U.S. regions, based upon the broad descriptions outlined in the previous section.

These regions are identified as follows:

- Zone 1: Appalachian
- Zone 1A: Atlantic
- Zone 5: Southern Ontario
- Zone 5A: Northern Shield
- Zone 5B: St. Lawrence Valley
- Zone 7: Dryland Prairie
- Zone 7A: Southern Alberta
- Zone 9: Rocky Mountains
- Zone 11: Dryland Interior
- Zone 12: Pacific
- Zone 14: Northern Prairie

The **Appalachian zone (Zone 1)**, extends throughout New Brunswick, Gaspé, and the Appalachian Region of Southern Québec. Humo-Ferric Podzols dominate this region with pockets of Gray Luvisols and Dystric Brunisols. These marginal to intermediate soils exist in an area of considerable relief, especially in mountainous areas of the Appalachians. A humid temperate climate exists in this region with low to intermediate values for most climatic indicators, such as corn heat units. In general, this region contains marginal agricultural capability with pockets of intermediate capability. Potatoes, grains, tame hay, and limited vegetable crops comprise the agriculture in this region.

A more favourable growing climate in the **Atlantic zone (Zone 1A)**, distinguishes it from Zone 1. As a result, this region has a greater potential for fruit and vegetable production compared to Zone 1.

The **Southern Ontario zone (Zone 5)**, extends from Windsor to the St. Lawrence River, just north of Kingston. Grey Brown Luvisols dominate this region with considerable areas of Humic Gleysols in the south and Melanic Brunisols in the north. These good soils result in high land capability ratings for agriculture under the Canada Land Inventory. The region experiences a moderate climate favourable to a wide variety of crops. Predominantly flat terrain is found in this region with some regional anomalies, such as the Niagara Escarpment. This zone is characterized by Canada's most diverse mix of crops, including extensive fruit, vegetable, grain and corn production.

Zone 5 also includes a small portion of Southern Manitoba. Although the soils and climate of this Manitoba region differ from Southern Ontario, it is included with Zone 5 in order to maintain integrity with the American delineation. Also, certain crops, notably corn, are found in both regions. However, in contrast to Southern Ontario, soils in this region are predominately Black Chernozemic on flat terrain. The climate is much drier than Southern Ontario, as indicated by the Dry Subhumid Thornthwaite Classification.

The **Northern Shield zone (Zone 5A)**, differs from both the St. Lawrence Valley and Southern Ontario zones, but in keeping with the American classification, remains related to those two zones. This region includes the various pockets of agriculture that extend from Manitoba to the north shore of the Gulf of St. Lawrence. The island of Newfoundland is also included. This region of the Canadian Shield is dominated by rough to rolling terrain of Humo-Ferric Podzols of marginal to poor agricultural capability. Agricultural activity occurs in pockets of Brunisols and Gleysols found throughout this region. Climatic conditions vary considerably throughout this region, but are generally not conducive to agricultural activity. Tame hay, grains, and some specialty fruits are the main crops of this region. Very little agricultural activity is found in Newfoundland. The island's topography, mountainous in some areas, is generally unsuitable for agriculture. The soils, climate, topography, and limited agriculture distinguish this region from Nova Scotia and New York State in U.S. Zone 1.

The **St. Lawrence Valley zone (Zone 5B)**, produces fruits, vegetables and corn similar to the crops of Southern Ontario. Climatological and soil characteristics are the main criteria for the boundary separating Zones 5 and 5B. The Montréal area is dominated by Melanic Brunisols of good agricultural capability. Down river, the soils change to Humic Gleysols and Humo-Ferric Podzols of marginal agricultural capability. Shorter frost-free periods and lower corn heat units are the main climatic differences that distinguish this region from Zone 5.

The **Dryland Prairie zone (Zone 7)**, extends from west of Regina to near the Alberta border. Brown and Dark Brown Chernozemic soils dominate this region with pockets of Brown

Solonetz and Orthic Regosol soils. Agricultural capability remains good with some limitations associated with a dry climate. The Thornthwaite Classification rates this region as semiarid to dry subhumid. Other key climatic indicators, such as growing degree days, indicate generally favourable growing conditions with minor limitations. Topography is flat with pockets of rolling terrain. Grains and hay are the main crops produced in this zone, with a lack of the specialty crops found in Subzone 7A, Zone 5, Manitoba, or Zone 14.

The **Southern Alberta Irrigation zone (Zone 7A)**, is an anomalous zone due to irrigation practices. All datasets, including soil and climatic variables, indicate that this region should be included with Zone 7. However, as a result of irrigation, several vegetable crops are found in this region, including sweet corn, green peas, sugar beets, potatoes and cucumbers.

The **Rocky Mountains zone (Zone 9)**, includes the moist region of the eastern reaches of the Canadian Rockies. Topography is hilly to mountainous with a variety of soils. The climate varies considerably, with Thornthwaite classes ranging from humid to dry subhumid. This region lacks the large, isolated areas of agricultural activity found in the United States. In Canada, small pockets of agriculture can be found in the southern portions of this zone. These areas of agriculture cannot be considered statistically valid for determining trends in crops for this zone.

The **Dryland Interior zone (Zone 11)**, encompasses the dryland interior of British Columbia. Mountainous topography limits agricultural activity to valleys. Considerable crop variation arises due to local topography, soils, and climate. Dark Brown and Dark Grey Chernozemic are the main soils in this region. Climate is dry subhumid to semiarid, but variables, such as sunlight hours, favour agriculture in these areas. Crops vary considerably in this region, from tame hay and grains in the Kamloops area to a variety of fruit and vegetable crops in the Okanagan Valley.

The **Pacific zone (Zone 12)**, includes the wet coastal regions of British Columbia and Vancouver Island. Agriculture is limited to the Fraser Valley and pockets on Vancouver Island. A Humic Gleysol soil characterizes the Fraser Valley, and Dystric Brunisols are found on Vancouver Island. Mountainous topography is a major limitation for agriculture in this region; however, the warm wet climate favours agricultural activity.

The **Northern Prairie zone (Zone 14)**, covers the Northern Prairies from Manitoba to the Peace River area of Northern Alberta. Agricultural activity is found primarily in Black Chernozemic and Luvisolic soils. This zone includes the Dark Brown Chernozems of Zone 7, and the Solonetzic soils of the Peace River area. Agricultural capability indicators in this region vary from excellent in the interior to marginal along the fringes, with non-agricultural soils in the Boreal Forest regions. Zone 14 experiences a predominantly dry subhumid continental climate; however, other climatological indicators, e.g., corn heat units and growing degree days, vary throughout the region. Crop production varies throughout this zone. Canola, barley, peas, and mustard seed are the crops that differentiate this zone from Zone 7.

Geographic Descriptions for Safe Zones within Crop Field Trial Regions

This subsection describes the field trial regions as geographic safe zones. Within each complex field trial region, simplified polygons have been delineated to provide latitude/longitude coordinates and/or easily recognizable physical or administrative features. The safe zones are considered as areas that are unequivocally within a given field trial region. See the Appendix VI map, *Canadian Major and Minor Crop Field Trial Regions - Safe Zones*.

Safe Zones:

The safe zones are considered as areas that are unequivocally within given field trial regions. They are indicated in the *Canadian Major and Minor Crop Field Trial Regions - Safe Zones* map. Areas close to the zone boundaries between safe zones are denoted as the transition zones. The size of these areas varies considerably from one place to another.

Locating a Trial Site in a Zone/Region:

Maps defining safe zone areas in major and minor crop field trial regions of each province of Canada are provided in hard copy colour (Appendix VI) and black/white (Appendix VII) formats. These maps are used alongside reference maps[3] to locate crop field trial sites in a safe zone. Coloured reference maps showing crop regions/zones overlayed on the Census Division maps are provided in Appendix VI. The petitioner may utilize these maps to assign a trial site to a given region/zone and may confirm its location in a safe zone by referring to the longitudinal/latitudinal coordinates listed below. In addition, the petitioner may utilize hand-held or other GPS monitors (Global or Geo Postioning System) to identify coordinates of their trial sites.

Crop field trials conducted in a transition zone may generate residue data that may or may not reflect the residue pattern seen in the safe zones. Therefore, the acceptability of the residue data from transition zones is assessed during the evaluation of the residue data.

The petitioner must indicate the location of trial sites on the black and white maps provided in Appendix VII and provide longtitudinal and latitudinal coordinates for each site.

[3] Geographical Classification SGC 1991 Volume II, published by authority of the Minister responsible for Statistics Canada, Catalogue 12-572, ISBN 0-660-56558-7. Other maps may be used, e.g., topographical maps.

Appalachian (Zone 1)
The safe zone includes all of the province of New Brunswick and most of the south shore of Québec, including all of the Gaspé Peninsula. The western boundary of the zone runs from the south shore of the St. Lawrence River at geographic map coordinate **(1) 47° 8' 31"N & 70° 20' 56"W to (2) 46° 50' 56"N & 70° 25' 55"W, (3) 46° 31' 44"N & 71° 11' 42"W, 4) 46° 1' 16"N & 71° 12' 50"W**. It meets the Québec/Vermont border at **(5) 44° 59' 17"N & 72° 36' 47"W**. The southern boundary follows the Québec/Vermont, Québec/New Hampshire, Québec/Maine and New Brunswick/Maine border. The northern boundary of the safe zone follows the south shore of the St. Lawrence River around the Gaspé Peninsula and Baie des Chaleurs.

Atlantic (Zone 1A)
The safe zone includes all of Nova Scotia, including Cape Breton Island, and Prince Edward Island.

Southern Ontario (Zone 5)
The Southern Ontario safe zone is split between two safe zone polygons. One of the polygons is located in Southern Manitoba south of Winnipeg. The other polygon includes most of Southern Ontario. It also includes Pelee Island in Lake Erie and Manitoulin Island in Georgian Bay.

The southern boundary of the safe polygon in Manitoba runs along the Canada/U.S. border at **(1) 49° 00' 00"N & 98° 5' 49"W to (2) 49° 00' 00"N & 96° 46' 12"W**. The polygon is also bounded by **(3) 49° 55' 44"N & 98° 21' 50"W** and **(4) 50° 8' 46"N & 96° 46' 55"W.**

The northern boundary of the safe zone polygon in Southern Ontario runs from Georgian Bay at **(1) 44° 29' 10"N & 80° 3' 32"W** to the St. Lawrence River at **(2) 44° 13' 1"N & 76° 28' 8"W**. All regions of Southern Ontario south of this line, including the Bruce Peninsula, are also included.

Northern Shield (Zone 5A)
The safe zone polygon includes large areas of Northern Ontario, Northern Québec, the island of Newfoundland and Anticosti Island. The safe zone also includes a small portion of Eastern Manitoba and the southern tip of Labrador.

The polygon follows the Ontario/Minnesota border beginning at **(1) 48° 33' 58"N & 93° 52' 12"W** where it meets the north shore of Lake Superior. The southern boundary of the polygon follows the north shore of Lake Superior, and the shoreline of North Channel and Georgian Bay. The polygon extends eastward from the shoreline of Georgian Bay at **(2) 44° 59' 35"N & 79° 58' 55"W** to **(3) 44° 31' 26"N & 76° 32' 10"W**. The polygon runs northwards where it meets the Ottawa River at **(4) 45° 40' 5"N & 76° 37' 26"W**. The boundary

continues eastward through Québec where it reaches the north shoreline of the St. Lawrence River at **(5) 47° 39' 29"N & 70° 6' 7"W.** The polygon follows the north shoreline of the St. Lawrence River until it reaches the northern shore of the Gulf of St. Lawrence (just east of the Labrador border) at **(6) 51° 43' 12"N & 56° 28' 55"W**. The northern boundary of the polygon runs westward across Northern Québec and Northern Ontario through **(7) 51° 18' 29"N & 64° 24' 14"W, (8) 51° 4' 55"N & 70° 3' 4"W, (9) 50° 22' 1"N & 70° 18' 54"W, (10) 49° 57' 11"N & 74° 13' 48"W, (11) 51° 43' 19"N & 74° 0' 14"W, (12) 51° 45' 36"N & 76° 6' 47"W, (13) 49° 2' 56"N & 77° 52' 55"W, (14) 49° 30' 4"N & 84° 12' 25"W** to the extreme western boundary at **(15) 52° 1' 23"N & 95° 41' 27"W**. The western boundary runs southward to **(16) 50° 14' 6"N & 95° 42' 32"W** and runs eastwards to meet **(17) 50° 13' 34"N & 93° 50' 46"W.** The polygon closes at the Ontario/Minnesota border at **(1) 48° 33' 58"N & 93° 52' 12"W.**

St. Lawrence Valley (Zone 5B)

The safe zone polygon includes the parts of Eastern Ontario, the Montréal region and parts of the North Shore and Eastern Townships of Québec. The polygon is bounded by geographic map coordinates **(1) 45° 6' 29"N & 74° 49' 8"W, (2) 45° 5' 53"N & 73° 2' 24"W, (3) 46° 8' 2"N & 71° 51' 14"W, (4) 46° 42' 29"N & 71° 52' 37"W, (5) 45° 36' 25"N & 74° 32' 28"W, (6) 45° 15' 29"N & 76° 4' 30"W** and **(7) 44° 38' 46"N & 75° 46' 8"W.**

Dryland Prairie (Zone 7)

The safe zone polygon is located in Alberta and Saskatchewan. The southern boundary of the polygon runs along the Canada/U.S. border between **(1) 49° 00' 00"N & 110° 41' 46"W** and **(2) 49° 00' 00"N & 102° 58' 41"W.** The polygon is also bounded by geographic map coordinates in latitude and longitude as follows: **(3) 50° 54' 29"N & 105° 12' 58" W, (4) 51° 36' 18"N & 104° 40' 12"W, (5) 52° 5' 38"N & 107° 28' 30"W, (6) 51° 36' 18"N & 107° 55' 37"W, (7) 51° 39' 40"N & 111° 8' 46"W, (8) 50° 31' 55"N & 112° 4' 5"W, (9) 50° 22' 52"N & 110° 12' 18"W, (10) 49° 42' 11"N & 109° 50' 49"W** and **(11) 49° 37' 41"N & 110° 36' 00"W.**

Southern Alberta (Zone 7A)

The safe zone polygon lies entirely within Alberta. The southern boundary of the polygon runs along the Canada/U.S. border between **(1) 49° 00' 00"N & 112° 12' 40"W** and **(2) 111° 7' 26"W**. The polygon is also bounded by geographic map coordinates in latitude and longitude as follows: **(3) 49° 57' 50"N & 110° 59' 42"W** and **(4) 50° 2' 31"N & 112° 22' 8"W.**

Rocky Mountains (Zone 9)

The safe zone polygon falls on both sides of the Alberta and British Columbia border. The southern boundary of the polygon runs along the Canada/U.S. border between **(1) 49° 00' 00"N & 115° 54' 47"W** and **(2) 49° 00' 00"N & 114° 24' 14"W.** The polygon is also bounded by geographic map coordinates in latitude and longitude as follows: **(3) 51° 37' 48"N**

& 115° 37' 1"W, (4) 54° 54' 22"N & 121° 13' 34"N, (4) 54° 54' 22"N & 122° 23' 38"W and, **(5) 51° 31' 1"N & 116° 24' 25"W.**

Dryland Interior (Zone 11)

The safe zone polygon lies entirely within mainland British Columbia. The southern boundary of the polygon runs along the Canada/U.S. border between **(1) 49° 00' 0"N & 121° 1' 55"W** and **(2) 49° 00' 0"N & 117° 20' 24"W.** The polygon is also bounded by geographic map coordinates in latitude and longitude as follows: **(3) 51° 16' 55"N & 117° 28' 34"W, (4) 53° 16' 41"N & 121° 34' 48"W, (5) 55° 34' 26"N & 124° 21' 58"W, (6) 54° 15' 25"N & 126° 37' 26"W and**, **(7) 51° 1' 8"N & 121° 52' 52"W.**

Pacific (Zone 12)

Includes the Queen Charlotte Islands, Vancouver Island and the Gulf Islands of British Columbia. The polygon is also bounded by geographic map coordinates in latitude and longitude as follows: **(1) 55° 25' 8"N & 127° 44' 42"W, (2) 53° 34' 26"N & 127° 48' 00"W, (3) 51° 51'' 39"N & 125° 34' 48"N** and, **(4) 50° 13' 23"N & 121° 57' 22"W.** The west border of the safe zone is bounded by the west coast of mainland British Columbia and begins in the south at the U.S. border (at **49° N**) running north along the coast to **129° 40' 8"N & 54° 57' 7"W**. To the east, the safe zone follows the Canada/U.S. border to **121° 57' 22"W.**

Northern Prairie (Zone 14)

The Northern Prairie (Zone 14) is split between two safe zone polygons. One of these polygons is located entirely within Manitoba, within the inter-lake district between Lake Winnipeg, Lake Winnipegosis, Lake Manitoba and Dauphin Lake. The other safe zone polygon is located in regions of Alberta, Saskatchewan and Manitoba. The geographic map coordinates of the safe polygon that is located entirely within Manitoba are expressed in latitude and longitude as follows: **(1) 53° 3' 7"N & 99° 12' 58"W, (2) 51° 48' 32"N & 98° 4' 37"W, (3) 51° 47' 24"N & 97° 27' 54"W, (4) 50° 26' 6"N & 97 ° 13' 12"W, (5) 50° 14' 13"N & 97° 47' 38"W** and **(6) 52° 46' 44"N & 99° 36' 40"W.**

The other safe zone polygon, the polygon that is located in portions of Alberta, Saskatchewan and Manitoba, runs along the Canada/U.S. border in Alberta between **(1) 49° 00' 00"N & 112° 35' 49"W** and **(2) 49° 00' 00"N & 113° 37' 41"W.** This polygon also runs along the Saskatchewan and Manitoba Canada/U.S. border between **(3) 49° 00' 00"N & 99° 32' 24"W and (4) 49° 00' 00"N & 101° 54' 11"W.** The polygon is also bounded by **(5) 49° 43' 44"N & 102° 24' 40"W, (6) 51° 8' 28"N & 104° 23' 17"W, (7) 52° 2' 42"N & 103° 35' 49"W, (8) 52° 41' 6"N & 107° 58' 59"W, (9) 52° 27' 32"N & 111° 38' 6"W** and, **(10) 50° 23' 17"N & 113° 17' 31"W, (11) 51° 7' 55"N & 99° 32' 24"W, (12) 52° 50' 42"N & 101° 25' 23"W, (13) 54° 1' 52"N & 101° 5' 2"W, (14) 54° 00' 43"N & 101° 52' 30"W, (15) 53° 26' 49"N & 103° 27' 22"N, (16) 54° 57' 11"N & 116° 17' 38"W, (17) 58° 18' 14"N & 115° 41' 31"W, (18) 58° 29' 31"N & 118° 24' 11"W, (19)**

57˚ 44' 20"N & 117˚ 14' 10"W, (20) 55˚ 55' 55"N & 120˚ 51' 00"W and **(21) 52˚ 48' 25"N & 115˚ 52' 48"W.**

Allocation of Crop Field Trials Among Regions

The number of field trials (Table 1, Appendix II) was distributed among the regions according to the share of crop area reported in each region in the 1991 Census of Agriculture. These distributions produced results with few whole numbers. In general, allocations were chosen that tended to distribute the field trials across as many different regions as seemed practical. The number of field trials by crop and region is presented in Table 2 (Appendix III). The areas of crops by region on an hectareage basis and acreage basis are presented in Table 3.1 (hectares, Appendix IV) and in Table 3.2 (acres, Appendix IV), respectively.

The above discussion focuses on the distribution of trials among regions. With respect to the distribution of multiple trials within a region, this should generally follow the relative production in the individual growing areas, i.e., provinces, of the region. However, the sites should also be sufficiently separated to reflect the diversity of the growing region, including soil types. In other words, if production is scattered throughout much of a region, the trials should not be clustered in one small portion of that region.

To aid the Agency's review process with regard to the distribution of trials among and within regions, petitioners are requested to include a copy of the map, *Canadian and U.S. Major and Minor Crop Field Trial Regions* (Appendix VIII), showing the locations of all sites of acceptable trials, i.e., those reflecting the proposed use, and generating viable samples. This map is to be used when trials overlap Canada and the U.S. within the same region.

For trials only in Canada, indicate on map, *Major and Minor Crop Field Trial Regions for Canada and the Northern U.S.*, (Appendix VIII), the location of these trials in appropriate regions. A final map, *Canadian Major and Minor Crop Field Trial Regions - Safe Zones*, (Appendix IX), is provided to guide petitioners in identifying zones that are unequivocally within a region.

9.7 Residue Decline Studies

Background

The withholding period is defined in the draft label as the period that must elapse between the last application of a chemical and harvesting of plants, or grazing (sometimes called the pregrazing interval) or cutting for livestock food. This period is termed the preharvest interval (PHI).

Objective

Terminal residues may *increase or decrease* in the edible portion of crops as a function of time posttreatment. Studies that elucidate this effect are termed residue decline studies.

The decline of an agricultural chemical deposit may be due to one or more of several factors, principally:

- physical removal, e.g., by rain, wind or volatization;
- chemical or photolytic degradation or metabolism in or on the plant; and
- apparent decline due to crop growth dilution.

Decline studies are of particular value in understanding the significance of these factors, especially when at the moment of application, a considerable amount of the future consumable part of the crop is already developed or when soil-applied, volatile or systemic agricultural chemicals are used.

The objective of a PHI is to provide users with the information that they require to ensure that residues in their treated produce will not exceed the MRL. This means that the data submitted must demonstrate that the MRL will not be exceeded when the appropriate PHI is observed. Residue studies from supervised field trials, then confirm the level of acceptable residues at the desired PHI.

The generation of residue decline information must be consistent with the following principles:

- For grazing of pastures or failed crops, residue samples must be taken:
    - at the earliest time after treatment when sufficient plant material exists for sampling;
    - at the time of any proposed PHI, i.e., the earliest stage that animals could graze;
    - at least one point in between unless the above sampling times coincide; and
    - at least one point after the sample taken at the proposed PHI.
- For crops not grazed or failed, the sampling regime must in principle be similar to that described above, with the following additional aspects:
    - The sampling regime utilized is dependent upon factors, such as the persistence of the agricultural chemical, its metabolism in the plant, whether it translocates, the use pattern and most importantly, whether expected finite residues at harvest have implications for trade.
    - A proposed sampling regime could be: 1, 3, 5, 7, 14 and 28 days postapplication for late season use of agricultural chemicals. Therefore, for such uses that result in

quantifiable residues, petitioners must attempt to stretch the harvest period by sampling immature fruit, tubers, etc., if necessary.

- for early season uses, residue data must be provided for samples taken 7 days pre- and 7 days post-PHI, i.e., at a proposed 30 day PHI, samples are to be harvested and analyzed at 23, 30 and 37 days after treatment.

- Depletion to nondetectable residue levels is only necessary where there are significant trade issues involving major export commodities, e.g., grains.

The petition must include proposals for the required PHI on produce and in situations where a grazing PHI is needed.

Residue decline data are needed for uses where (1) the agricultural chemical is applied when the edible portion of the crop has formed, or (2) it is clear that quantifiable residues may occur on the food or feed commodities at, or close to, the earliest harvest time, or (3) the PHI is # 14 days.

Purposes

The primary purpose of these studies is to determine the behaviour of residues over time in the treated crop. Areas of concern include residue levels that increase over time, i.e., residue concentrations as a function of time posttreatment, especially at times around harvest and for stored commodity scenarios, as well as expected half-life estimates.

Number of Residue Decline Studies

Residue decline studies are not required for crops needing #3 total trials, if PHI is > 14 days; see flow chart below. The number of decline studies needed is one for crops requiring 5-12 total trials and two for crops requiring 16-20 total trials. These studies are included in the 5-12 or 16-20 total trials, i.e., not in addition to these numbers of trials.

See Attachment II (p. 67) for a discussion of Residue Decline Studies in support of provincial registrations.

Design

- Sampling Times

The design of the decline studies must include three to five sampling times in addition to the requested PHI. All of the sampling times must fall within the crop stage when harvesting is reasonably expected to occur. The time points must be approximately equally spaced and, where possible, represent both shorter and longer PHIs than that requested. The PMRA discourages the use of a 0 day PHI. However, if a 0 day PHI is used, a residue decline should

be provided at 1, 2 and 3 days after application. In addition, for an atplant/preplant use, the PHI is usually predetermined by the length of the growing season of the crop and must be stated on the label.

Samples

Only one composite sample is required for each time point in a decline study. Refer to Codex, *Guidelines on Minimum Sample Sizes for Agricultural Commodities from Supervised Field Trials for Residue Analysis*, ALINORM 87/24A, 1987, Attachment I (Appendix I). However, petitioners are advised to take two or more samples to prevent method and sampling variability from masking or appearing to create residue changes with time.

Crop Considerations

For most agricultural chemicals, it is anticipated that residue decline studies will not be necessary for all crops.

- For a given agricultural chemical, additional decline studies are not required within a crop group if studies on representative crop(s) indicate that residues do not increase with longer preharvest intervals. This provides some assurance that the MRLs represent the maximum residues that occur from proposed or registered uses of an agricultural chemical. The representative crop approach is described in Section 5, *Storage Stability Data.* See Subsection 5.3.2, *Representative commodities to be analyzed*.

- If an agricultural chemical is to be applied to all types of crops, decline data must be obtained on the following five representative commodities: a tree fruit, root crop, leafy vegetable, grain, and fruiting vegetable. Some flexibility in the choice of crops is permitted. For example, a legume vegetable can be substituted for a fruiting vegetable. However, the crop should be chosen from the representative crops listed for crop groups in Section 15, *Crop Groups*.

9.8 Uses Resulting in No Quantifiable Residues

A petitioner may elect to conduct 25% fewer trials for crops normally requiring $8 trials, provided that metabolism data or field trial data on related crops indicate quantifiable residues are not likely.

Conditions

The 25% reduction in the number of field trials is acceptable if the following four conditions are met:

i) All of the trials show residues below the method's LOQ. Note that, if all of these trials do not show residues below the LOQ, then a full set of trials is required.

ii) The method has a sufficiently low LOQ, both from an analytical chemistry standpoint and for risk assessment purposes. This means that the LOQ needs to be in the #0.01-0.05 parts per million (ppm) range in most cases.

iii) The trials represent all significant regions of production. Distribution of trials across regions is discussed in more detail in subsection 9.6 of this Section.

iv) No other reduction has previously been applied, i.e., 25% for a major crop within a crop group.

Crop Considerations

- As explained earlier in this document, the 25% reduction in the number of field trials for residues below the LOQ cannot be applied to representative commodities being used to establish crop group MRLs.

- The reduction is not applicable to crops that require #5 field trials.

- For crops that have more than one RAC, the 25% reduction for residues below the LOQ may be applied to one commodity even if the others have quantifiable residues. For example, if an agricultural chemical is applied to an early stage of corn, it is possible to find residues on silage, but not in the grain. In this case, 9 trials may be acceptable for grain, even though 12 were required. This is not meant to imply that separate trials are to be conducted for different crop parts. In other words, corn grain and silage are to be collected from each trial site. If no residues are found on grain from a minimum of 9 geographically representative sites, the grain collected at other sites need not be analyzed.

To take advantage of this option, petitioners must submit adequate recovery data and chromatograms establishing the LOQ of the method. See Section 3, *Residue Analytical Method,* (Reference No. 5). For a definition of LOQ and LOD (limit of detection), petitioners should refer to the article, *Principles of Environmental Analysis*, *Analytical Chemistry*, 1983, 55, pp. 2210-2218. See Reference No. 4.

9.9 Early Season Uses on Annual Crops

Applications Prior to Crop Emergence

For agricultural chemical applications made prior to crop emergence, many labels give options, such as allowing the use to be preplant, atplant, or preemergence. These three types of application can be grouped for the purposes of determining the total number of field trials. In other words, the trials for a specific crop can be divided among these three applications at the petitioner's discretion. For example, the 12 trials for a particular agricultural chemical on corn for grain may consist of 3 preplant, 3 atplant, and 6 preemergence applications, plus the

maximum rate and number of any proposed postemergence applications; see the last paragraph of this subsection.

Surface Application versus Incorporation Into the Soil

The label may give a choice for surface application versus incorporation into the soil. In this instance, data reflecting both of these modes of application are required. Two options on how to conduct and determine the number of trials in this case are offered: the preferred option and the alternative option.

Preferred Option

The preferred option is for each trial to include both the surface and the incorporated applications on side-by-side plots. Only one composite, treated sample is required for each plot. The minimum number of trials is as designated in Table 1 (Appendix II). This means that the total number of samples is equivalent to that required for most other uses on the same crop. Using corn for grain, again as the example, at least 12 trials are needed with each having two samples, i.e., one for surface applied and one for soil incorporated. As described above, the 12 trials can be divided among preplant, atplant and preemergence applications if all these appear on the label.

Alternative Option

The alternative option is to divide the total number of trials in Table 1, Appendix II, (but note the caveat below) roughly equally between those having only the surface treatment and those reflecting only soil incorporation. Two composite treated samples are needed in each trial. Since the trials for each mode of application need to have adequate geographic representation, this option may result in a greater number of trials for those crops that have one region or more normally needing only one trial. Using canola as an example, the result would be at least two additional trials (16 + 2 = 18 total) since regions 5 and 7 (normally needing only one trial) would each need to have two trials, one for surface and one for incorporation. If the side-by-side option above was chosen, only one trial would be required in each of those regions.

Preemergence versus Postemergence Applications

Particularly in the case of herbicides, the label may permit pre- and/or postemergence applications. If both are allowed, all field trials must include both applications. This refers to crops and not to weeds. If the choice is limited to one or the other, the full number of trials as specified in Table 1 (Appendix II) must be conducted for that type of application. However, a 25% reduction of total trials is accepted if some side-by-side studies show a consistent pattern between the residues from the pre- and postemergence uses. In this instance, the full number of trials is needed only for the mode of application consistently resulting in higher residues. Note that the discussion in this paragraph refers to applications made before or after the emergence of the food/feed crop. Occasionally, labels specify application timing in terms of before or after

weeds emerge. The critical factor for purposes of this discussion is whether or not the food/feed crop has emerged.

9.10 Formulations

In subsection 9.4 of this section, *Number of Field Trials for Individual Crops*, it is stated that the numbers of field trials are based upon only one formulation type being requested for use on each crop. The number of trials needed to register additional formulation types or classes is addressed on a case-by-case basis. In some instances, the full number of trials is also needed for a new type of formulation, whereas other formulation classes are registered with a few bridging studies, or perhaps no field trials at all. The decision depends upon how similar the formulations are in composition and physical form, the mode of application, and the timing of the application. More details are provided below.

Microencapsulated or Controlled Release Formulation

One type of formulation that normally requires a full set of field trials is the microencapsulated or controlled release formulation. Since these are designed to control the release rate of the active ingredient (ai), the same number of field trials is needed as to obtain an original MRL, regardless of the timing and mode of its application and the amount of data available on other formulation classes.

Other Types of Formulations

Most of the remaining types of formulations can be divided into two groups: those that are diluted with water prior to application and those that are applied intact. Granules and dusts are the most common examples of the latter.

Granular Formulation Types

Granular formulations generally require the full number of field trials regardless of what data are already available for other formulation classes. This is based on several observed cases of residue uptake being quite different for granules versus other types of formulations of the same ai.

No residue data are required for dusts if data are available at the same application rate and PHI for a formulation applied as a wetting spray, e.g., emulsifiable concentrates (EC) and wettable powders (WP).

Dilute Formulation Types

The most common formulation types that are diluted in water prior to application include ECs, WPs, water dispersible granules (WDG; WG) or dry flowables (DF), flowable concentrates (FC), and soluble concentrates (liquid or solid)(SC; SL). Residue data for one formulation may be transferable between these classes of formulations, for applications that are made prior to

crop emergence , i.e., preplant, atplant, and preemergence applications, or just after crop emergence. Data may also be transferable between these formulation classes for applications directed to the soil, as opposed to foliar treatments.

Foliar Treatments

For mid- to late season foliar applications of formulation types listed in the previous paragraph, three options are available:

i) The new type of formulation can be treated similarly to an amended registration (see *Amended Registrations* below, subsection 9.12): 25% fewer trials than those required for the formulation class used to obtain the original MRL are required.

ii) Alternatively, side-by-side studies, often referred to as bridging data, can be conducted. These involve applications of the registered formulation, i.e., the type used to obtain the MRL, and the new type of formulation to side-by-side plots, using the same rates and preharvest intervals.

If residues from the new formulation are comparable to or less than those from the registered formulation, the new formulation can be registered.

However, if residues are higher from the new formulation in the side-by-side comparison, the full number of trials specified in Table 1 (Appendix II) is required for that formulation to determine the higher MRL level needed to cover its registration.

The exact number of side-by-side studies required is decided on a case-by-case basis. A representative crops approach can be used if the new formulation is requested for use on numerous crops. Submission of protocols outlining the crops and sites to be used in these bridging studies is encouraged.

iii) Also, the number of total field trials can be reduced by half to a minimum of two field trials, while maintaining the original number of samples, i.e., twice the number of plots and samples per site. If the total number of field trials is an odd number, then the reduced number of trials must be rounded up to the nearest whole number.

Registration of Two or More Formulation Classes

The subsection, *Foliar Treatments*, addresses the data requirements for a new type of formulation when a registered one already exists. If a petitioner wishes to register two or more formulation classes when obtaining the initial MRL and registration, the same basic concepts apply. A complete set of trials as specified in Table 1 (Appendix II) must be conducted on one type of formulation and the additional formulation classes handled like an amended registration i.e., 25% fewer trials than the primary formulation, or compared to the primary type of

formulation, using side-by-side studies.

Other Statements

A few other statements can be made concerning data requirements for formulations.

- DF or WDG formulations are sufficiently similar to WPs to allow transference of residue data between them. Placing a formulation, typically WP, in a water-soluble bag does not require additional residue data, provided that adequate data are available for the unbagged product.

- Some agricultural chemicals, e.g., phenoxy herbicides, can be applied as one or more salts and/or esters. Generally, different salts or esters of an ai will be treated as new formulations of that ai for purposes of determining the number of crop field trials. Thus, a new salt can be treated like an amended registration, i.e., 25% fewer trials than the original salt or form of the ai, or compared to the registered form of the ai, using side-by-side studies.

9.11 Spray Volumes - Ground versus Aerial Equipment

Provided that the agricultural chemical product label specifies that aerial applications are to be made in a minimum of 20 litres water per hectare/2 gallons per acre, or 95 litres per hectare/10 gallons per acre in the case of tree or orchard crops, crop field trials reflecting aerial application will be waived in those cases where adequate data are available from use of ground equipment reflecting the same application rate, number of applications, and PHI. This data waiver does not apply to aerial applications using diluents other than water, e.g., vegetable oils. In addition, the Agency reserves the right to require aerial data if special circumstances warrant it.

Based on the above, there are only a few instances where the number of field trials is affected by the spray volumes or type of equipment, at least for aerial versus ground, specified on the label. However, the following two exceptions are to be kept in mind:

Ultra-low Volume Uses

Ultra-low volume (ULV) uses (<20 litres spray per hectare/2 gallons per acre; <95 litres per hectare/10 gallons per acre for orchards) in mid- to late season are treated as separate use patterns, regardless of the nature of the diluent, e.g., water, vegetable oil, etc., and require crop residue data based on the application of the product using this technigue.

If the ULV application is the first use on the crop, i.e., not registered for use, the minimum number of field trials specified in Table 1 (Appendix II) is required.

If data are already available reflecting higher spray volumes, two options are available:

i) The ULV application can be handled similarly to an amended registration, i.e., 25% fewer trials than specified in Table 1 (Appendix II), providing that these trials show the existing MRL is adequate. See *Amended Registrations*, below, subsection 9.12.

ii) Alternatively, side-by-side studies can be conducted.

It is acceptable for petitioners to demonstrate, using side-by-side studies, that residues from the ULV applications are comparable to or less than those from higher spray volumes.

However, if residues are higher from the ULV application in these side-by-side studies, the full numbers of trials specified in Table 1 (Appendix II) are required for this use.

Fumigation Areas

In addition to fumigation treatments at the proposed use conditions, treatments at exaggerated rates are desirable. The studies should adequately represent various treatments, including oily foods, e.g., peanuts and butter; high surface area foods, e.g., flour; large and small fruitbodies, e.g., grains and tubers, such as potatoes; and types of packaging allowable under the direction for use. The studies should reflect the effect of parameters, such as times of exposure, dosage, method of application, temperature, pressure, geometry and air tightness of the container upon residue levels. The effect of aeration time and procedure upon residue reduction should be demonstrated.

Treatment of Orchards

For treatment of orchards, dilute sprays, typically 950 to 3,750 litres per hectare/100 to 400 gallons per acre, and concentrate sprays, typically 190 to 950 litres per hectare/20 to 100 gallons per acre, are treated as separate uses. The number of trials depends upon which of the two options is chosen, analogous to the discussion earlier in this document for surface applied versus soil incorporation. See *Early Season Uses on Annual Crops*, subsection 9.9.

Preferred Option

If side-by-side plots, i.e., dilute versus concentrate sprays, are included at all sites, the numbers of trials in Table 1 (Appendix II) apply, and one composite treated sample from each plot, instead of the normally required two, is acceptable.

Alternative Option

Alternatively, the total number of trials can be divided roughly equally between dilute and concentrate sprays with adequate geographic representation required for each type of spray. In

this case, two composite treated samples are needed at each site, and the total number of required trials may exceed that in Table 1 (Appendix II). If one or more regions require only one study, then two studies would be required, one for each treatment type, i.e., dilute and concentrate spray. Refer to the example for canola in the subsection 9.9, *Early Season Uses on Annual Crops*.

If either dilute or concentrate sprays are already approved for use on an orchard crop, the request to add the other type of spray to the label is treated as the following:

i) an amended registration requiring 25% fewer trials than specified in Table 1, Appendix II. See *Amended Registrations*, subsection 9.12, or

ii) a number of side-by-side studies, establishing that residues from the requested type of spray are not higher than those from the registered one. The exact number of side-by-side studies required should be one-half the number shown in Table 1 (Appendix II) to a minimum of two. Submission of protocols outlining the locations and numbers of sites is encouraged.

One final comment on spray volumes concerns chemigation, i.e., the application of agricultural chemicals by injection into irrigation water. The Agency views this as a type of ground application using very large spray volumes. Provided that data are available for typical ground spray volumes, data reflecting chemigation are not required.

9.12 Amended Registrations

For amended registration requests that involve a change of more than ± 20% for any one component of gap, (unless the component has a significant effect on residues), application rate (either individual or seasonal), interval between applications, or preharvest interval, the number of trials required is as follows:

i) The number of field trials required is normally 25% less than that needed to establish an original MRL, provided that the original MRL is shown by the reduced number of trials to be adequate to cover the new use.

ii) However, if the reduced number of trials indicates that the original MRL is inadequate, or if the original number of trials is #5 (see flowchart Attachment II) or already includes a 25% reduction (crop group or residues < LOQ), the number of trials for an amended registration is the same as that for the original MRL.

On a case-by-case basis, the Agency may require less additional data than described above for an amended registration. This is particularly true when residue decline studies are available, reflecting a proposed change in a preharvest interval. In some instances, no additional data are

necessary. An example is a request to reduce the application rate for a use that already does not produce quantifiable residues.

9.13 Requirements for Provincial Registrations

The preceding discussion in this document on determining the number of crop field trials addresses national registration of agricultural chemicals. Since provincial* registration is accepted by the Agency under certain circumstances, separate guidance has been developed as detailed in Attachment II (Appendix V). This attachment also addresses field trial requirements within provincial boundaries. In summary, the basic concept described in Attachment II (Appendix V) is that the number of trials for a provincial registration should be determined by multiplying the number of field trials required for national registration by the proportion of the crop, on an hectareage/acreage basis, grown in the province(s) in which registration is sought. However, regardless of the hectareage/acreage in the specific province(s) for which the provincial registration is requested, at least two field trials are required.

Within a province(s) that contains more than one crop region, the number of field trials must be distributed among the relevant crop regions in approximately the same proportions as the national distribution among the applicable regions in that province.

9.14 Data Report Format

Submitted studies will be screened for completeness before being accepted for evaluation. Study-specific screening forms are available on the PMRA web site or may be obtained upon request from the PMRA.

The following describes the order and format for a study report:

9.14.1 Data reporting - Crop Field Trials

Purpose

i) Crop field trials provide residue chemistry data on the magnitude of the residue in or on RACs to support registration of any pesticide intended for use on a food or feed crop. Residue chemistry data on RACs are used by the Agency to estimate the exposure of the general population to pesticide residues in food, and for setting and enforcing tolerances for pesticide residues in or on raw agricultural foods or feeds.

ii) Residue chemistry data are also needed to support the adequacy of one or more methods for the enforcement of the tolerance.

* Provincial registration may include any subset of the provinces and/or territories.

iii) Guidelines section 1, *Chemical Identity,* through section 10, *Processed Food/Feed,* and the *Guidelines on Pesticide Residue Trials,* developed under the auspices of the Codex Committee on Pesticide Residues (*FAO Plant Protection Bulletin,*

29:1/2,1981, pp. 12-27) provide information to aid petitioners/registrants in conducting crop field trials.

Objective

i) This Guideline is designed to aid the petitioner in generating reports that are compatible with the Agency's review process. While following this guidance is not mandatory, data submitters are encouraged to submit complete reports that can be efficiently reviewed by the Agency.

ii) The Agency recognizes that there are sections in the Guidelines that do not apply in all cases. Therefore, petitioners should exercise scientific judgement in deciding which portions are germane to a specific data submission.

iii) This Guideline is intended to organize the submission of data to facilitate the review process.

iv) The petitioner's report on crop field trials on a RAC should include all of the information necessary to provide a complete and accurate description of field trial treatments and procedures; sampling, (harvesting), handling, shipping, and storage of the RAC; storage stability validation, or reference thereto, of the test chemical and metabolites of toxicological concern in a plant matrix; residue analyses of field samples for the ROC and for individual components of toxicological concern; validation, i.e., recovery studies, of the residue analytical methodology; reporting of the data and statistical analyses; and, quality control measures/precautions taken to ensure the fidelity of these operations.

Format of the data report

The following describes the order and format for a study report.

i) Master Cover Page. Title page and additional documentation requirements, i.e., requirements for data submission and procedures for claims of confidentiality of data, if relevant to the study report, should precede the contents of the study formatted below.

ii) Table of Contents. The table of contents should indicate the overall organization of the study, including tables and figures.

iii) Summary/Introduction.

A) Purpose of studies.

B) Results, including explanations for apparently aberrant, atypical values, or outliers; discussion of geographical representation, i.e., major growing areas; seasonal

variation, e.g., summer/winter, wet/dry, etc.; and representativeness of types and varieties of the RAC.

C) Field procedures.

D) Analytical procedures/instrumentation.

E) Method recovery validation data.

F) Storage stability.

G) Discussion, including quality control measures taken; statistical treatment(s) of data; information on the level(s) of the ROC, including any individual component(s) of the ROC of special concern, in or on the RAC, i.e., specific plant part(s), arising from the use of the pesticide formulated product on the test crop under specific use conditions. Results should also be correlated to the storage stability study.

H) Conclusions.

iv) Data Tables and Other Graphic Representations.

A) Summary map of Canada with regions as shown in Appendix VII. Include outside U.S., if applicable, of crop field study sites (by crop).

B) Summary table(s) of residue results of individual field trials.

C) Graphic representation(s), e.g., residue decline, figures, flowcharts, etc.

D) Summary tables(s) of recovery data via the analytical methodology.

E) Summary table(s) of storage stability validation data.

v) Information/Raw Data on Individual Field Trials. Specifically, each individual field trial report should include the following information:

A) Test substance (pesticide).

1) Identification of the test pesticide ai, including chemical name, common name, (ANSI, BSI or ISO), and company developmental/experimental name.

2) Identification of the pesticide formulated product(s) used in the field trial, including trade name, type, e.g., EC, WP, G, etc., and amount of ai per liter and gallon, kilogram and pound, etc., and the manufacturer.

3) Information on other relevant parameters, as pertinent, e.g., tank mate(s), spray additive(s) and carrier, e.g., encapsulating polymer, etc.

4) Other. Any and all additional information that the petitioner considers appropriate and relevant to provide a complete and thorough description of the test chemical.

B) Test commodity (RAC).

1) Identification of the RAC, including type/variety (cultivar) and crop group classification (Section 15, *Crop Groups*).

2) Identification of specific crop part(s) that have been harvested, used in residue analytical methodology validations, and subjected to residue analysis for a determination of the ROC.

3) The developmental stage(s), general condition, e.g., immature/mature, green/ripe, fresh/dry, etc., and size(s) of the RAC at time of pesticide application(s) and at harvesting(s).

4) Any and all additional information that the petitioner considers appropriate and relevant to provide a complete and thorough description of the RAC.

vi) Test Procedures.

A) A detailed description of the experimental design and procedures followed in the growing of the RAC, application(s) of the pesticide formulated product(s), and harvesting(s) of samples. The information provided, which may be presented on standardized field sheets, should include the following, in addition to a description of the test substance and test commodity:

1) Trial identification number.

2) Cooperator. Name and address, test location, i.e., region/zone number as shown in Appendix VI (maps 1 and 2), county and province/state, as well as country, if outside Canada or the U.S., and year.

3) Field trial layout. Size and number of control and experimental plots, number of plants per plot/unit area, number of rows per plot, and length of rows and row spacing.

4) Cultural treatment(s). Farming practice, i.e., cultivation, irrigation, etc., and cropping system.

5) Soil characteristics. The name/designation of the soil type, and all conventional soil physicochemical characteristics that describe soil properties, such as percent of organic matter, pH, etc., should also be described.

6) Method(s) of application, i.e., air or ground, of the pesticide formulated product(s); description of the application equipment; type of application, i.e., band/broadcast, soil/foliar/directed, ULV/concentrate/dilute, chemigation, or other; and, calibration of pesticide application equipment, including methods and dates.

7) Dose rate(s). Amount of ai and formulated product per hectare, acre, row, volume, etc.; spray volume(s) per hectare and acre; and maximum rate per season.

8) Number and timing of application(s). Total number, during dormancy, preplant, preemergence, prebloom, etc., between-application-interval(s), and treatment-to-sampling interval(s), also known as PHI(s).

9) Other pesticide(s) applied. Identity, i.e., name and type of formulated product(s), ai(s), rate(s), date(s), tankmate or separate, and purpose of use.

10) Climatological data. Record of temperature and rainfall during the growing season from the nearest weather station, and wind speed during application, as well as, average values for these data, i.e., at least five year averages.

11) Date(s). Planting/sowing/transplanting, as applicable; other significant dates in the growing of the crop, e.g., husk split for tree crops; pesticide application(s); and harvest(s).

12) Harvest procedures. Method of harvesting, i.e., mechanical/hand, from the plant/ground/flotation, etc.; type of equipment used; number/weight of samples collected per replication and number of replications per treatment level; statistical nature of sampling, e.g., fruit taken from upper, middle, and lower portions of tree exterior and interior; and sample coding which is to be cross-referenced to sample history, etc.

13) Quality control. Control measures/precautions followed to ensure the fidelity of the crop field test.

14) Any and all additional information that the petitioner considers appropriate and relevant to provide a complete and thorough description of the growing of the RAC, application(s) of the pesticide formulated product(s), and harvesting of samples.

B) A detailed description of the handling, preshipping storage, and shipping procedures for harvested RAC samples. The information provided, which may be presented on a standardized form, should include the following in addition to a description of the test substance and the test commodity:

1) Sample identification. Means of labeling/coding.

2) Conditions. Temperatures, container type(s)/size(s), sample size(s), etc., and duration of storage before shipping.

3) Method(s) of packaging for shipment. Container type(s)/size(s), sample size(s), ambient/iced, labeling/coding, etc.

4) Means of transport from the field to the laboratory.

5) Dates of harvest, preshipping storage, shipping, and receipt in the laboratory.

6) Quality control. Control measures/precautions followed to ensure the fidelity of

harvested samples during handling, preshipping storage, and shipping operations.

7) Any and all additional information that the petitioner considers appropriate and relevant to provide a complete and thorough description of the handling, preshipping storage, and shipping procedures for harvested samples.

C) A detailed description of the conditions and length of storage of harvested RAC samples, following their receipt in the laboratory.

D) A detailed description of the residue analyses used in determining the ROC in RAC field trial and storage stability samples. If the specified information is provided elsewhere within the overall data submission package, it need not be reiterated here. In that case, a reference to the relevant analytical methodology would be sufficient.

E) Method recovery validation studies should be run concurrently with the residue analyses of crop field trial samples from each individual field trial in order to provide information on the recovery level(s) of the test compounds from the test substrate(s) at various spiking level(s) using the residue analytical methods, and to establish a validated limit of quantification (LOQ). The following information specific to the method validations, that may be presented on a standardized form, should include:

1) Experimental design. Identity of test substrate(s), i.e., specific plant part(s), and test compounds, i.e., parent/specific metabolite(s). Number and magnitude of spiking levels, number of replicate samples per test compound per spiking level, sample coding, control samples, etc.

2) Spiking procedure. Detail the preparation of the test compound(s) and test substrate(s) and the manner in which the test compound(s) was/were introduced to the test substrate(s).

3) Dates. Test sample preparation, i.e., maceration/extraction/etc.; test compound(s) preparation, i.e., standard solution(s) of known concentration; and residue analyses.

4) Residue results. Raw data, ppm found uncorrected (corrected values may also be reported but the basis of correction should be explained), procedure(s) for calculating percent recoveries, recovery levels (range), sensitivity and LOQ.

5) Any and all additional information that the registrant/petitioner considers appropriate and relevant to provide a complete and thorough description of analytical methodology validation procedures.

vii) Organization of Data Tables and Forms.

A) Table(s) of residue assay data for specific plant parts analyzed. Residue levels should be reported uncorrected. Corrected values may also be presented, but the procedure needs to be explained.

B) Table(s) on residue recovery values.

C) Graph(s), as pertinent, e.g., residue decline.

D) Form(s) containing field trial history information.

E) Form(s) containing harvesting, shipping, and storage information.

F) Table(s) of weather data if unusual conditions claimed to result in aberrant residues.

viii) Certification. A signed and dated certification of authenticity, and identifying information, i.e., typed name, title, affiliation, address, and telephone number, of the personnel responsible for the various phases of this report, e.g., Study Director, Field Supervisor, and Laboratory Supervisor.

ix) References

x) Appendices.

A) Representative chromatograms, spectra, etc., of reagent blanks, solvent blanks, reference standards, controls, field samples, spiked samples, etc., cross-referenced to individual field trial study reports.

B) Reprints of published and unpublished literature, company reports, letters, analytical methodology, etc., cited or used by the petitioner, unless physically located elsewhere in the overall data report, in which case cross-referencing will suffice.

C) Any relevant material not fitting into any of the other sections of this report.

9.14.2 Data reporting - specialty applications

Foreword

This data reporting section of specialty applications is divided into three parts: 1) classification of seed treatments and treatment of crops grown for seed use only as food uses; 2) postharvest fumigation of crops and processed foods and feeds; and 3) postharvest treatment, except fumigation, of crops and processed foods and feeds. Each part gives the format/outline

recommended by the Agency to be used by the petitioner for reports on the particular specialty application study.

Format of the data report - seed treatments

For study data waivers concerning seed treatments, data from a radiotracer study are needed, demonstrating no translocation of radioactivity to the aerial portion and root (both human and livestock consumption) portion of the crop. If the radiotracer study demonstrates that the particular seed treatment results in no residues above 10 ppb in any tissue, i.e., stem, foliage, roots and seed, no further studies are needed. If the seed treatment is classified as a food use, data as given in the appropriate sections of the Guidelines are required, e.g., plant metabolism and crop field trials.

The following guidance is a format/outline for reporting the radiotracer study, determining whether the seed treatment results in uptake of radioactivity to the aerial edible and root portions of the crop.

i) Master Cover Page. Title page and additional documentation requirements, i.e., requirements for data submission and procedures for claims of confidentiality of data, if relevant to the study report, should precede the contents of the study formatted below.

ii) Table of Contents. The table of contents should indicate the overall organization of the study, including tables and figures.

iii) Introduction.

A) Background and historical information on the pesticide.

1) Brief summary of the nature of the residue in plants, including the structures of the parent and the residues that are considered to be of toxicological concern.

B) Purpose of study.

C) Abstract of study.

1) Brief summary of application and field procedures.

2) Results, including unexpected problems.

3) Conclusions.

iv) Materials and Methods.

A) Test substance.

1) Identification of the test pesticide ai, including chemical name, common name (ANSI, BSI, ISO), registrant developmental/experimental name and chemical structure.

2) Description of the radiolabeled test material. Identify the radiolabel and the site of the label. A rationale should be provided for selection of a radiolabel other than ^{14}C and for the site of the label; where possible, the ring position should be labeled. The purity, specific activity in Curries/mole and disintegrations per minute per gram (dpm/g) should be reported here.

3) Identification of the pesticide formulated product(s) in which the radiolabeled pesticide ai was applied, including trade name, type, e.g., EC, WP, G, etc., pounds of ai per gallon, percent ai by weight, and manufacturer.

4) Physical state and nature of the solvent, carrier, bait, adjuvant or other matrix in which the pesticide was applied.

B) Test crop.

1) Identification of the test crop, including variety.

2) Identification of specific crop part(s) that were harvested and subjected to analysis for radioactivity.

3) Developmental stage(s); general condition, e.g., immature/mature, green/ripe, fresh/dry, etc.; and size(s) of the test crop at time of harvest.

C) Test site.

1) Description of test site. Overall testing environment, e.g., outdoor test plots, greenhouse, or plant growth chamber; location, i.e., county and province/state; environmental conditions, i.e., temperature, rainfall and sunlight; and soil type.

2) Location, i.e., county, province/state.

3) Cooperator.

D) Field trial methods.

1) Detailed description of the application of radiolabeled pesticide to seeds. Information to be reported includes dose rate, kilograms/pounds ai and formulated product per kilograms/pounds seed, concentration of treatment solution, volume of application solution per kilograms/pounds seed, formulation, physical state in which pesticide is applied, diluent, additives, etc., and method of application, e.g., hopper box, commercial equipment, etc. The pesticide should be applied at the maximum proposed application rate.

2) Field trial layout. Information to be reported includes size of plots/pots, number of plants per plot/pot, number of plots/pots, number of plants per unit area, length of rows and row spacing.

3) Farming practice. Information on practices, such as cultivation, irrigation, and treatments with other pesticides, should be included here.

4) Harvest procedures, including the number of days between planting and harvesting.

E) Sampling, handling and storage.

1) Dates of sampling, shipping, storage, and analyses.

2) Description of sampling procedure and size of samples.

3) Handling, preshipping, shipping and postshipping storage conditions, including storage times.

F) Analytical procedures/instrumentation.

1) Description of sample preparation, i.e., dissection, grinding, lyophilization, number of plants contained in one sample, etc., prior to analyses of radioactivity.

2) Details of analytical method to measure radioactivity, including descriptions of equipment and instrument parameters.

G) Quality control. Description of control measures and precautions followed to ensure the fidelity of the field tests, samples and measurement of the residue.

H) Other pertinent information on materials and methods.

v) Results and Conclusions.

A) Brief summary of study procedures.

1) The summary of the study procedures should include the number of field trials; descriptions of the application of the radiolabeled pesticide to the seed, i.e., dose rate, method and formulation; the site, e.g., greenhouse, outdoors or plant growth chamber; number of days between planting and harvest; number of plants sampled; part of the plant analyzed for radioactivity; and the method of detection.

B) Results.

1) Total recovered, i.e., combustible, radioactivity on seeds at time of planting, if measured. The radioactivity should be reported as the following:

a) disintegrations per minute (dpm).

b) dpm/Fg.

c) ppm equivalents, expressed as parent compound. A sample calculation of ppm from radioactive counts should be provided, especially if other units, i.e., not dpm, are used.

2) The distribution of radioactivity in the treated crop at the time of harvest or sampling. The data to be reported are the total recovered, i.e., combustible, radioactivity remaining at time of sampling or harvest on the whole plant and on the plant's parts of interest, i.e., the aerial and edible root portions of the plant. The radioactivity for the whole plant and the plant parts should be reported in tabular format as the following:

a) dpm.

b) dpm/Fg.

c) ppm equivalents, expressed as parent compound.

For the plant parts, the radioactivity should also be expressed as the following:

d) the percentage of the total, recovered radioactivity in the whole plant.

e) ppm for all plant parts.

3) Graphs and figures of the results.

Graphs, if provided, should be accompanied by tables of actual values from which graphs were constructed.

4) Narrative of results. Narrative should include a discussion of the quantitative accountability for a majority of the total radioactivity recovered from the aerial and root portions of the plant. Also, a discussion of unexpected problems, the way in which they were resolved, and explanations for apparently aberrant, atypical values should be included.

C) Conclusions. The petitioner's conclusion on whether the results of this study and any other relevant studies support data waivers for the seed treatment in question should be given.

vi) Raw Data and Information on Individual Field Trials.

A) Details of radioactive counting data for selected representative samples.

Details should include counting time; total counts recorded; corrected counts; counting efficiencies; other raw data, e.g., sample sizes, ppm equivalents found, sensitivity and limit of detection; and other pertinent information that is needed to check the petitioner's calculations.

B) Description of calculations, including examples.

C) Description of statistical tests, including examples.

D) Representative raw data figures. As applicable, printout sheets, chromatograms, spectra, etc.

E) Any additional information that the registrant considers appropriate and relevant to provide a complete and thorough description of the study.

vi) Certification. Certification of authenticity by the Study Director, including signature, typed name, title, affiliation, address, telephone number and date.

vii) References.

viii) Appendices.

A) Reprints of published and unpublished literature, company reports, letters, etc., not expected to be in Health Evaluation Division (HED) files, but which the petitioner feels will aid the review of the study.

B) Other pertinent information that does not fit into any other section of this outline.

9.14.3 Data reporting - postharvest fumigations

Foreword.

Fumigation may be defined as as the act of releasing and dispersing a toxic chemical so that it reaches the organism wholly or primarily in the gaseous or vapor state. Both the RACs and their processed products may be treated postharvest by fumigation.

The report for a study on the postharvest fumigation of raw crops and processed foods should include all information necessary to provide a complete and accurate description of the study.

Format of the data report - fumigation

i) Master Cover Page. Title page and additional documentation requirements, i.e., requirements for data submission and procedures for claims of confidentiality of data, if relevant to the study report, should precede the contents of the study formatted below.

ii) Table of Contents. The table of contents should indicate the overall organization of the study, including tables and figures.

iii) Introduction.

A) Background and historical information on the pesticide.

1) Brief summary of the nature of the residue in plants, including the structures of the parent, and residues considered to be of toxicological concern.

B) Purpose of study.

C) Abstract of study.

1) Brief summary of application procedures.

2) Results, including unexpected problems.

3) Conclusions.

iv) Materials and Methods.

A) Test Substance.

1) Identification of the test pesticide ai, including chemical name, common name, (ANSI, BSI, ISO), petitioner developmental/experimental name and chemical structure.

2) Identification of the pesticide formulated product(s) in which the pesticide ai was applied, including trade name, type, e.g., ED, WP, G, etc., pounds of ai per gallon, percent ai by weight, and manufacturer.

3) Information on the matrix in which the formulated pesticide was applied and about any additives.

4) Physical/chemical parameters on the test substance.

B) Test raw or processed commodity.

1) Identification of the raw or processed test commodity, including variety/cultivar.

2) Identification compared with specific crop part(s) that were harvested.

3) Developmental stage(s); general condition, e.g., immature/mature, green/ripe, fresh/dry, etc.; and size(s) of the test commodity at time of fumigation.

4) Size and kind of containers holding the commodity, e.g., wood, burlap, etc.

5) Information on whether the raw or processed commodity, or its storage container, had been treated prior to the test postharvest treatment, including application rates, PHIs, and the residue prior to the test postharvest treatment.

C) Test site.

1) Description of fumigation chamber. Information to be reported includes the following:

a) Type of fumigation chamber, e.g., grain elevator and flat storage, tarpaulin covering, shophold, fumigation vault, vacuum chamber, etc.

b) Size and geometry of fumigation chamber.

c) Measures taken to seal the fumigation chamber, e.g., covering surfaces with asphalt paper or plastic tarpaulins, sealing of vents, windows, cracks, etc.

d) Temperature inside the chamber.

e) The relative size of the chamber as compared to the commodity load.

2) Location of fumigation chamber. Information to be reported includes the following:

a) County and state.
b) Environmental conditions, if applicable, i.e., temperature, wind and humidity.

c) Cooperator.

D) Application of the pesticide.

1) Type of fumigant dispensing system and method of fumigant volatilization.

2) Measures taken to hasten gas circulation.

3) Dose rate, exposure time, temperature and pressure.

4) Layout of the fumigation chamber, i.e., discharge points and positioning of circulating fans/blowers in relation to arrangement of commodities, size of stacks of commodities, etc.

5) Number and date(s) of application(s).

6) Formulation.

E) Aeration of the commodities.

1) The aeration time and the dates of the aeration.

2) Description of aeration procedures inside, e.g., removal of seals and covers, opening of doors and windows and the use of exhaust fans and an air suction system, as well as outside the fumigation chamber.

3) Description of any aeration following sampling.

F) Sampling, handling, and storage.

1) Dates of sampling, shipping, storage and analyses.

2) Description of sampling procedure, including the location of the sampling (e.g., top, bottom or side outer layer or center of stack; side or middle of chamber), size of the samples, and measures taken to prevent desorption of the fumigant during sampling.

3) Handling, preshipping, shipping, and postshipping storage conditions, including storage times, special measures taken to prevent desorption of the fumigant during the time between sampling and analysis, and description of sample containers and storage temperature.

G) Analytical procedures/instrumentation.

1) Description of sample preparation, e.g., compositing, subsampling, grinding, extraction, etc., and measures taken to prevent desorption of the fumigant during sample preparation.

2) Details of the analytical method to measure residue, including descriptions of equipment/instrumentation and instrument parameters.

H) Quality control. Description of control measures and precautions to ensure the fidelity of the test, samples and measurement of the residue.

I) Any other pertinent information on material and methods.

v) Results and Conclusions.

A) Brief summary of the study procedures. The summary of the study procedures should include the number of trials, the commodities, whether the commodities had been previously treated with the test ai, descriptions of the fumigations and fumigation chambers, the fomulation, aeration time, and the method of detection.

B) Results of analyses of treated and control samples and fortified samples.

1) Tables of the results. Residue data should be given in a tabular format, providing the following information:

a) Commodity.

b) Plant part.

c) Type of fumigation chamber.

d) Dose.

e) Exposure time.

f) Temperature.

g) Aeration time.

h) Residue. Residue testing should extend beyond sampling immediately after the label specified aeration, to include studies to follow the rate of residue decline that could be expected under various shipping and storage conditions and temperature.

2) Graphs and figures of the results. Graphs, if provided, should be accompanied by tables of actual values from which graphs were constructed.

3) Narrative on the results. Narrative should include a discussion of unexpected problems and ways in which they were resolved and explanations for apparently aberrant, atypical values.

E) Conclusions on the appropriate MRL(s) for the proposed use(s).

vi) Raw Data and Information on Individual Trials.

A) Raw data tables for residue analyses of treated, control and spiking recovery samples and standards.

B) Representative raw data figures.

1) As applicable, printouts, spectra, chromatograms of treated samples, control samples, spiked samples and standards, etc.

2) Calibration curves.

C) Description of calculations, including examples.

D) Description of statistical tests, including examples.

E) Any additional information that the petitioner considers appropriate and relevant to provide a complete and thorough description of the study.

vii) Certification. Certification of authenticity by the Study Director, including signature, typed name, title, affiliation, address, telephone number and date.

viii) References.

ix) Appendices.

A) Reprints of published and unpublished literature, company reports, letters, etc., not expected to be in HED files, but which the petitioner feels will aid the review of the study.

B) Other pertinent information that does not fit into any other section of this outline.

9.14.4 Data reporting - postharvest treatment, except fumigation

Foreword.

Postharvest treatments of foods and feeds are applied by various means, including dips, drenches, mechanical foamers, and spray and brush applicators. The pesticide may be applied directly to the commodity or indirectly to the storage bin. Often, the application of a wax coating on the commodity is involved. Both the RAC and its processed product may be treated postharvest. The report for a study on the postharvest treatment of raw crops and processed foods and feeds should include all information necessary to provide a complete and accurate description of the study.

Format of the data report

i) Master Cover Page. Title page and additional information requirements, i.e., requirements for data submission and procedure for claims of confidentiality of data, if relevant to the study report, should precede the content of the study formatted below.

ii) Table of Contents. The table of contents should indicate the overall organization of the study, including tables and figures.

iii) Introduction.

A) Background and historical information about the pesticide.

1) Brief summary of the nature of the residue in plants, including the structures of

the parent and the residues considered to be of toxicological significance (ROC).

B) Purpose of study.

C) Abstract of study.

1) Brief summary of application procedures.

2) Results, including unexpected problems.

3) Conclusions.

iv) Materials and Methods.

A) Test Substance.

1) Identification of the test pesticide ai, including chemical name, common name, (ANSI, BSI, ISO), petitioner, developmental/experimental name and chemical structure.

2) Identification of the pesticide formulated product(s) in which the pesticide ai was applied, including trade name, type, e.g., EC, WP, G, etc., kilograms/pounds of ai per liter/gallon, percent ai by weight, and manufacturer.

3) Information on the matrix, e.g., water or wax, in which the formulated pesticide was applied and on any additives.

B) Test raw or processed commodity.

1) Identification of the raw or processed test commodity, including variety.

2) Identification of specific crop part(s) treated and analyzed.

3) Developmental stage(s); general condition, e.g., mature/immature, green/ripe, fresh/dry, etc.; and size(s) of the test commodity at time of treatment.

4) Information on whether the commodity or storage container had been treated with the test ai prior to the test postharvest treatment, including application rates, PHIs, and the residue prior to the test postharvest treatment.

C) Test site.

1) Description of test site. Overall testing environment, e.g., outdoor, indoor, climate controlled packinghouse, etc., and temperature.

2) Location, i.e., county, province/state.

3) Cooperator.

D) Application of the pesticide.

1) Physical state in which the pesticide was applied.

2) Description compared with method/equipment for pesticide application, e.g., directly applied to commodity or indirectly applied to storage container, dips, drenches, mechanical towers, spray applicators, brush applicators or wax applicators.

3) Kilograms/pounds ai and formulation per kilograms/pounds treated commodity, concentration of treatment solution, volume of treatment per kilograms/pounds treated commodity, exposure time, number of treatments, and temperature of solution.

4) Description of postharvest practices accompanying the postharvest treatment, such as application of wax coatings after treatment, detergent washes, and rinses, including number, timing, and volume.

5) Date(s) of application(s).

6) Formulation.

E) Sampling, handling, and storage.

1) Dates of sampling, shipping, storage, and analyses.

2) Description of sampling procedure and size of the samples.

3) Handling, preshipping, shipping, and postshipping storage conditions, including storage time.

F) Analytical procedures/instrumentation.

1) Description of sample preparation, e.g., compositing, subsampling, grinding, extraction, etc.

2) Details of analytical method to measure residue, including descriptions of equipment/ instrumentation and instrument parameters.

G) Quality control. Description of control measures and precautions to ensure the fidelity of the field test, samples and measurement of the residue.

H) Any other pertinent information on materials and methods.

v) Results and Conclusions.

A) Brief summary of study procedures. The summary of the study procedures should include the number of trials; the commodities; whether the commodities had been previously treated with the test ai; description of the postharvest treatment, e.g., concentration, exposure time, and temperature; the formulation; and the method of detection.

B) Results of analyses of treated and control samples and spiked samples.

1) Tables of the results. Residue data should be given in a tabular format, providing the following information, as applicable:

I) Commodity.

II) Plant part.

III) Method/equipment for pesticide application.

IV) Kilograms/pounds ai per kilograms/pounds commodity.

V) Concentration of treatment solution.

VI) Volume treatment solution per pounds commodity.

VII) Exposure time.

VIII) Number of treatments.

IX) Other pertinent information affecting the level of residue, e.g., use of wax, rinse, volume and time of rinse.

X) Formulation.

XI) Residue. Residue testing should provide information on the rate of residue decline that could be expected under various shipping and storage conditions and temperatures.

2) Graphs and figures of the results. Graphs, if provided, should be accompanied by tables of actual values from which graphs were constructed.

3) Narrative on the results. Narrative should include a discussion of unexpected problems and ways in which they were resolved and explanations for apparently aberrant, atypical values.

C) Conclusions on the appropriate tolerance(s) for the proposed use(s).

vi) Raw Data and Information on Individual Trials.

A) Raw data tables for residue analyses of treated, control and fortification recovery samples, and standards.

B) Representative raw data figures.

1) As applicable, printouts, spectra, chromatograms of treated samples, control samples, spiked samples and standards, etc.

2) Calibration curves.

C) Description of calculations, including examples.

D) Description of statistical tests, including examples.

E) Any additional information that the petitioner considers appropriate and relevant to provide a complete and thorough description of the study.

vii) Certification. Certification of authenticity by the Study Director, including signature, typed name, title, affiliation, address, telephone number and date.

viii) References.

ix) Appendices.

A) Reprints of published and unpublished literature, company reports,letters, etc., not expected to be in HED files, but which the registrant feels will aid the review of the study.

B) Other pertinent information that does not fit into any other section of this outline.

9.15 References

The source material for this Guideline is taken from the following set of documents.

1. Codex Alimentarius, *Pesticide Residues in Food,* Volume 2, 2nd Ed., 1993 or later.

2. Codex *Guidelines on Minimum Sample Sizes for Agricultural Commodities from Supervised Field Trials for Residue Analysis,* ALINORM 87/24A (1987). See Attachment I.

3. Department of National Health and Welfare, *Nutrition Canada Food Consumption Patterns Report,* 1975.

4. L.H. Keith, et al, *Principles of Environmental Analysis, Analytical Chemistry,* 1983, 55, pp. 2210-2218.

5. The PMRA Guidelines Section 3, *Residue Analytical Method*.

6. The PMRA Guidelines Section 5, *Storage Stability Data.*

7. The PMRA Guidelines Section 5, *Storage Stability Data*, subsection 5.3.2.

8. The PMRA Regulatory Directives Dir98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product,* and Dir98-03, *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products.*
9. Statistics Canada, *Agricultural Profile of Canada - Part 1*, Catalogue no. 93-350.

10. Statistics Canada, *Census of Agriculture,* 1991.

11. Statistics Canada, *Field Crop Reporting Series,* Catalogue no. 22-002.

12. Statistics Canada, *Fruit and Vegetable Production,* Catalogue no. 22-003.

13. Statistics Canada, *Greenhouse Industry*, Catalogue no. 22-202.

14. Statistics Canada, *Spatial Analysis and Geomatics Applications (SAGA), The Delineation of Canadian Major and Minor Crop Field Trial Regions*. Report prepared for the PMRA, HED, Health Canada, Ottawa, February 1996.

15. Statistics Canada, Spatial Analysis and Geomatics Applications (SAGA), *Methodology and Delineation Criteria Used for the Delineation of Canadian Crop Area and Arable Land Regions*. Report prepared for the PMRA, HED, Health Canada, Ottawa, 1996.

16. The U.S. EPA, *Pesticide Reregistration Rejection Rate Analysis Residue Chemistry*, Prevention, Pesticides and Toxic Substances (7508W). EPA 738-K-94-001. Report prepared with Senior Scientists Advisory Council, Chemistry Branches, Health Effects Division (1994). *EPA, Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances*, June 1994.

17. The U.S. EPA, *Pesticide Registration Notice PR 86-5, Standard Format for Data Submitted under the FIFRA and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)*, May 3, 1986.

18. The PMRA, Health Canada, HED Section 15, *Crop Groups*, *Residue Chemistry Guidelines*, Dir98-02, 1998.

19. The U.S. FDA, *Pesticide Analytical Manual*, Volume I (PAM I), Section 142.

20. The PMRA, Health Canada, *Tank Mixing of Pesticides*, Interim Registration Procedure, January 02, 1995.

21. *Manual for Field Trials in Plant Protection*, 3rd edition, Ciba-Geigy Ltd., Switzerland, 1992.

22. *Analytical Methods for Pesticide Residues in Foods*, Health Canada, 2nd edition, 1986, Catalogue No. H49-33/1986E (ISBN 0-660-12213-8).

23. *Guidelines on Pesticide Residue Trials to Provide Data for the Registration of Pesticides and the Establishment of Maximum Residue Limits, FAO Plant Protection Bulletin*, 29, (1/2), 1981.

APPENDIX I

ATTACHMENT I

"Provisionally Adopted" by 19th CCPR
ALINORM 87/24A para 251, 1987
Revised from the CCPR 1987, ALINORM 87/24A, APPENDIX IV, ANNEX I

Guidelines on Minimum Sample Sizes for Agricultural Commodities From Supervised Field Trials for Residues Analysis

The Guidelines on agricultural chemical residue trials to provide data for the registration of pesticides and the establishment of maximum residues limits includes a section entitled, *Guide to Sampling*, in which minimum sample sizes are recommended for a number of crops that are selected as examples. Practical experience in sampling in recent years has indicated the need to reconsider the recommendations in the Guidelines for the sample sizes and an ad hoc Working Group on the Development of Residues Data and Sampling in Canada (the PMRA, Health Canada) recommends that the PMRA revised ANNEX II which follows this ANNEX I be utilized as a sampling guidance document. Only revisions have been made for the purposes of improved clarity, i.e., more specific guidance, and/or for commodities not covered but grown or imported into Canada.

The major changes are the results of adopting a general principle that, with certain exceptions, such as very small items like berries, nuts, grain, and immature vegetables, it is more appropriate to recommend taking a number of crop units rather than a minimum weight.

A number of crops can be harvested mechanically and in these cases, 12 primary samples from the harvester as it proceeds through the treated plot are recommended.

Although it is not normally recommended, it may sometimes be necessary to subsample bulky or heavy items before shipment to the residue laboratory. This practice must be limited to special sampling problems identified in ANNEX II, always bearing in mind the importance of maintaining a fully representative subsample and avoiding any possible contamination or deterioration of the material. It is essential that it should only be done if a clean area is available and if the personnel involved have received specific instruction or training in this respect.

The ad hoc Working group emphasised that the recommendations for minimum sizes are for samples of crops at the stage of growth at which they would be harvested for commercial harvest when taken from supervised trials that frequently involve relatively small plots. It may be necessary to take larger samples in certain circumstances, especially if larger plots or fields are being sampled. Larger samples of some crops may also be needed if particularly low limits of determination are involved, thus possibly requiring larger analytical samples, or for multi-residue determinations, requiring larger, or multiple, analytical samples. The small sample size required by most analytical methods is not the major factor in deciding the size of field samples - obtaining representative material must be the priority in the field. Alternative considerations may apply when deciding on the quantities of immature crops required from residue dissipation trials.

RECOMMENDED SAMPLE SIZE FOR FIELD TRIALS		
SAMPLE TYPE	**CODEX NO.**	**RECOMMENDED SAMPLE SIZE / PLOT**
ALL PLANTS, TUBERS, ETC. SHOULD BE SAMPLED FOR AVERAGE SIZES		
ROOT CROPS		
fodder and sugar beets	VR 0596 AM 1051	12 plants
potatoes	VR 0589	24 tubers or 12 of very large from at least 6 plants
other root crops eg., carrots, red beets, Jerusalem artichoke, sweet potato, celeriac, turnip, swede, parsnip, horseradish, salsify, chicory, radish, scorzonera	Group 016	12 large roots or 24 (or more) small for minimum sample weight of 2 kg
leeks	VA 0384	12 plants
spring onions	VA 0389	24 or more plants for a minimum sample weight of 2 kg
garlic, shallots	VA 0381 VA 0388	24 bulbs or cloves from at least 12 plants
LEAFY VEGETABLES		
small-leaf salad crops eg., cress, dandelion, corn salad	Group 013	0.5 kg from at least 12 plants (or sites in plot)
spinach, chicory leaves	VL 0469 VL 0502 VL 0503	1 kg from at least 12 plants
lettuce	VL 0482 VL 0483	12 plants or 1 kg from at least 12 plants if individual leaves are collected
endive	VL 0476	12 plants
kale forage	AV 0480 VL 0480	2 kg from at least 12 plants kale sampled at least 2 levels on the plant

RECOMMENDED SAMPLE SIZE FOR FIELD TRIALS		
SAMPLE TYPE	**CODEX NO.**	**RECOMMENDED SAMPLE SIZE / PLOT**
ALL PLANTS, TUBERS, ETC. SHOULD BE SAMPLED FOR AVERAGE SIZES		
green cruciferous eg., fodder crops, rape mustard, green oil poppy	Group 023	2 kg from at least 12 separate areas of plot (b)
large brassica crops cauliflower, cabbage	Group 010	12 mature plants
Brussels spouts broccoli	Group 010	1 kg from at least 12 plants, Brussels spouts sampled from least 2 levels on the plant
kohlrabi	VB 0405	12 mature plants
celery	VS 0624	12 mature plants
rhubarb	VS 0627	12 sticks from at least 12 separate plants for a minimum sample weight of 2 kg
asparagus	VS 0621	24 sticks from at least 24 separate plants for a minimum sample weight of 2 kg
globe artichoke	VS 0620	12 mature heads
BEANS		
soybeans	VS 0541	1 kg seeds without pods from at least 12 separate areas of plot
peas, phaseolus beans (French, kidney, runner, etc.)	Group 014	1 kg (fresh green or dry seeds)
broad beans, field beans lentils	Group 015	1 kg (fresh green or dry seeds)
MELON & FRUIT VEGETABLES		

RECOMMENDED SAMPLE SIZE FOR FIELD TRIALS		
SAMPLE TYPE	**CODEX NO.**	**RECOMMENDED SAMPLE SIZE / PLOT**
ALL PLANTS, TUBERS, ETC. SHOULD BE SAMPLED FOR AVERAGE SIZES		
tomatoes, green peppers	Group 012	24 fruits or 12 from large fruiting varieties from at least 12 plants (more if necessary for a minimum sample weight of 2 kg)
aubergines (egg plants)	VO 0440	12 fruits from 12 separate plants
cucumbers	VO 0424	12 fruits from 12 separate plants
gherkins, courgettes, squash	Group 011	24 fruits from at least 12 plants (more if necessary to make a minimum weight of 2 kg)
gourds, pumpkins	Group 011	12 fruits from 12 separate plants
sweet corn	VO 0447	12 or more ears for a minimum sample weight of 2 kg
TREE FRUITS		
citrus fruits eg., orange, lemon, clementine, mandarin, pomelo, grapefruit, tangelo, tangerine	Group 001	24 or more fruits for a minimum sample weight of 2 kg; samples must be collected from several places on at least 4 individual trees
pome fruits eg., apples, pears, quinces, medlars	Group 002	24 or more fruits for a minimum sample weight of 2 kg; samples must be collected from several places on at least 4 individual trees
larger stone fruits e.g., apricots, nectarines, peaches, plums	Group 003	24 or more fruits for a minimum sample weight of 2 kg; samples must be collected from several places on at least 4 individual trees
small stone fruits	Group 003	1 kg fruits from several places on at least 4 trees

RECOMMENDED SAMPLE SIZE FOR FIELD TRIALS		
SAMPLE TYPE	**CODEX NO.**	**RECOMMENDED SAMPLE SIZE / PLOT**
ALL PLANTS, TUBERS, ETC. SHOULD BE SAMPLED FOR AVERAGE SIZES		
miscellaneous small fruits eg., olives, dates, figs	Group 005	1 kg from several places on at least 4 trees
grapes	FB 0269	1 kg samples from 12 bunches, or parts of 12 bunches from separate vines
melon fruits e.g., water melons, cantaloups, muskmelon	Group 011	6 - 12 fruits from separate plants
currants, raspberries, blueberries, Saskatoon berries and other small berries	Group 004	0.5 kg from at least 12 separate areas of several bushes
strawberries, gooseberries	FB 0268 FB 0275 FB 0276	1 kg from at least 12 separate areas of several bushes
bananas	FI 0327	24 fruits from at least 6 bunches of separate trees and from several places of each of the bunches
pineapples	FI 0353	12 fruits
miscellaneous fruits eg., avocados, guavas, mangoes, pawpaws, pomegranates, persimmons, kiwi fruit, litchi	Group 006	24 or more average size fruits for a minimum sample weight of 2 kg from at least 4 separate trees or plants
GRAIN CROPS		
grain of wheat, barley, oats, rye, triticale, and other small grain cereals; maize (off the cob),rice, sorghum	Group 020	1 kg of grain from at least 12 separate areas of a plot or treatment lot (applies to both field and postharvest trials)

RECOMMENDED SAMPLE SIZE FOR FIELD TRIALS		
SAMPLE TYPE	**CODEX NO.**	**RECOMMENDED SAMPLE SIZE / PLOT**
ALL PLANTS, TUBERS, ETC. SHOULD BE SAMPLED FOR AVERAGE SIZES		
straw of the above crops (for animal bedding only)	Group 051	0.5 kg from at least 12 separate areas of a plot (b)
maize, straw/stover/fodder (animal feed)	AF 0645	12 plants (a)
green forage/silage eg., alfalfa, clover, fodder peas and beans, vetch, sainfoin. lotus, fodder soybeans, ryegrass, fodder cereals, sorghum (animal feed)	Group 050	1 kg from at least 12 separate areas of a plot
dry hay of the above crops (animal feed)	Group 050	0.5 kg from at least 12 separate areas of plot (b)
peanuts	SO 0697	1 kg from at least 24 plants
TREE NUTS		
walnuts, chestnuts, almonds, etc.	Group 022	1 kg (with or without shells)
coconut	TN 0665	12 nuts (shell and milk)
OIL SEED CROPS		
rapeseed, flax, & wild mustard	Group 023	0.5 kg seeds from at least 12 separate areas of a plot (b)
sunflower, safflower	SO 0702	21 heads or 1 kg seeds from 12 separate areas of a plot (b)
cottonseed	SO 0691	12 heads or 1 kg seeds with or without fibre
OTHER CROPS		

RECOMMENDED SAMPLE SIZE FOR FIELD TRIALS		
SAMPLE TYPE	**CODEX NO.**	**RECOMMENDED SAMPLE SIZE / PLOT**
ALL PLANTS, TUBERS, ETC. SHOULD BE SAMPLED FOR AVERAGE SIZES		
garden herbs and medicinal plants e.g., parsley, thyme	Group 027 Group 028 Group 057	0.5 kg fresh 0.2 kg dry
tea	Group 066	0.2 kg dry leaves
mushroom	VO 0450	12 items or more for a minimum sample weight of 0.5 kg
sugarcanes	GS 0659	12 x 20 cm lengths of stem from 12 areas of the plot(s) (a)
hops	DM 1100	0.5 kg of dry cones
beer, wine, cider, fruit juices	Group 070	1 litre

a) Divide each stem with leaves attached into 3 equal lengths. Take top, middle and bottom portions respectively from each of three groups of four stems ensuring that parts of all 12 stems are included in the sample.

b) Crops which are harvested mechanically can be sampled from the harvester as it proceeds through the crop.

APPENDIX II

TABLE 1 - MINIMUM NUMBERS OF CROP FIELD TRIALS AND TREATED SAMPLES ON INDIVIDUAL CROPS, CROP AREAS AND DIETARY SHARE							
CROP	**AREA 1991 ACRES[3]**	**AREA 1995 ACRES[4]**	**AREA 1991 HECTARES**	**AREA 1995 HECTARES**	**SHARE OF THE DIET**	**MINIMUM NUMBER OF FIELD TRIALS**	**MINIMUM NUMBER OF TREATED SAMPLES**
FIELD CROPS							
WHEAT	34,997,892	28,141,800	14,163,143	11,388,300	10.10	20	40
TAME HAY[1]	14,793,563	16,430,500	5,986,742	6,649,000	< 0.10	12	24
CANOLA	7,762,385	13,215,000	3,141,325	5,348,000	< 0.40	16	32
BARLEY	11,180,156	11,506,200	4,524,448	4,656,300	0.10	16	32
OATS	3,047,074	3,883,000	1,233,107	1,571,400	0.75	16	32
CORN FOR GRAIN	2,732,235	2,477,400	1,105,696	1,002,500	0.12	12	24
FLAXSEED	1,236,107	2,165,000	500,235	876,100	< 0.10	8	16
SOYBEANS	1,478,812	2,028,700	598,454	821,000	< 0.40	12	24
DRY FIELD PEAS	495,649	2,025,000	200,582	819,400	< 0.10	8	16
LENTILS	589,297	820,000	238,480	331,800	< 0.10	5	10

[1] Includes alfalfa and alfalfa mixtures, other tame hay, forage seed and sod.

TABLE 1 - MINIMUM NUMBERS OF CROP FIELD TRIALS AND TREATED SAMPLES ON INDIVIDUAL CROPS, CROP AREAS AND DIETARY SHARE							
CROP	**AREA 1991 ACRES[3]**	**AREA 1995 ACRES[4]**	**AREA 1991 HECTARES**	**AREA 1995 HECTARES**	**SHARE OF THE DIET**	**MINIMUM NUMBER OF FIELD TRIALS**	**MINIMUM NUMBER OF TREATED SAMPLES**
MUSTARD SEED	279,274	660,000	113,018	267,000	< 0.10	5	10
RYE	637,494	459,700	257,985	186,000	0.16	8	16
CORN FOR SILAGE	491,498	424,000	198,902	171,500	< 0.10	5	10
CANARY SEED	237,436	365,000	96,087	147,600	< 0.10	5	10
POTATOES	302,435	350,000	122,391	141,640	5.80	16	32
DRY FIELD BEANS	235,496	265,900	95,302	107,600	< 0.02	5	10
SUNFLOWERS	206,049	120,000	83,385	48,600	< 0.02	5	10
TOBACCO[1]	74,131	64,550	30,000	26,122	< 0.02	5	10
SUGAR BEETS	61,543	61,500	24,906	24,900	< 0.02	5	10
TRITICALE	19,702	57,000	7,973	23,067	< 0.02	5	10
BUCKWHEAT	58,430	42,400	23,646	17,100	< 0.02	5	10

[1] 1995 area estimates are not available. 1994 estimates are used.

TABLE 1 - MINIMUM NUMBERS OF CROP FIELD TRIALS AND TREATED SAMPLES ON INDIVIDUAL CROPS, CROP AREAS AND DIETARY SHARE							
CROP	**AREA 1991 ACRES[3]**	**AREA 1995 ACRES[4]**	**AREA 1991 HECTARES**	**AREA 1995 HECTARES**	**SHARE OF THE DIET**	**MINIMUM NUMBER OF FIELD TRIALS**	**MINIMUM NUMBER OF TREATED SAMPLES**
MILLET FOR GRAIN	39,814	-	16,112	-	< 0.02	5	10
SAFFLOWER	6,719	5,000	2,719	2,023	< 0.02	3	6
CARAWAY SEED	1,659	-	671	-	< 0.02	2	8
GINSENG	1,337	-	541	-	< 0.02	2	8
VEGETABLES							
SWEET CORN	89,026	84,636	36,027	34,251	0.52	8	16
GREEN PEAS	48,727	45,718	19,719	18,501	0.37	8	16
TOMATOES	29,584	27,788	11,972	11,245	1.75	12	24
GREEN OR WAX BEANS	22,190	24,250	8,980	9,814	0.66	5	10
CARROTS	18,875	21,049	7,639	8,518	0.63	5	10
CABBAGE	10,577	12,744	4,280	5,157	0.36	5	10
DRY ONIONS	10,876	12,187	4,401	4,932	0.21	5	10
BROCCOLI	8,779	9,036	3,553	3,657	0.09	5	10

TABLE 1 - MINIMUM NUMBERS OF CROP FIELD TRIALS AND TREATED SAMPLES ON INDIVIDUAL CROPS, CROP AREAS AND DIETARY SHARE							
CROP	**AREA 1991 ACRES[3]**	**AREA 1995 ACRES[4]**	**AREA 1991 HECTARES**	**AREA 1995 HECTARES**	**SHARE OF THE DIET**	**MINIMUM NUMBER OF FIELD TRIALS**	**MINIMUM NUMBER OF TREATED SAMPLES**
LETTUCE	7,693	8,167	3,113	3,305	0.45	5	10
CAULIFLOWER	7,558	7,175	3,059	2,904	0.05	5	10
SQUASH, ZUCCHINI & PUMPKINS	6,915	7,076	2,798	2,864	0.06	5	10
CUCUMBERS & GHERKINS	6,940	7,061	2,809	2,857	0.34	5	10
RUTABAGAS	6,200	6,035	2,509	2,442	0.16	5	10
PEPPERS	5,164	5,347	2,090	2,164	0.04	5	10
ASPARAGUS	4,128	3,013	1,671	1,219	0.08	5	10
BEETS	2,000	2,546	810	1,030	0.07	5	10
RADISHES	1,884	2,197	763	889	< 0.02	3	6
CELERY	2,205	2,017	892	816	0.17	5	10
GREEN ONIONS & SHALLOTS	1,334	1,573	540	637	< 0.02	2	8
SPINACH	1,232	1,407	499	569	$ 0.02	3	6

TABLE 1 - MINIMUM NUMBERS OF CROP FIELD TRIALS AND TREATED SAMPLES ON INDIVIDUAL CROPS, CROP AREAS AND DIETARY SHARE							
CROP	**AREA 1991 ACRES[3]**	**AREA 1995 ACRES[4]**	**AREA 1991 HECTARES**	**AREA 1995 HECTARES**	**SHARE OF THE DIET**	**MINIMUM NUMBER OF FIELD TRIALS**	**MINIMUM NUMBER OF TREATED SAMPLES**
BRUSSELS SPROUTS	1,442	1,377	584	557	< 0.02	2	8
CHINESE CABBAGE	1,304	-	528	-	< 0.02	2	8
PARSNIPS	682	1,019	276	412	0.02	3	6
LEEKS	385	794	156	321	< 0.02	2	8
RHUBARB	511	511	207	207	0.06	3	6
FRUITS							
APPLES	86,136	80,780	34,858	32,690	2.41	12	24
BLUEBERRIES	64,152	75,023	25,961	30,361	0.07	8	16
STRAWBERRIES	17,764	19,123	7,189	7,739	0.25	5	10
GRAPES	16,321	16,120	6,605	6,524	0.28	5	10
RASPBERRIES	10,031	10,660	4,060	4,314	0.06	5	10
PEACHES	10,720	9,530	4,338	3,857	0.40	5	10
PEARS	5,719	5,359	2,314	2,169	0.22	5	10
CHERRIES	5,360	5,025	2,170	2,034	0.06	5	10

TABLE 1 - MINIMUM NUMBERS OF CROP FIELD TRIALS AND TREATED SAMPLES ON INDIVIDUAL CROPS, CROP AREAS AND DIETARY SHARE							
CROP	**AREA 1991 ACRES[3]**	**AREA 1995 ACRES[4]**	**AREA 1991 HECTARES**	**AREA 1995 HECTARES**	**SHARE OF THE DIET**	**MINIMUM NUMBER OF FIELD TRIALS**	**MINIMUM NUMBER OF TREATED SAMPLES**
CRANBERRIES	3,354	4,415	1,357	1,787	< 0.02	3	6
PLUMS & PRUNES	2,865	2,455	1,159	994	0.13	5	10
MELONS	1,039	1,230	420	498	0.38	3	6
SASKATOONS	556	1,100	225	445	< 0.02	2	8
APRICOTS	918	835	371	338	0.04	3	6
NECTARINES	204	690	83	279	0.03	3	6
HAZELNUTS & FILBERTS	642	-	260	-	< 0.02	2	8
GREENHOUSE CROPS	(SQUARE FEET)	(SQUARE FEET)	(SQUARE METERS)	(SQUARE METERS)			
TOMATOES[2]	14,951,582	14,503,100	1,389,047	1,347,382		2	8
CUCUMBERS[2]	11,554,139	12,357,900	1,073,415	1,148,086		2	8
PEPPERS[2]	1,899,389	2,338,710	176,459	217,273		2	8

TABLE 1 - MINIMUM NUMBERS OF CROP FIELD TRIALS AND TREATED SAMPLES ON INDIVIDUAL CROPS, CROP AREAS AND DIETARY SHARE							
CROP	**AREA 1991 ACRES[3]**	**AREA 1995 ACRES[4]**	**AREA 1991 HECTARES**	**AREA 1995 HECTARES**	**SHARE OF THE DIET**	**MINIMUM NUMBER OF FIELD TRIALS**	**MINIMUM NUMBER OF TREATED SAMPLES**
LETTUCE[2]	1,308,686	1,401,250	121,581	130,180		2	8
MUSHROOMS[2]	6,844,430	7,033,000	635,868	653,387		2	8

3. Sources: ***Agricultural Profile of Canada - Part 1*** (Catalogue no. 93-350) + unpublished data from the 1991 Census of Agriculture, Statistics Canada.

4. Sources: ***Field Crop Reporting Series*** (Catalogue no. 22-002), ***Fruit and Vegetable Production*** (Catalogue no. 22-003) and ***Greenhouse* Industry** (Catalogue no. 22-202), Statistics Canada.

APPENDIX III

TABLE 2 - NUMBER OF FIELD TRIALS BY CROP AND REGION												
CROP	REGION											
	TOTAL	1	1A	5	5A	5B	7	7A	9	11	12	14
FIELD CROPS												
WHEAT	20			2			7	1				10
TAME HAY[1]	12	1		2	1	1	1					6
CANOLA	16			1			1					14
BARLEY	16			1		1	2					12
OATS	16	1		1	1	1	2					10
CORN FOR GRAIN	12			8		4						
FLAXSEED	8			2			1					5
SOYBEANS	12			11		1						
DRY FIELD PEAS	8			2								6
LENTILS	5			1			2					2
MUSTARD SEED	5						2					3
RYE	8			1			3					4
CORN FOR SILAGE	5			3		2						
CANARY SEED	5						4					1
POTATOES	16	3	4	3	1	1		1			1	2
DRY FIELD BEANS	5			4				1				
SUN-FLOWERS	5			2			1					2
TOBACCO	5			4		1						
SUGAR BEETS	5			2				2				1

[1] Includes alfalfa and alfalfa mixtures, other tame hay, forage seed and sod.

TABLE 2 - NUMBER OF FIELD TRIALS BY CROP AND REGION												
CROP	REGION											
	TOTAL	1	1A	5	5A	5B	7	7A	9	11	12	14
TRITICALE	5			1			2					2
BUCKWHEAT	5			1	1	1						2
MILLET FOR GRAIN	5			1			1					3
SAFFLOWER	3						1	1				1
CARAWAY SEED	2						1					1
GINSENG	2			1						1		
VEGETABLES												
SWEET CORN	8			4		2		1			1	
GREEN PEAS	8	1	1	3		2					1	
TOMATOES	12			11		1						
GREEN OR WAX BEANS	5		1	2		2						
CARROTS	5		1	2		2						
CABBAGE	5			2		2					1	
DRY ONIONS	5			3		2						
BROCCOLI	5			2		2					1	
LETTUCE	5			1		3					1	
CAULI-FLOWER	5			2		2					1	
SQUASH, ZUCCHINI & PUMPKINS	5		1	2		1					1	
CUCUMBERS & GHERKINS	5			2		2					1	
RUTABAGAS	5		1	2	1	1						
PEPPERS	5			4		1						
ASPARAGUS	5			3		1				1		
BEETS	5			2	1	2						

TABLE 2 - NUMBER OF FIELD TRIALS BY CROP AND REGION												
CROP	REGION											
	TOTAL	1	1A	5	5A	5B	7	7A	9	11	12	14
RADISHES	3			1		2						
CELERY	5			2		3						
GREEN ONIONS & SHALLOTS	2			1		1						
SPINACH	3			1		1					1	
BRUSSELS SPROUTS	2					1					1	
CHINESE CABBAGE	2			1		1						
PARSNIPS	3		1	1		1						
LEEKS	2			1		1						
RHUBARB	3			1		1					1	
FRUITS												
APPLES	12	1	1	4		3				3		
BLUE-BERRIES	8	1	3		3						1	
STRAW-BERRIES	5	1		1	1	1					1	
GRAPES	5			4						1		
RASP-BERRIES	5			1		1					3	
PEACHES	5			4						1		
PEARS	5		1	3						1		
CHERRIES	5			3						2		
CRANBERRIES	3					1					2	
PLUMS & PRUNES	5		1	3						1		
MELONS	3			2		1						

TABLE 2 - NUMBER OF FIELD TRIALS BY CROP AND REGION												
CROP	**REGION**											
	TOTAL	**1**	**1A**	**5**	**5A**	**5B**	**7**	**7A**	**9**	**11**	**12**	**14**
SASKATOONS	2						1					1
APRICOTS	3			1						2		
NECTARINES	3			2						1		
HAZELNUTS & FILBERTS	2									1	1	
GREENHOUSE CROPS												
TOMATOES	2			1		1						
CUCUMBERS	2			1							1	
PEPPERS	2			1							1	
LETTUCE	2			1		1						
MUSHROOMS	2			1							1	

APPENDIX IV

TABLE 3.1 - AREA OF CROPS BY REGION (HECTARES) - 1991 CENSUS

CROP	REGION										
	1	1A	5	5A	5B	7	7A	9	11	12	14
FIELD CROPS											
WHEAT	4,439	6,128	818,103	23,874	36,945	5,295,587	415,606	17,151	7,467	523	7,537,319
TAME HAY[1]	371,189	119,594	861,066	406,317	548,656	420,943	59,989	83,910	177,751	44,490	2,892,833
CANOLA	18	39	155,260	7,925	547	140,545	21,541	14,821	6,341	15	2,794,275
BARLEY	55,745	39,372	291,211	52,203	120,059	425,408	96,284	17,274	14,639	943	3,411,310
OATS	38,179	11,479	87,464	46,359	47,096	153,766	6,472	11,468	9,680	1,226	819,918
CORN FOR GRAIN	7,146	1,729	718,949	7,418	359,802	1,136	2,121	15	147	52	7,180
FLAXSEED	-	8	127,616	4,082	34	47,415	4,127	127	77	--	316,748
SOYBEANS	486	2,563	557,153	954	36,943	64	14	-	2	-	275
DRY FIELD PEAS	122	221	35,692	396	418	7,205	1,781	400	228	8	154,110
LENTILS	94	-	31,994	136	1	118,464	1,350	-	--	-	86,440
MUSTARD SEED	44	44	737	10	35	35,172	7,082	-	12	-	69,880
RYE	1,034	1,984	28,972	728	3,259	100,821	2,904	690	674	203	116,714
CORN FOR SILAGE	4,615	2,813	111,719	10,055	44,550	3,108	1,732	148	3,659	5,681	10,820
CANARY SEED	-	-	5,927	39	-	74,781	68	-	-	-	15,272

[1] Includes alfalfa and alfalfa mixtures, other tame hay, forage seed and sod.

- nil or zero

-- amount too small to be expressed.

TABLE 3.1 - AREA OF CROPS BY REGION (HECTARES) - 1991 CENSUS

CROP	REGION										
	1	1A	5	5A	5B	7	7A	9	11	12	14
POTATOES	22,729	33,274	23,531	6,205	10,617	2,335	6,855	114	534	2,720	13,476
DRY FIELD BEANS	81	801	72,964	943	4,334	2,969	8,235	-	1	26	4,947
SUN-FLOWERS	6	-	40,344	173	51	2,957	499	-	4	3	39,348
TOBACCO	99	888	26,937	41	2,035	-	-	-	-	-	-
SUGAR BEETS	-	-	10,140	7	-	1,069	10,568	-	-	-	3,122
TRITICALE	23	76	950	66	73	2,390	633	1	43	34	3,683
BUCK-WHEAT	528	195	7,191	2,012	3,458	348	-	3	4	2	9,905
MILLET FOR GRAIN	403	-	3,275	527	555	1,338	8	-	-	-	10,006
SAFF-LOWER	-	-	42	-	--	607	1,280	-	-	-	790
CARAWAY SEED	7	3	150	-	-	269	20	-	-	-	222
GINSENG	-	2	390	1	--	-	-	-	86	20	40
VEGETABLES											
SWEET CORN	656	458	19,637	740	11,137	199	1,259	8	323	1,357	253
GREEN PEAS	1,505	1,456	8,767	34	4,654	50	856	25	153	1,666	552
TOMATOES	82	41	10,567	61	1,070	5	2	1	103	22	18
GREEN OR WAX BEANS	293	855	3,308	97	3,366	67	153	1	114	687	39
CARROTS	198	831	2,397	320	3,154	138	145	4	44	212	197

TABLE 3.1 - AREA OF CROPS BY REGION (HECTARES) - 1991 CENSUS

CROP	REGION										
	1	1A	5	5A	5B	7	7A	9	11	12	14
CABBAGE	173	236	1,596	201	1,476	79	45	6	27	264	175
DRY ONIONS	10	64	2,563	27	1,427	8	69	--	48	122	62
BROCCOLI	142	174	1,132	120	1,281	16	6	1	37	589	53
LETTUCE	48	131	652	50	1,825	16	3	1	11	348	27
CAULI-FLOWER	118	86	1,299	60	936	4	26	--	31	412	86
SQUASH, ZUCCHINI & PUMPKINS	112	181	1,498	60	566	87	41	2	35	187	29
CUCUMBERS & GHERKINS	39	41	1,396	57	985	25	21	2	41	120	82
RUTABA-GAS	142	289	968	313	612	42	23	5	11	64	40
PEPPERS	11	10	1,526	8	457	2	--	--	35	35	5
ASPA-RAGUS	16	7	1,215	20	247	1	1	10	134	13	6
BEETS	36	36	248	67	314	13	2	1	9	52	30
RADISHES	4	4	204	10	431	23	9	--	6	52	19
CELERY	3	5	294	4	492	1	4	3	3	77	6
GREEN ONIONS & SHALLOTS	8	7	217	12	197	18	4	--	4	55	16
SPINACH	5	36	205	6	177	6	2	--	10	39	13
BRUSSELS SPROUTS	27	37	91	8	133	1	--	--	21	264	2

TABLE 3.1 - AREA OF CROPS BY REGION (HECTARES) - 1991 CENSUS											
CROP	REGION										
	1	1A	5	5A	5B	7	7A	9	11	12	14
CHINESE CABBAGE	4	4	334	9	112	1	--	--	1	36	26
PARSNIPS	1	29	97	16	101	8	2	1	1	7	14
LEEKS	4	--	30	5	109	-	-	-	1	7	1
RHUBARB	4	17	85	6	53	2	1	1	1	29	8
FRUITS											
APPLES	1,836	3,879	12,703	411	7,967	5	--	136	7,604	289	27
BLUE-BERRIES	3,765	10,955	221	8,989	131	-	-	6	25	1,851	19
STRAW-BERRIES	836	522	1,894	821	1,841	39	5	8	107	799	316
GRAPES	46	69	5,637	7	59	3	-	--	706	74	2
RASP-BERRIES	220	59	430	187	643	13	--	5	132	2,293	77
PEACHES	3	32	3,566	--	9	--	--	5	708	14	--
PEARS	15	200	1,455	5	57	1	-	6	532	41	2
CHERRIES	14	26	1,251	6	25	1	--	8	798	35	5
CRAN-BERRIES	1	42	2	25	148	--	-	-	1	1,137	--
PLUMS & PRUNES	24	57	733	18	45	2	--	4	229	44	4
MELONS	4	9	259	1	112	--	1	-	32	1	1
SASKA-TOONS	--	-	21	--	-	24	--	3	1	--	175
APRICOTS	--	1	86	1	1	--	-	3	272	5	1

TABLE 3.1 - AREA OF CROPS BY REGION (HECTARES) - 1991 CENSUS											
CROP	REGION										
	1	1A	5	5A	5B	7	7A	9	11	12	14
NEC-TARINES	-	1	46	-	-	-	-	--	35	--	-
HAZELNUTS & FILBERTS	-	--	26	--	-	-	-	-	84	149	-
GREENHOUSE CROPS	**(SQUARE METERS)**										
TOMATOES	112,380	36,826	669,227	76,857	249,928	11,617	2,123	2,717	26,354	171,319	29,699
CUCUM-BERS	41,711	25,394	576,883	19,526	92,203	91,960	20,132	2,223	27,286	144,905	31,191
PEPPERS	1,558	1,013	60,155	876	1,588	72	-	26	496	110,256	419
LETTUCE	5,670	1,544	27,275	10,246	46,455	44	580	68	1,113	26,160	2,426
MUSH-ROOMS	9,823	6,246	308,727	3,733	53,283	2,823	-	620	8,796	200,945	40,872

TABLE 3.2 - AREA OF CROPS BY REGION (ACRES) - 1991 CENSUS											
CROP	REGION										
	1	1A	5	5A	5B	7	7A	9	11	12	14
FIELD CROPS											
WHEAT	10,970	15,142	2,021,577	58,995	91,294	13,085,681	1,026,985	42,382	18,451	1,292	18,625,123
TAME HAY[1]	917,229	295,524	2,127,740	1,004,032	1,355,758	1,040,172	148,236	207,346	439,233	109,938	7,148,346
CANOLA	45	96	383,655	19,583	1,352	347,294	53,229	36,624	15,669	38	6,904,805
BARLEY	137,748	97,290	719,597	128,997	296,673	1,051,206	237,924	42,686	36,174	2,331	8,429,532
OATS	94,343	28,364	216,128	114,556	116,377	379,964	15,993	28,337	23,920	3,030	2,026,061
CORN FOR GRAIN	17,659	4,273	1,776,562	18,330	889,090	2,806	5,242	36	364	129	17,743
FLAXSEED	-	19	315,345	10,088	84	117,165	10,197	315	191	1	782,701
SOY-BEANS	1,201	6,333	1,376,754	2,358	91,288	157	35	-	5	-	680
DRY FIELD PEAS	302	547	88,198	978	1,034	17,803	4,402	989	564	20	380,814
LENTILS	233	-	79,060	336	3	292,730	3,337	-	1	-	213,597
MUSTARD SEED	108	109	1,822	24	87	86,913	17,501	-	30	-	172,677
RYE	2,555	4,903	71,591	1,798	8,053	249,134	7,177	1,705	1,666	502	288,407
CORN FOR SILAGE	11,404	6,952	276,064	24,846	110,086	7,679	4,279	365	9,042	14,039	26,736
CANARY SEED	-	-	14,646	96	-	184,788	167	-	-	-	37,739
POTATOES	56,165	82,222	58,147	15,334	26,236	5,770	16,938	282	1,319	6,722	33,300

[1] Includes alfalfa and alfalfa mixtures, other tame hay, forage seed and sod.

- nil or zero

-- amount too small to be expressed.

TABLE 3.2 - AREA OF CROPS BY REGION (ACRES) - 1991 CENSUS

CROP	REGION										
	1	1A	5	5A	5B	7	7A	9	11	12	14
DRY FIELD BEANS	200	1,980	180,297	2,331	10,710	7,336	20,350	-	3	65	12,225
SUNFLOWERS	15	-	99,691	427	127	7,306	1,232	-	9	8	97,232
TOBACCO	244	2,194	66,563	101	5,029	-	-	-	-	-	-
SUGAR BEETS	-	-	25,056	17	-	2,641	26,115	-	-	-	7,714
TRITICALE	56	189	2,347	164	181	5,907	1,563	2	106	84	9,102
BUCKWHEAT	1,305	482	17,770	4,971	8,544	860	-	7	9	6	24,476
MILLET FOR GRAIN	996	-	8,093	1,302	1,371	3,306	21	-	-	-	24,725
SAFFLOWER	-	-	104	-	1	1,500	3,163	-	-	-	1,951
CARAWAY SEED	17	8	371	-	-	664	50	-	-	-	549
GINSENG	-	6	964	2	1	-	-	-	213	50	100
VEGETABLES											
SWEET CORN	1,621	1,132	48,523	1,828	27,521	492	3,111	20	799	3,353	625
GREEN PEAS	3,719	3,598	21,665	85	11,499	123	2,116	63	379	4,117	1,364
TOMATOES	202	101	26,111	152	2,644	13	6	3	255	54	45
GREEN OR WAX BEANS	724	2,113	8,174	239	8,317	164	378	2	282	1,698	97
CARROTS	489	2,052	5,924	790	7,793	342	358	9	108	523	487
CABBAGE	429	583	3,945	498	3,648	195	111	16	66	653	434

TABLE 3.2 - AREA OF CROPS BY REGION (ACRES) - 1991 CENSUS											
CROP	REGION										
	1	1A	5	5A	5B	7	7A	9	11	12	14
DRY ONIONS	25	158	6,334	67	3,527	20	172	1	119	302	152
BROCCOLI	352	431	2,797	297	3,166	41	16	1	92	1,456	131
LETTUCE	118	324	1,611	124	4,509	40	9	3	28	860	68
CAULIFLOWER	292	214	3,211	147	2,313	9	64	1	76	1,019	212
SQUASH, ZUCCHINI & PUMPKINS	276	448	3,702	147	1,398	216	102	5	87	462	72
CUCUMBERS & GHERKINS	97	101	3,450	140	2,435	61	53	5	101	295	202
RUTABAGAS	351	715	2,392	773	1,511	105	58	13	27	158	98
PEPPERS	27	24	3,770	20	1,130	6	1	--	87	86	13
ASPARAGUS	40	17	3,002	49	611	3	2	25	331	31	16
BEETS	90	90	614	167	775	32	5	2	21	129	75
RADISHES	9	10	503	25	1,066	57	22	1	15	130	47
CELERY	7	12	726	11	1,217	2	10	7	9	191	15
GREEN ONIONS & SHALLOTS	20	17	537	29	487	45	11	1	10	135	41
SPINACH	14	88	505	14	437	15	5	--	26	97	31
BRUSSELS SPROUTS	66	91	224	21	328	1	1	--	52	653	4
CHINESE CABBAGE	10	10	825	23	277	2	1	--	2	89	65
PARSNIPS	2	71	239	39	250	19	6	1	3	18	34

TABLE 3.2 - AREA OF CROPS BY REGION (ACRES) - 1991 CENSUS											
CROP	REGION										
	1	1A	5	5A	5B	7	7A	9	11	12	14
LEEKS	9	1	73	12	268	-	-	-	2	16	2
RHUBARB	10	42	210	16	131	5	2	1	4	71	20
FRUITS											
APPLES	4,536	9,585	31,389	1,017	19,686	12	1	337	18,790	715	68
BLUEBERRIES	9,303	27,071	547	22,213	323	-	-	14	61	4,573	48
STRAWBERRIES	2,067	1,291	4,680	2,029	4,550	97	12	20	265	1,974	780
GRAPES	115	170	13,929	18	146	8	-	1	1,745	183	5
RASPBERRIES	544	145	1,063	461	1,589	33	1	13	327	5,666	190
PEACHES	7	80	8,813	1	21	--	--	13	1,750	35	--
PEARS	37	493	3,596	11	141	2	-	16	1,316	102	5
CHERRIES	35	64	3,090	16	62	3	--	20	1,972	87	12
CRANBERRIES	3	105	5	62	365	--	-	-	3	2,811	--
PLUMS & PRUNES	60	141	1,811	44	111	4	--	9	566	108	10
MELONS	10	22	641	2	277	1	1	-	80	3	3
SASKATOONS	--	-	53	1	-	60	1	7	3	1	431
APRICOTS	1	3	212	3	4	1	-	6	673	13	2
NECTARINES	-	2	113	-	-	-	-	1	87	--	-
HAZELNUTS & FILBERTS	-	--	65	--	-	-	-	-	208	369	-

TABLE 3.2 - AREA OF CROPS BY REGION (ACRES) - 1991 CENSUS											
CROP	REGION										
	1	1A	5	5A	5B	7	7A	9	11	12	14
GREENHOUSE CROPS	(SQUARE FEET)										
TOMATOES	1,209,649	396,391	7,203,497	827,286	2,690,200	125,045	22,854	29,247	283,667	1,844,067	319,680
CUCUMBERS	448,973	273,342	6,209,515	210,174	992,464	989,847	216,704	23,928	293,699	1,559,748	335,738
PEPPERS	16,770	10,900	647,502	9,426	17,097	770	-	275	5,343	1,186,791	4,515
LETTUCE	61,036	16,622	293,590	110,282	500,041	473	6,242	733	11,975	281,582	26,109
MUSHROOMS	105,731	67,232	3,323,112	40,185	573,534	30,385	-	6,674	94,683	2,162,951	439,943

APPENDIX V

Attachment II

Number of Field Trials Required with Geographically Restricted Registration - Provincial Registrations

Throughout this document, additional guidance has been provided regarding field trial data requirements for MRLs with national registrations. This attachment provides guidance concerning the number of field trials required for MRLs with geographically restricted registrations, i.e., provincial registrations. Sampling requirements and other criteria that are presented elsewhere in this document also apply to the data requirements discussed in this attachment. A flow chart follows the text below to facilitate determination of field trial data requirements.

MRLs for provincial registrations may be established on crops for major or minor agricultural uses. Comments below address the data requirements for establishing MRLs on crops for provincial registrations.

The number of field trials required for a MRL with provincial registration is equal to the number of field trials required for the commodity for a national MRL or registration, multiplied by the proportion (by hectares/acres) of the crop grown in that province(s), rounded off to the nearest whole number. However, regardless of the hectareage/acreage in the specific province for which the provincial registration is requested, at least two field trials are required. Two composite samples per plot are generally required. However, when three or fewer field trials are required for any registration, the registrant may choose to (a) obtain samples from 1X application rates from separate plots in each of four field trials, i.e., one composite sample taken from each of four separately treated plots, resulting in four total samples per field trial, or (b) perform three field trials in different locations at the 1X rate, i.e., two composite samples obtained from each plot[1].

Field trial locations must be representative of growing conditions throughout the region that is covered by the provincial registration. This may result in more field trials than those calculated using just the provincial portion of the national requirement.

For provinces containing more than one field trial region, the same guidelines for defining the number of trials used nationally apply, i.e., number of field trials by region (Table 2, Appendix III) and applicable reductions. Within a province(s) that contains more than one crop region, the number of field trials must be distributed among the relevant crop regions in approximately the same proportions as the national distribution between the applicable regions in that province. A trial(s) is required in every zone in the province that requires a trial(s) nationally.

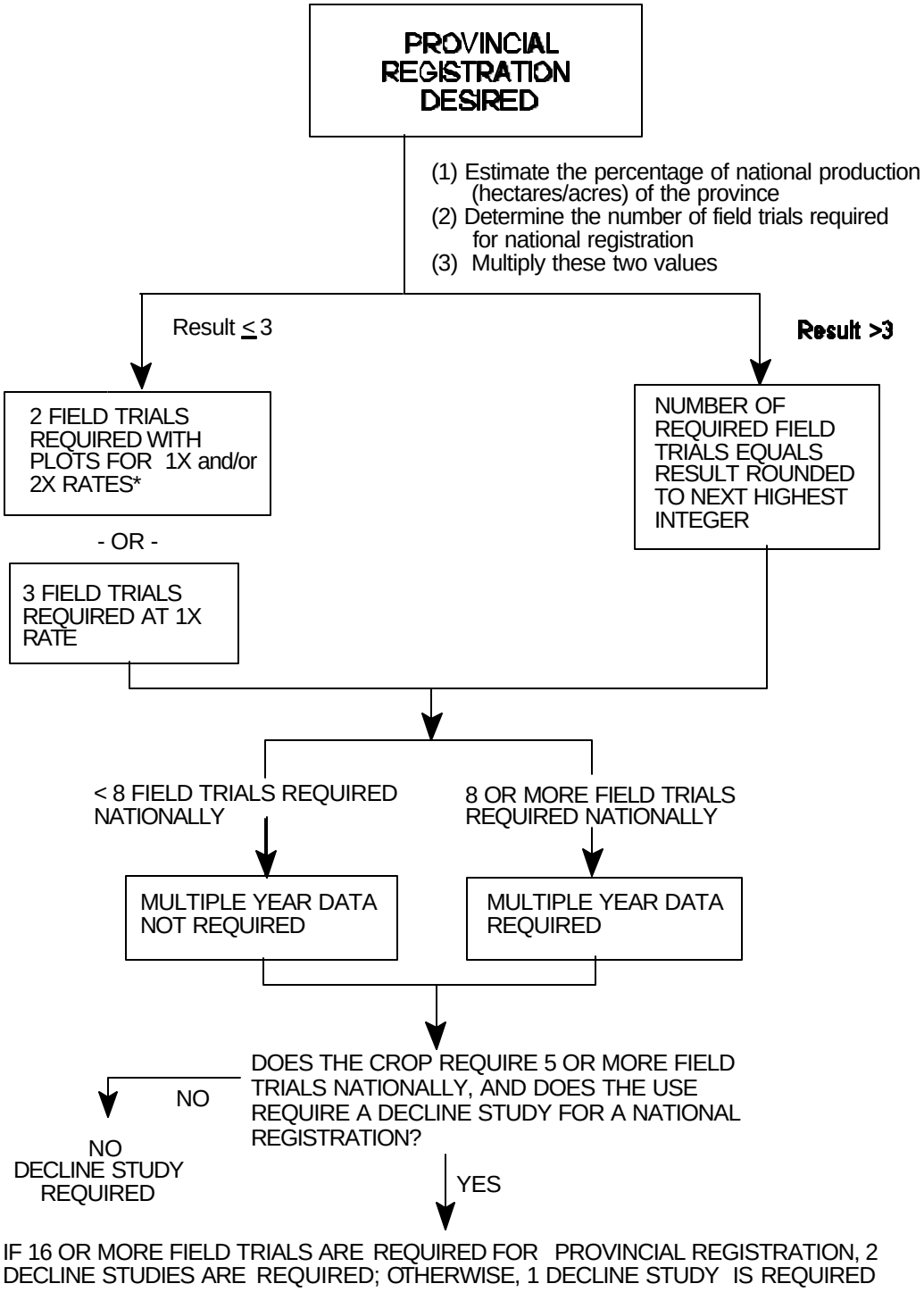
For registrations requested for two or more neighboring provinces, data from one province will be

[1] Two alternative designs. See Attachment III (Appendix VI).

accepted for a use in a neighboring province only if (1) the provinces, or pertinent parts thereof, are in the same geographical region as defined in this document, (2) a sufficient number of field trials are available from the province to fulfill the requirements of the paragraph above for the hectareage/acreage of commodity grown in both provinces, and (3) field trials are performed in sufficiently diverse areas such that conditions likely to be found in both provinces are represented in the field trials.

For crops requiring eight or more field trials nationally, provincial registrations require multiple year field trial data. Multiple year data are required to account for variability due to varying climatic conditions and other factors that would normally be expected to be seen by obtaining field trial data from more diverse regions, but would not be seen for provincial registrations since field trial data are obtained from more limited geographical areas. The total required number of field trials must be performed over at least two different years, e.g., if four total field trials are required, two would be performed in one year, and two in the next year. Multiple year data are not required if sufficient nationally representative or multiple year data are available for other agricultural chemical formulations of the same ai or similar uses from which the Agency can estimate likely variability.

For crops normally requiring a decline study for national registration, (discussed elsewhere in this guidance, section 9.7), one or more decline studies will be required for a provincial registration. The number of decline studies required for a use will not exceed the number required for a national registration for that commodity. See the flow chart for further details.



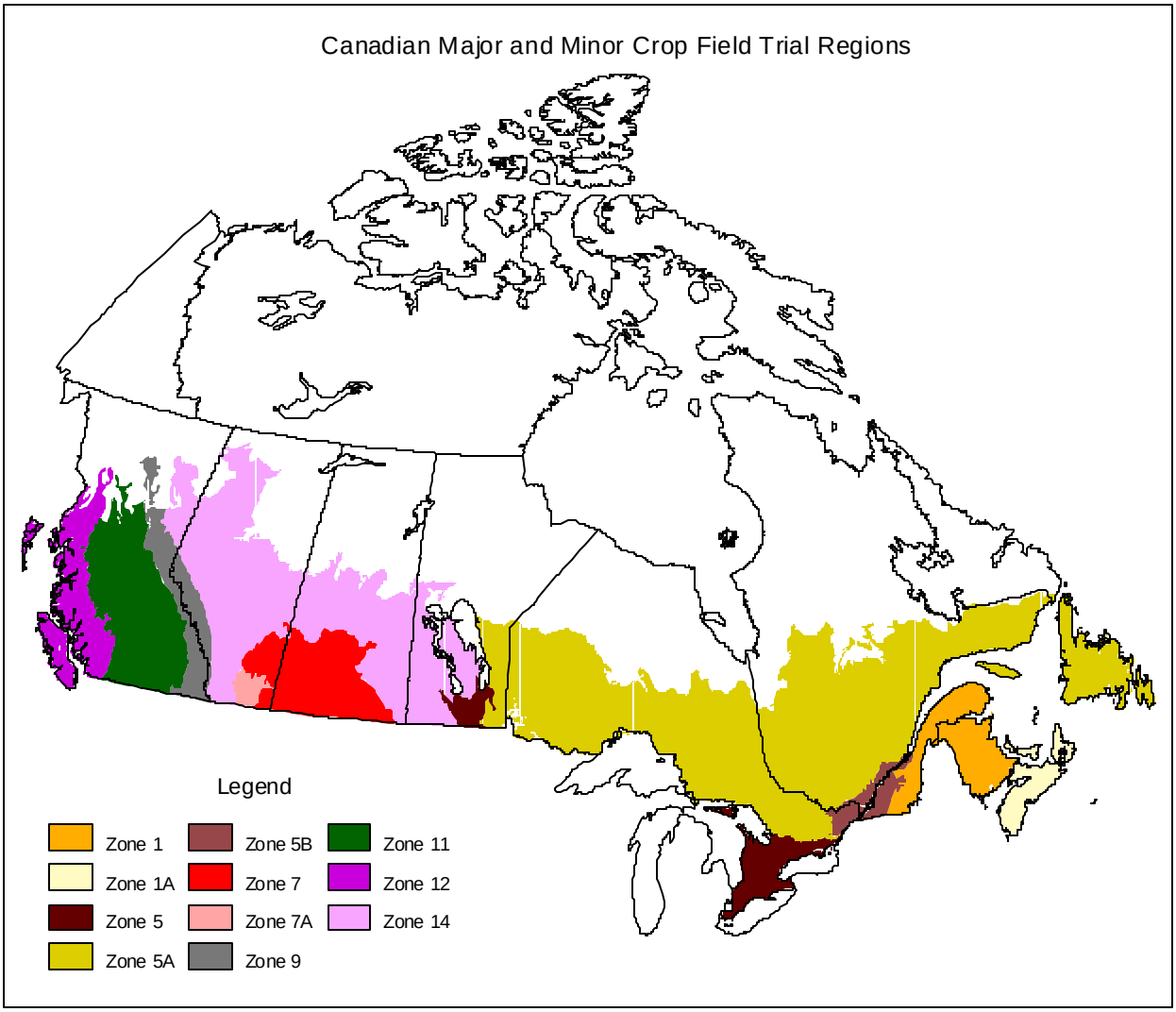
* For crops requiring only **2** field trials nationally, only 2 field trials are required for a provincial registration.

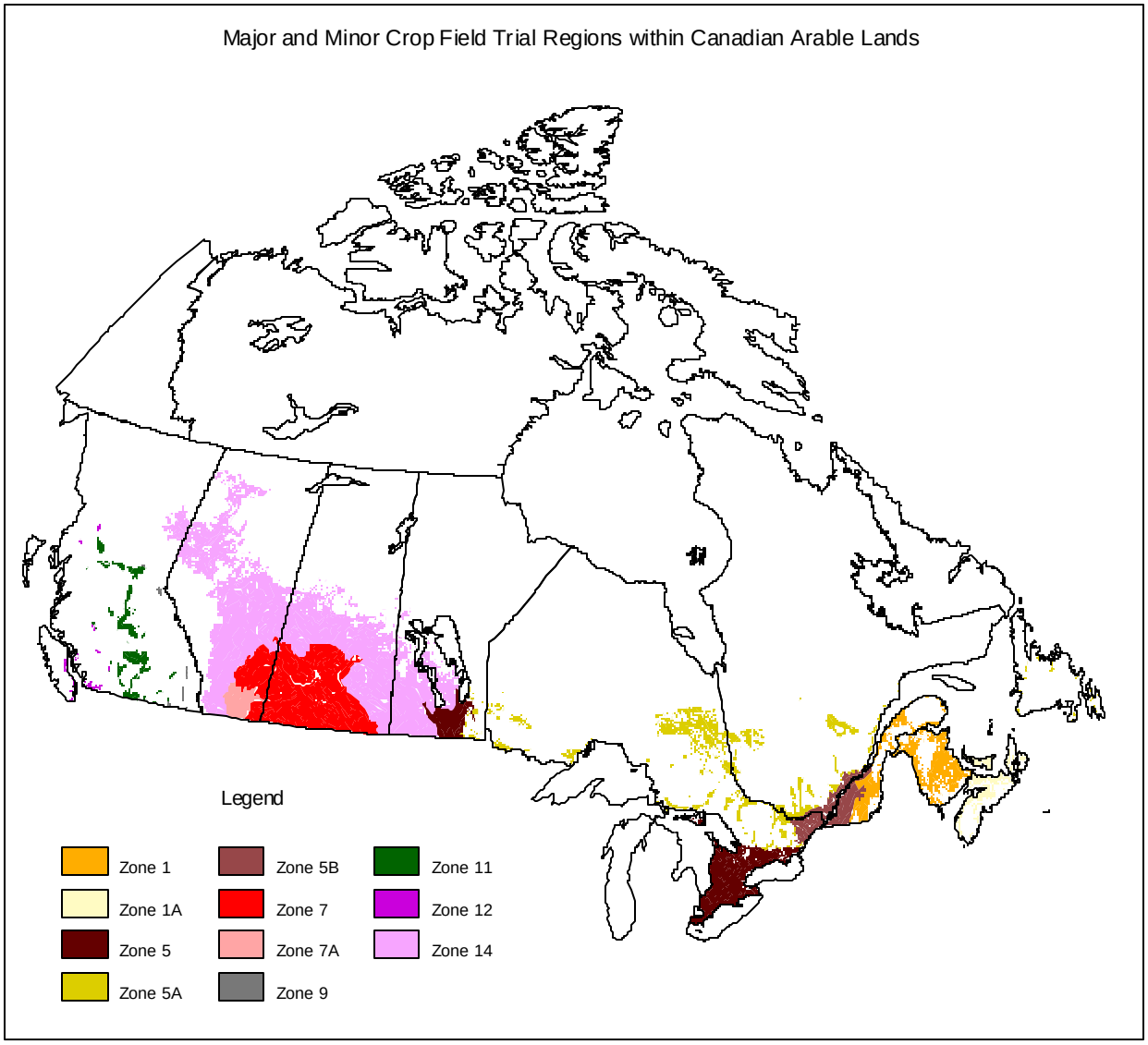
Examples

Example 1: A provincial registration is desired for use of an agricultural chemical on apples in British Columbia (BC). Since BC accounts for approximately 23% of national apple production, and since 12 field trials are required for apples nationally, 3 field trials will be required from BC for this use (0.23 x 12 = 2.8 or 3 field trials). Since greater than 8 field trials are required nationally (12), multiple year data will be required (2 field trials the first year, 1 the second year). Finally, if the use was one requiring a decline study, 1 decline study would also be required.

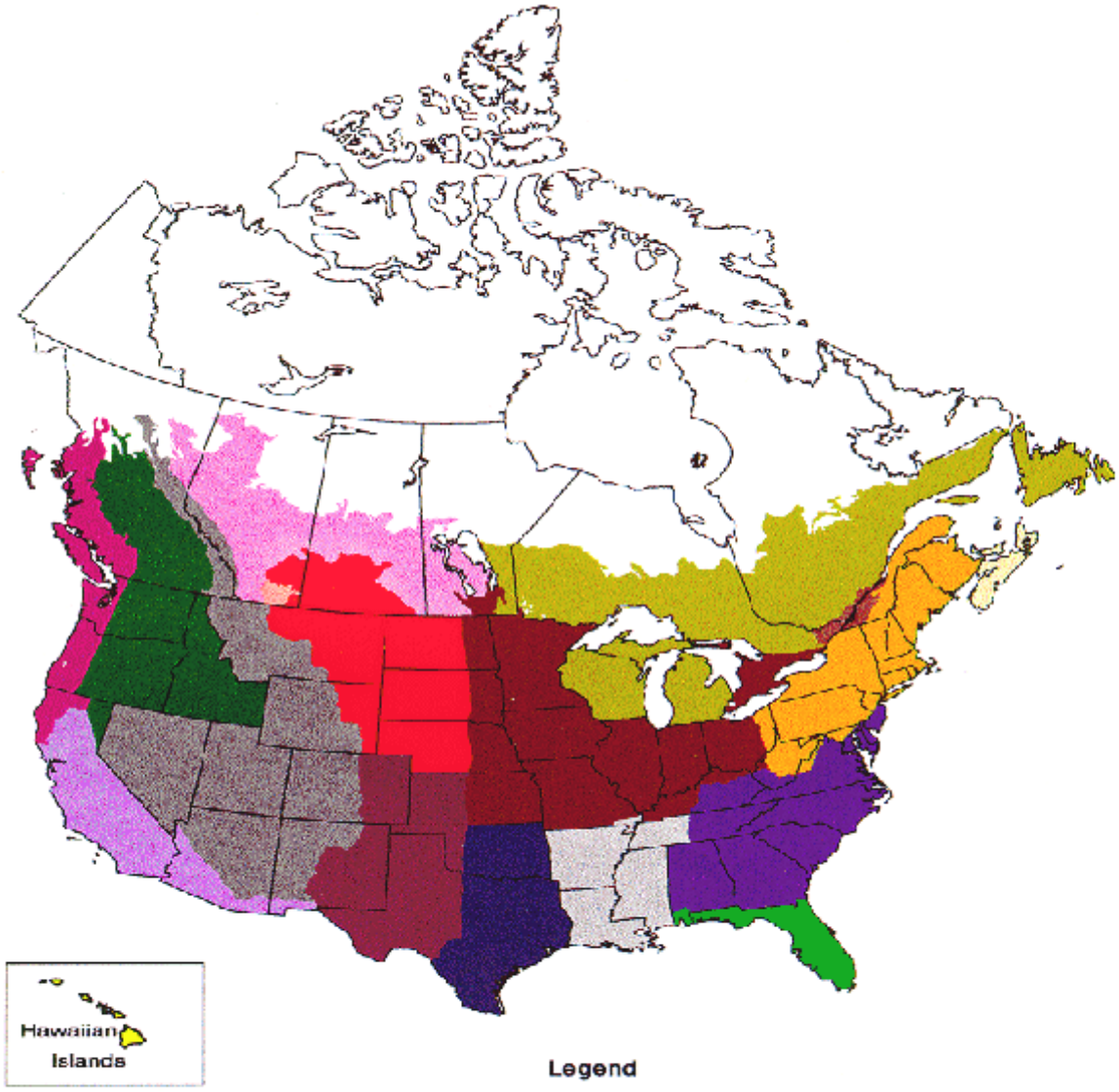
Example 2: A provincial registration is desired for use of an agricultural chemical on tame hay in Ontario. Since Ontario accounts for approximately 18% of tame hay grown nationally, and since 12 field trials are required for tame hay nationally, 2 field trials will be required from Ontario to support this registration (0.18 x 12 = 2.16). Since greater than 8 field trials are required nationally (12), the two required field trials would have to be distributed over two years, i.e., one field trial in each of two years. Since tame hay requires greater than 5 field trials for a national registration (12), one of these studies would have to be a decline study if the use pattern requires a decline study. For the other study, one sample from each of 4 separately treated plots (two at 1X and two at 2X rates) would be required.

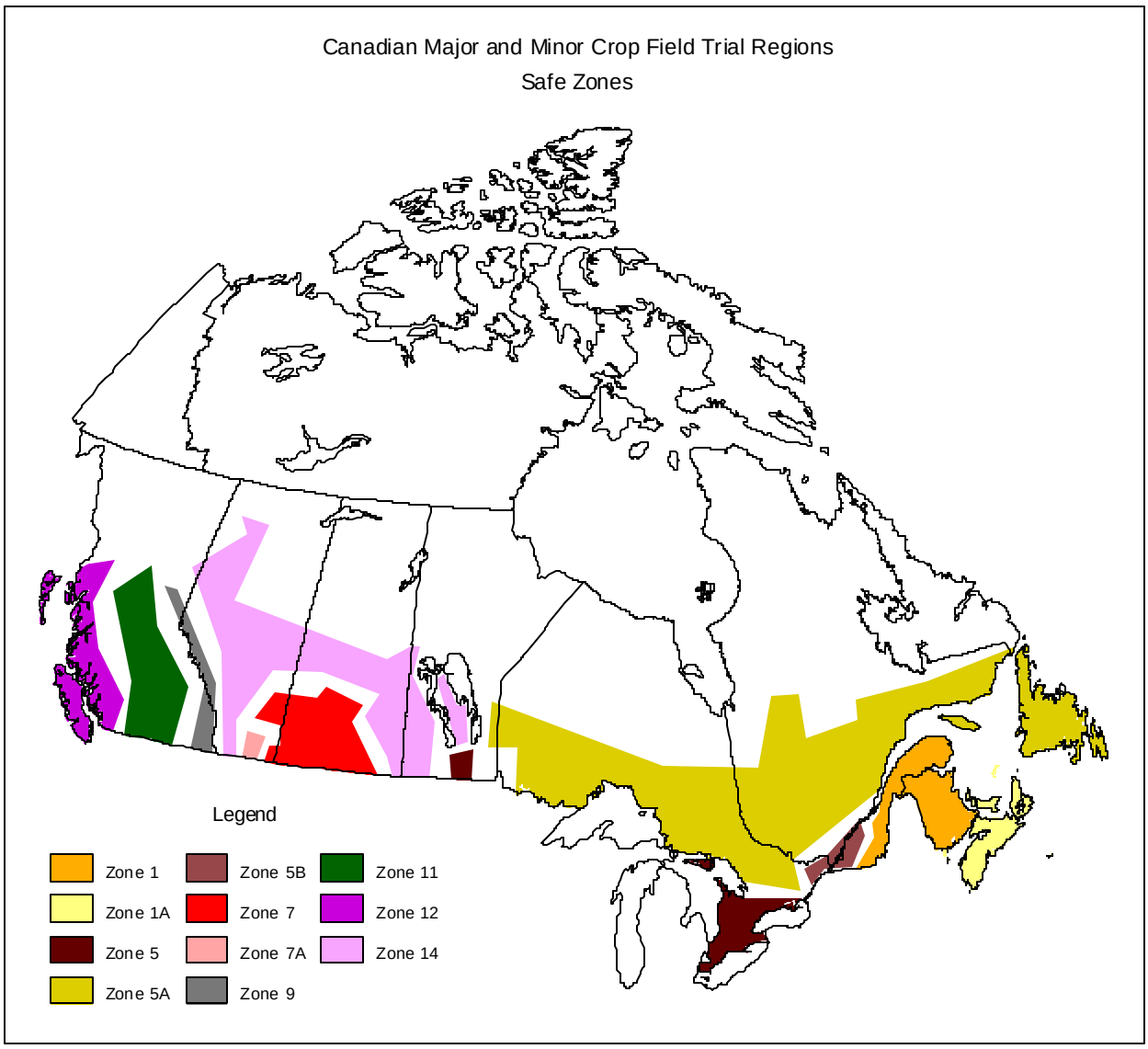
APPENDIX VI

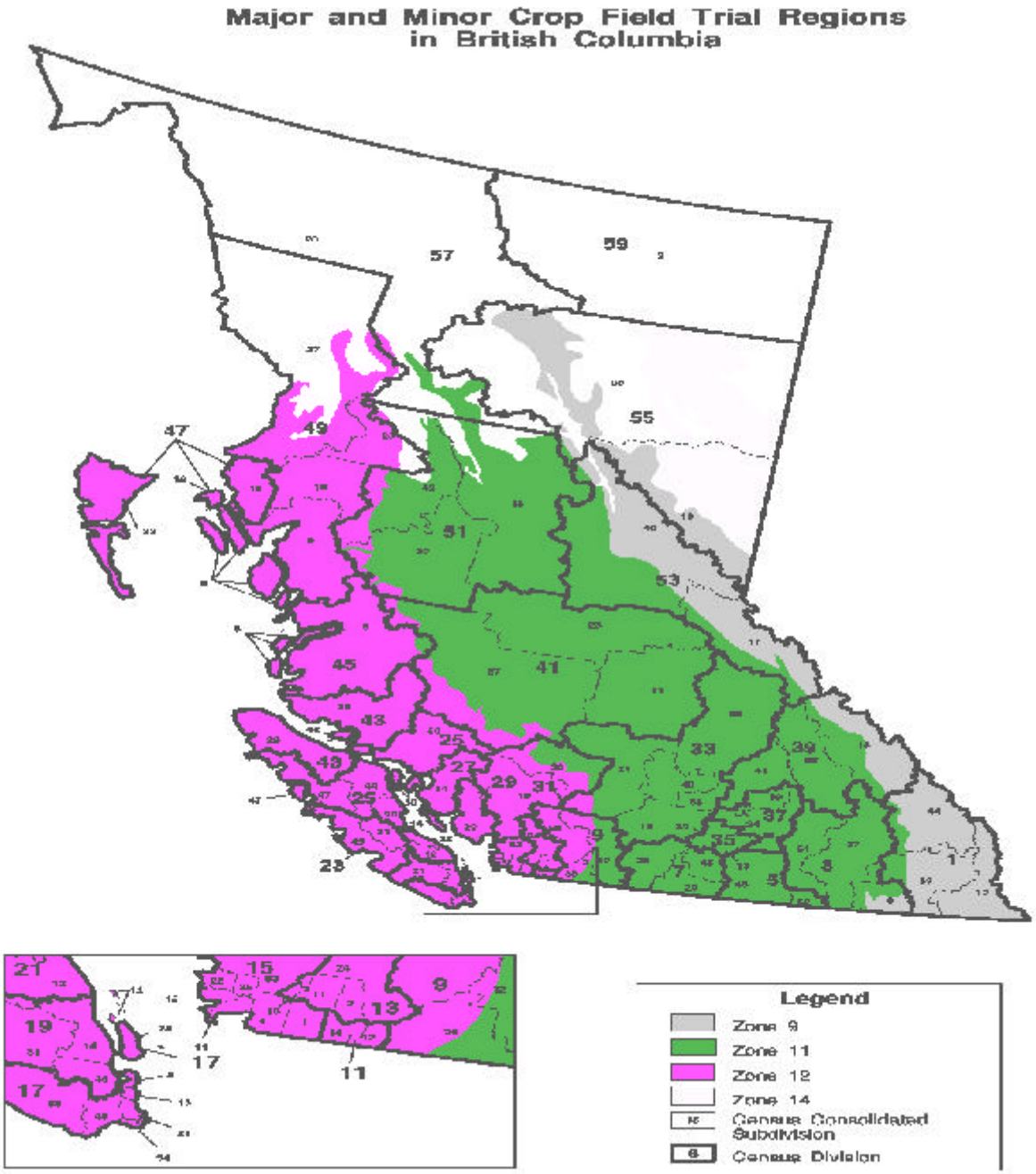

Canadian Major and Minor Crop Field Trial Regions
Legend
Zone 1
Zone 1A
Zone 5
Zone 5A
Zone 5B
Zone 7
Zone 7A
Zone 9
Zone 11
Zone 12
Zone 14
Prepared for Pest Management Regulatory Agency, Health Canada
Produced by SAGA, Agriculture Division, Statistics Canada


Major and Minor Crop Field Trial Regions within Canadian Arable Lands
Legend
Zone 1
Zone 1A
Zone 5
Zone 5A
Zone 5B
Zone 7
Zone 7A
Zone 9
Zone 11
Zone 12
Zone 14
Prepared for Pest Management Regulatory Agency, Health Canada
Produced by SAGA, Agriculture Division, Statistics Canada

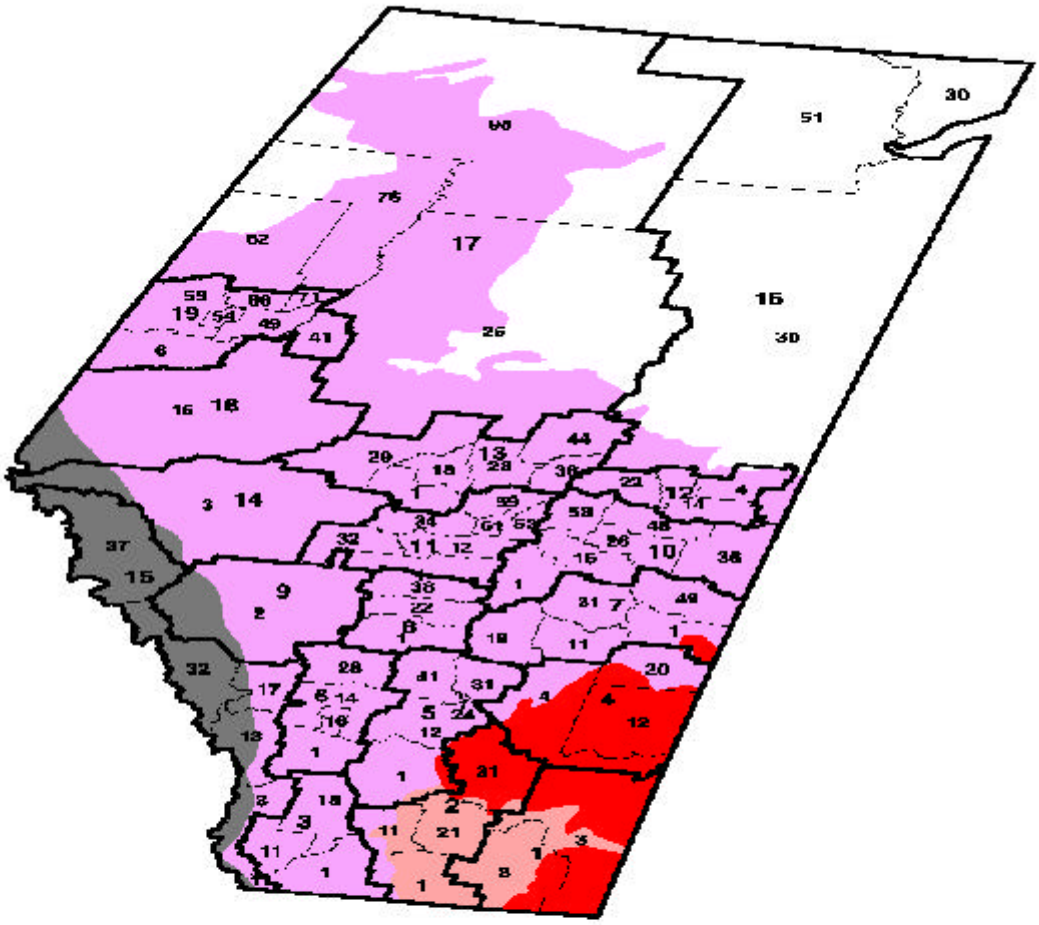
Canadian and U.S. Major and Minor Crop Field Trial Regions



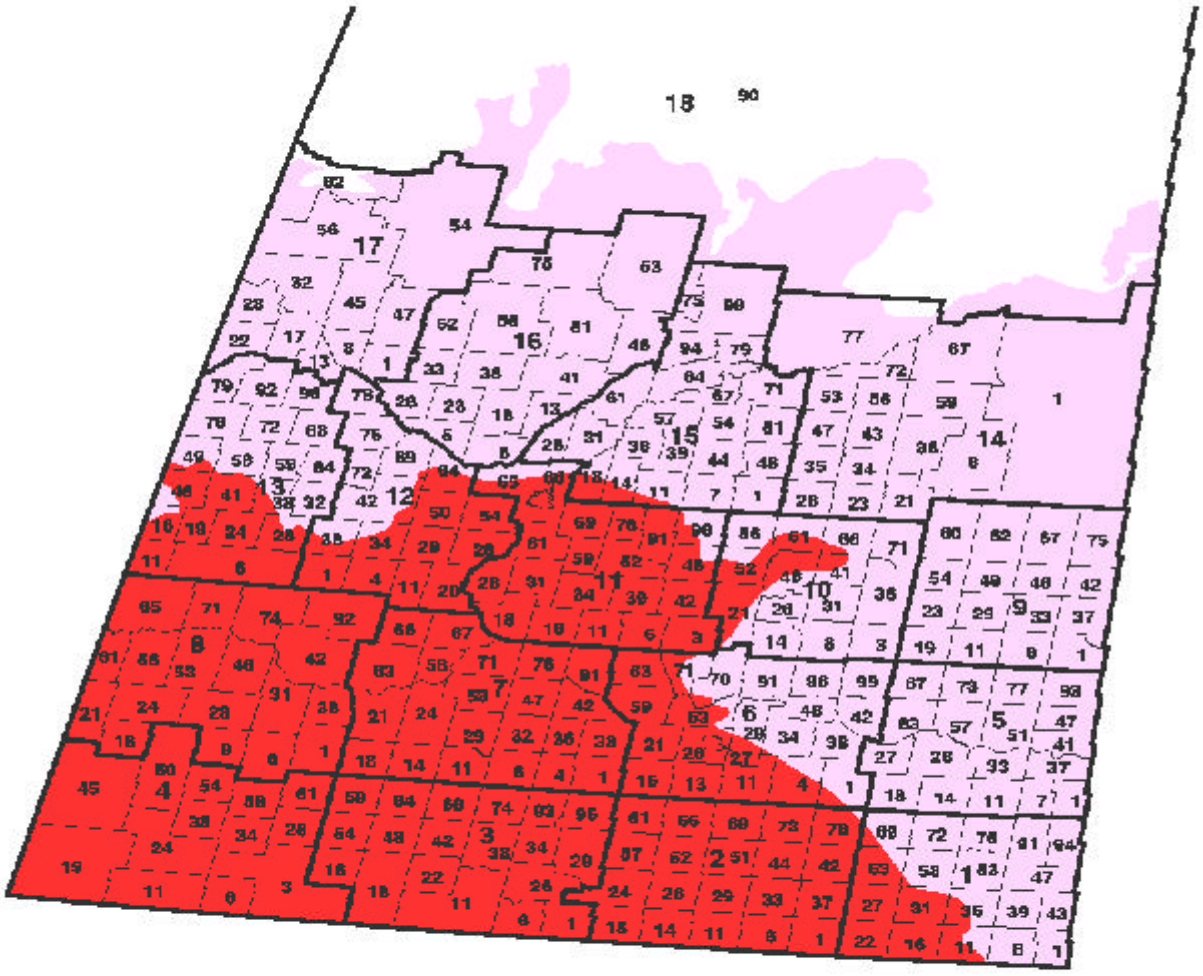

Canadian Major and Minor Crop Field Trial Regions
Safe Zones
Legend
Zone 1
Zone 1A
Zone 5
Zone 5A
Zone 5B
Zone 7
Zone 7A
Zone 9
Zone 11
Zone 12
Zone 14
Prepared for Pest Management Regulatory Agency, Health Canada
Produced by SAGA, Agriculture Division, Statistics Canada

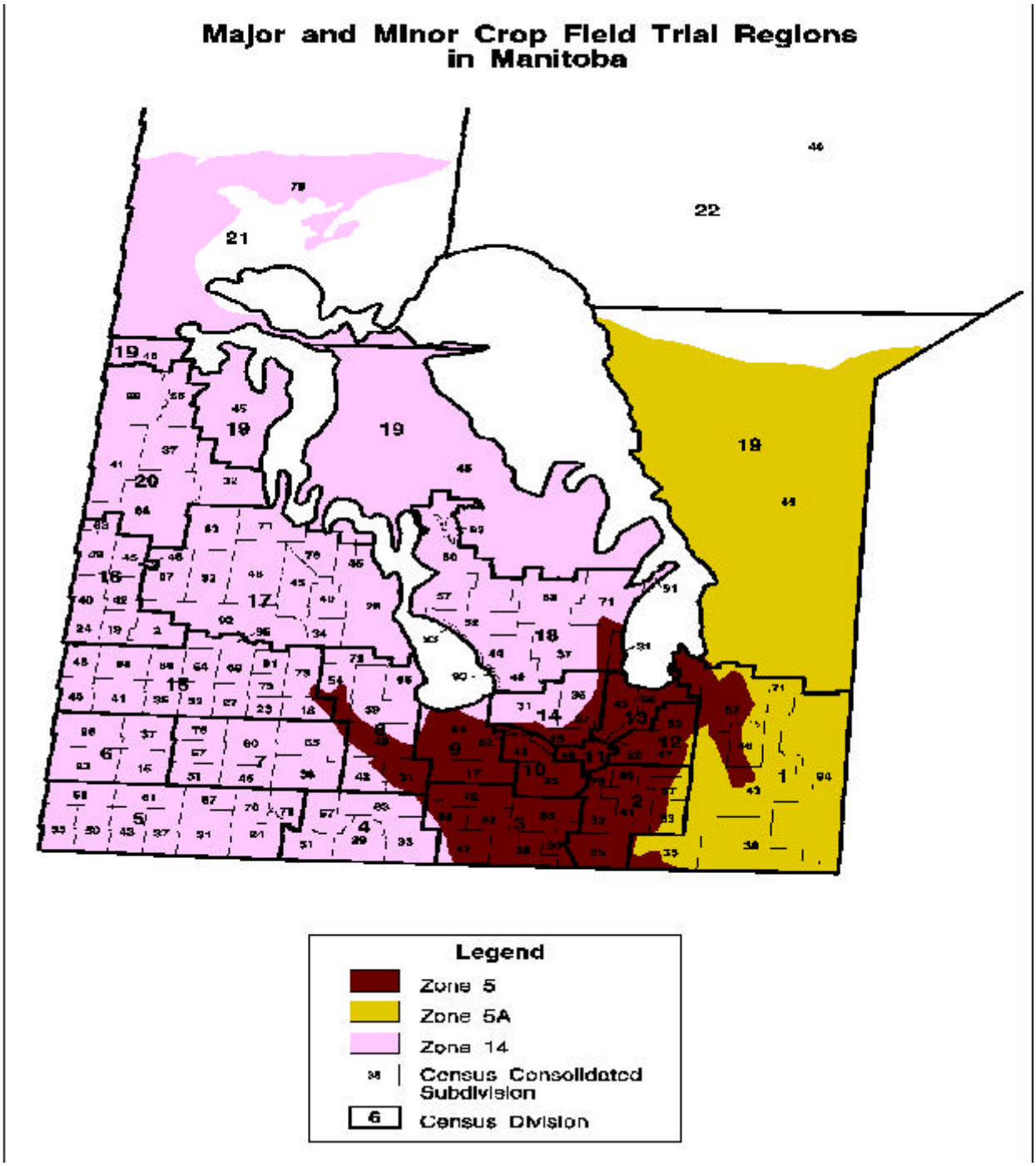

Major and Minor Crop Field Trial Regions
in British Columbia
Legend
Zone 9
Zone 11
Zone 12
Zone 14
Census Consolidated Subdivision
Census Division

Major and Minor Crop Field Trial Regions In Alberta

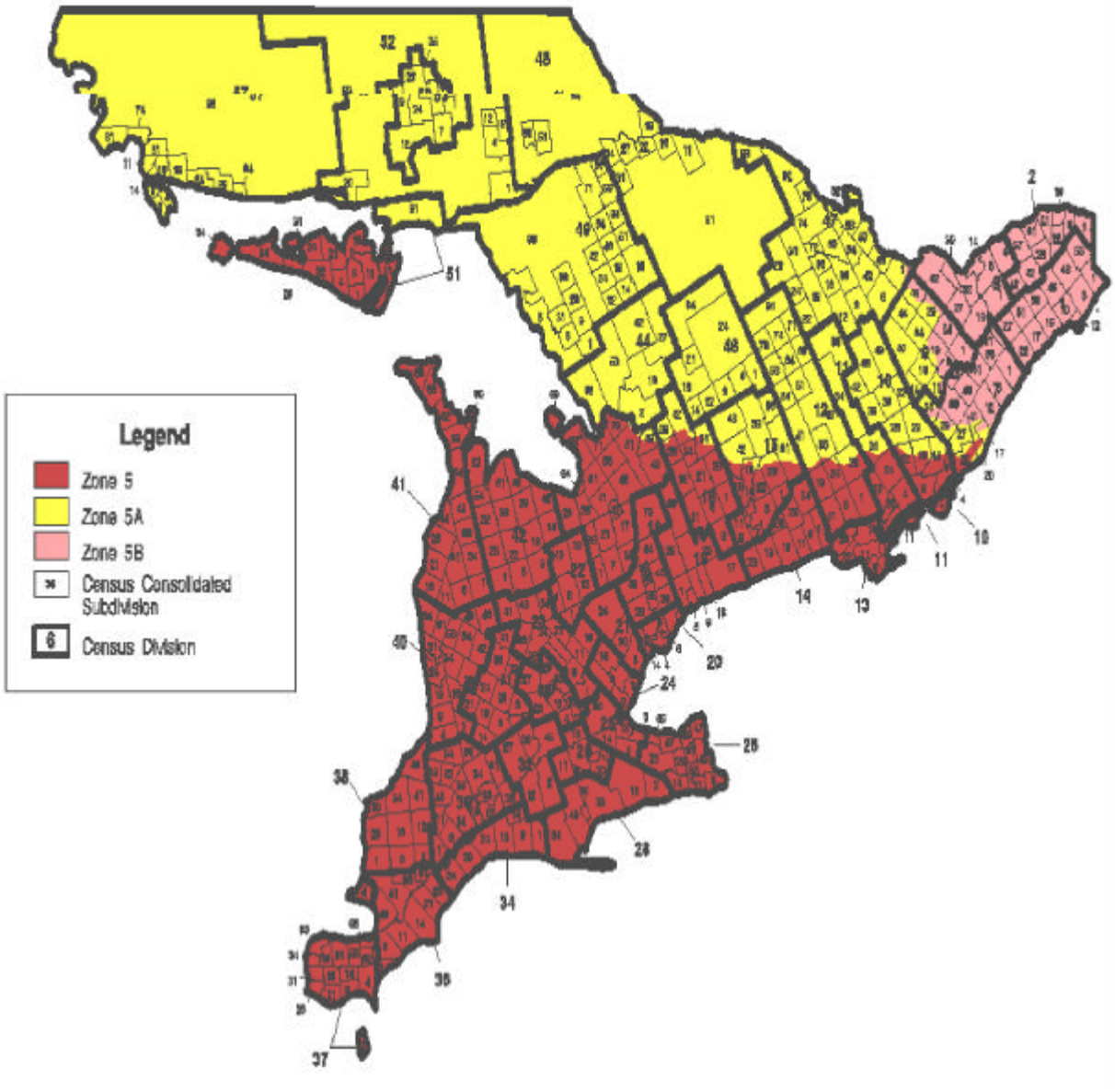


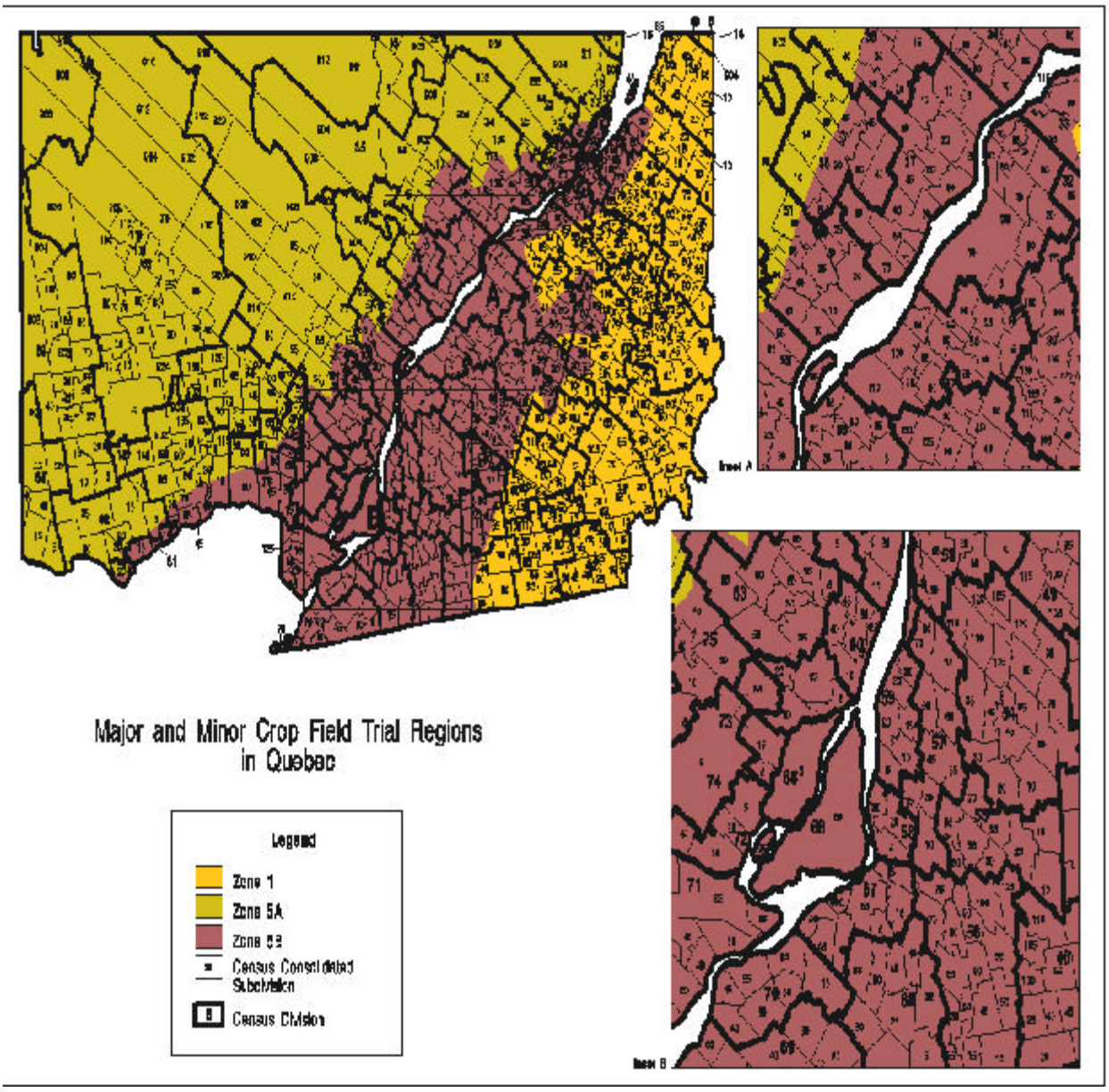
Major and Minor Crop Field Trial Regions in Saskatchewan




Major and Minor Crop Field Trial Regions
in Manitoba
21
22
19
20
18
17
16
15
14
13
12
11
10
9
8
7
6
5
4
3
2
1
Legend
Zone 5
Zone 5A
Zone 14
Census Consolidated Subdivision
Census Division

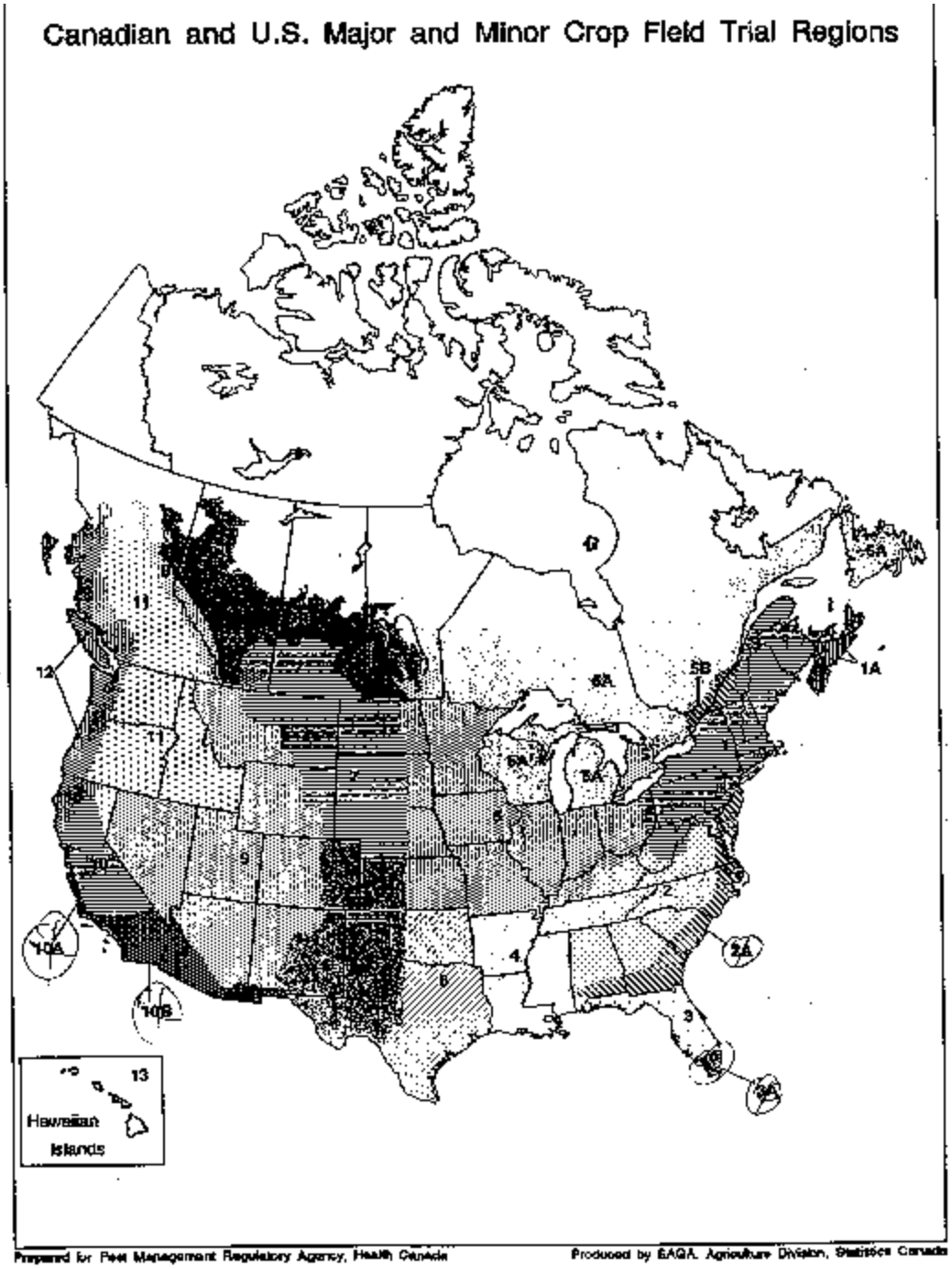
Major and Minor Crop Field Trial Regions in Ontario

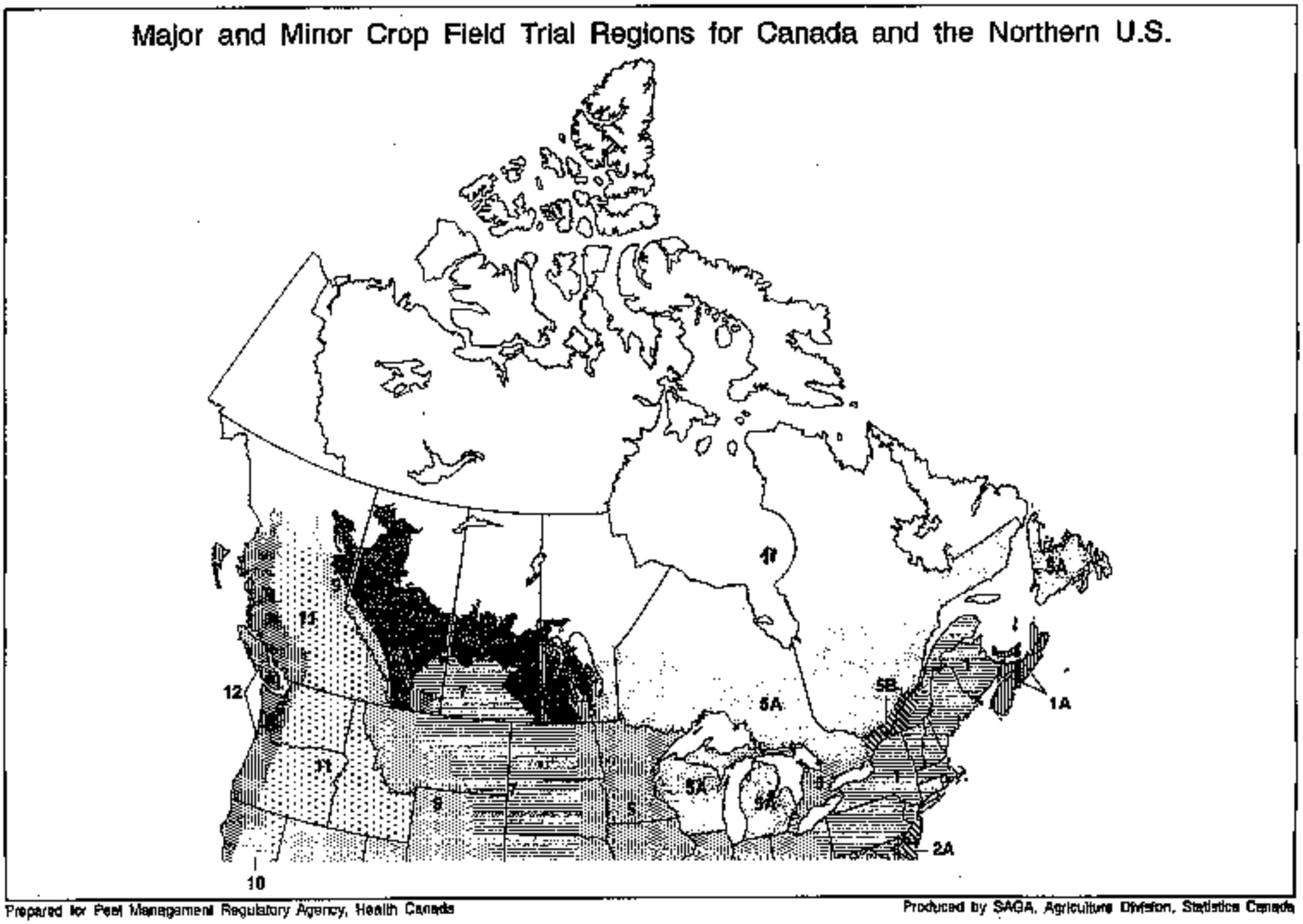


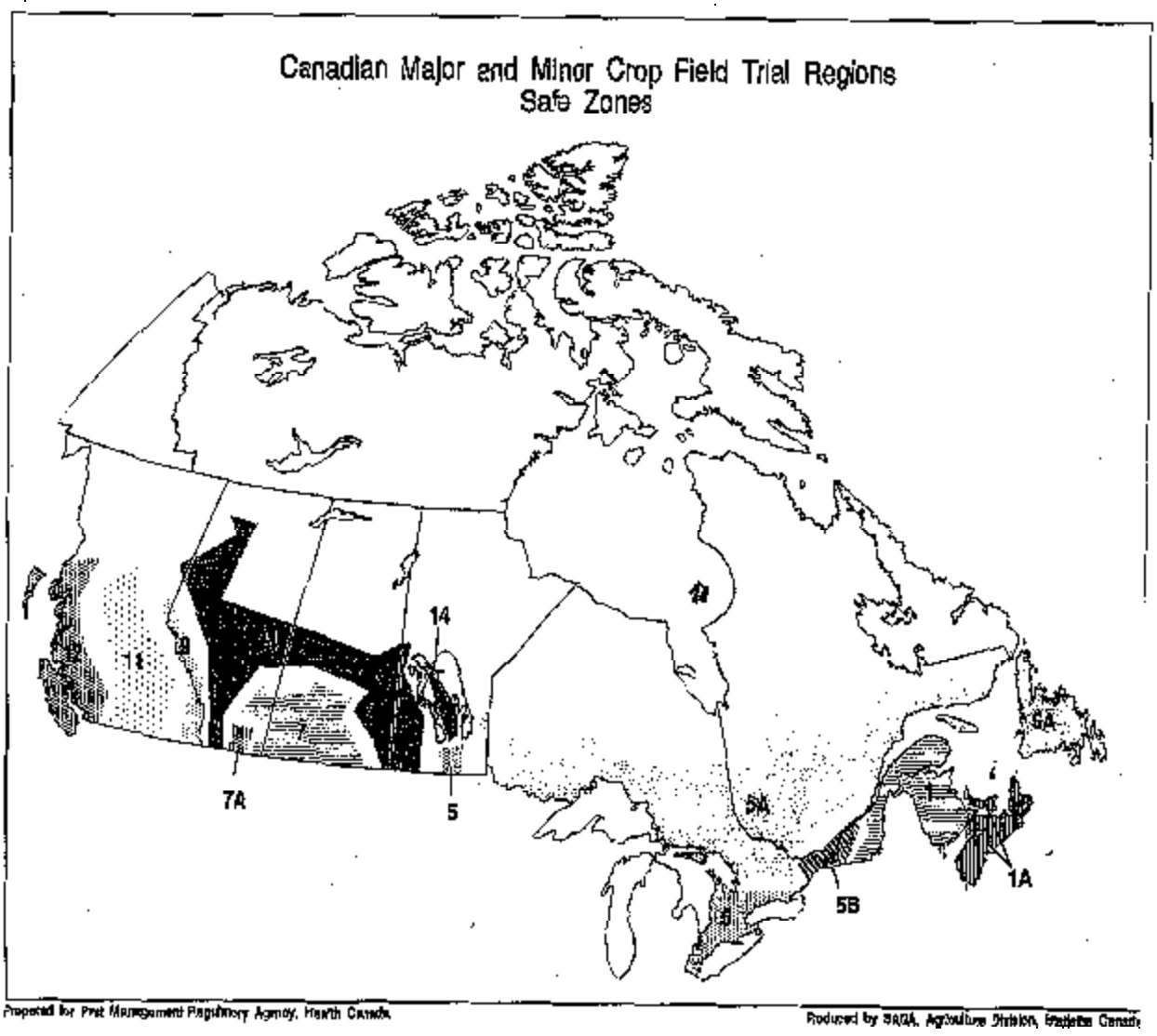

Major and Minor Crop Field Trial Regions
in Quebec
Legend
Zone 1
Zone 5A
Zone 5B
Census Consolidated Subdivision
Census Division

APPENDIX VII

(Maps for petitioner to use)


Canadian and U.S. Major and Minor Crop Field Trial Regions
Hawaiian Islands
Prepared for Pest Management Regulatory Agency, Health Canada
Produced by EAGA, Agriculture Division, Statistics Canada


Major and Minor Crop Field Trial Regions for Canada and the Northern U.S.
Prepared for Pest Management Regulatory Agency, Health Canada
Produced by SAGA, Agriculture Division, Statistics Canada


Canadian Major and Minor Crop Field Trial Regions
Safe Zones
14
7A
5
5A
5B
1A
6A
Prepared for Pest Management Regulatory Agency, Health Canada
Produced by SAGA, Agriculture Division, Statistics Canada

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