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ACVM
DATA REQUIREMENTS FOR
A FOOD OR FEED USE
CLEARANCE
PLANT COMPOUNDS

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Endorsement:

Date:

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ACVM DATA REQUIREMENTS FOR A FOOD OR FEED USE CLEARANCE PLANT COMPOUNDS

1 INTRODUCTION

This document describes the minimum requirements for residue data and other information that must be supplied to enable assessment of the dietary intake risks associated with a proposed use of a plant compound on food or feed crops, the promulgation of an appropriate maximum residue limit (MRL) to support the proposed use, and the granting of a clearance for the use of a plant compound on a food crop, feed crop or other agricultural food or feed commodity.

Such a clearance must be obtained before registration (or a variation to the existing registration conditions) of a trade name product involving use on a food crop, feed crop or agricultural food or feed commodity can be finalised, unless a waiver has been granted by the Agricultural Compounds and Veterinary Medicines (ACVM) Group of the New Zealand Food Safety Authority (NZFSA).

It is important that these guidelines be followed. If you wish to vary the conditions outlined in the guidelines, then an information waiver must be obtained. Waivers may also be granted by NZFSA to reduce the number of studies or type of data that an applicant must submit.

Applicants should note that they are responsible for providing all the required information. Applications that do not contain the required information will be declined. If further advice is required, applicants are advised to contract the services of an appropriate consultant prior to submitting the application.

Additional guidance can be found in the guidelines for residue data developed by the FAO (JMPR), Australia (Australian Pesticides and Veterinary Medicines Authority), USA (Environmental Protection Agency) and the European Commission. However, where the information in these reference guidelines differs from specific requirements in this document, the New Zealand requirements take precedence.

1.1 Request for a food/feed use clearance

When applying for a clearance to use a plant compound on a new food crop, feed crop or agricultural food or feed commodity (i.e. both for a new plant compound or to extend the existing uses of a plant compound to include a new food crop, feed crop or agricultural food or feed commodity), the applicant must include a Supporting Data Package containing an Overview of the available data, together with the associated supporting data, with the application.

The Overview must identify the trade name product and the proposed use pattern. It must address each active ingredient and significant residue component in the formulation, with clear references to the appropriate studies or reports in the supporting data.

Where data for currently registered trade name products are cross-referenced, the data package summary must provide references to the previously submitted data.

1.2 Purpose

This document is intended as a guide for applicants on the data required to determine the acceptability of any proposed use of a plant compound on food crops, on crops grown for animal feed, and on stored food or feed.

1.3 Scope

These guidelines should be used when requesting a clearance to use a plant compound on a food or feed crop, or when requesting a variation to an existing plant compound food or feed crop use.

1.4 Definitions and abbreviations

Active ingredient

The substance or substances in a formulated product responsible for the biological or other effects that cause the product to meet the definition of an agricultural compound or veterinary medicine.

ACVM Group

The Agricultural Compounds and Veterinary Medicines Group, New Zealand Food Safety Authority.

ADI

Acceptable daily intake. The daily intake of a compound which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time of the evaluation of the chemical. It is expressed in milligrams of the compound per kilogram of body weight.

Acute Reference Dose (Acute RfD)

The estimate of the amount of a compound in food or drinking water, expressed on a body weight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer on the basis of all the known facts at the time of evaluation. It is expressed in milligrams of the compound per kilogram of body weight.

Agricultural compound

Any substance, mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land, place, or water on or in which the plants and animals are managed, for the purpose of:

- managing or eradicating pests, including vertebrate pests; or
- maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or
- fulfilling special nutritional requirements; or
- manipulating, capturing, or immobilising animals; or
- diagnosing the condition of animals; or
- preventing or treating conditions of animals; or
- enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or
- marking animals;

and includes:

- any veterinary medicine, any substance, mixture of substances, or biological compound used for post-harvest pest control or disinfection of raw primary produce; and
- any substance, mixture of substances, or biological compound declared to be an agricultural compound.

Codex

Codex Alimentarius Commission.

Environmental fate data

Scientific data that characterise a plant compound's fate and distribution in the ecosystem, including the influence of factors associated with degradation (light, water, microorganisms), degradation pathways, and the resultant degradation products.

FAO

United Nations Food and Agriculture Organisation.

Feed

Any commodity intended for animal or livestock consumption and includes:

- pasture, lucerne and other forage crops that are grazed;
- harvested plant material (including fodder crops, hay, silage, grain);
- failed crop remains or stubble; and
- processed or manufactured stock feedstuffs.

Good Agricultural Practice (GAP)

The safe uses of a plant compound under actual conditions necessary for effective use. GAP may encompass a range of use patterns necessary to achieve the desired effect without excessive use, with the plant compound being applied in a manner that leaves a residue, which is the smallest amount practicable.

Good Laboratory Practice (GLP)

The system, process and conditions under which studies are planned, monitored, recorded and reported. GLP applies to both the field work associated with any residue trial and the laboratory work involved in analysing the samples. The requirements for GLP are provided in the following documents:

OECD GLP Guidelines:

- Number 1 The OECD Principles of Good Laboratory Practice. Environment monograph No. 45, Paris (1992, as revised in 1997).
- Number 6 GLP Consensus Document. The Application of the GLP Principles to Field Studies. Environment monograph No. 50, Paris (1992).

or

- Code of Federal Regulations section 40 part 160. (Good Laboratory Practice Standards), USA.

Limit of Detection (LoD)

The lowest concentration of a pesticide residue or contaminant that can be identified in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

Limit of Quantitation (LoQ)

The smallest concentration of the analyte that can be quantified. It is commonly defined as the minimum concentration of analyte in the test sample that can be determined with acceptable precision (repeatability) and accuracy under the stated conditions of the test. Generally, the LoQ of an analytical method for residues in specified substrates is the lowest level where satisfactory recoveries were achieved. Formerly known as the Limit of Determination.

Maximum residue limit (MRL)

The maximum concentrations of an agricultural compound residue legally permitted in or on food commodities, generally at the first point of sale. MRLs are based on Good Agricultural Practice (GAP), and residues in foods derived from commodities that comply with the respective MRLs are assessed to ensure they are toxicologically acceptable. MRLs are based on a toxicological assessment of the pesticide and its residue, a review of residue data from supervised trials reflecting GAP, and the subsequent assessment of the dietary residue intake, such that foods produced according to GAP are safe for human consumption.

Metabolism

The changes that occur to a chemical within an organism, including uptake and distribution, changes and elimination of the chemical and its metabolites.

National Estimate of Dietary Intake (NEDI)

A prediction of the long-term daily intake of a pesticide residue on the basis of the assumptions of average daily food consumption per person and median residues from supervised trials, allowing for residues in the edible portion of a commodity and including residue components specified in the residue definition. Changes in residue levels resulting from preparation, cooking, or commercial processing are included. When information is available, dietary intake of residues resulting from other sources is also included. The NEDI is expressed in milligrams of residue per person per day.

National Estimate of Short-Term Intake (NESTI)

A prediction of the short-term intake of a pesticide residue on the basis of the assumptions of high (97.5 percentile) daily food consumption per person and highest residues from supervised trials, allowing for residues in the edible portion of a commodity and including residue components specified in the residue definition. The NESTI is expressed in milligrams of residue per kilogram of body weight per day.

Plant compounds

Any substance, mixture of substances, or biological compound used or intended for use in the direct management of a plant. It also includes compounds used in the post-harvest treatment of unprocessed agricultural commodities of plant origin.

Pre-Harvest Interval (PHI)

The time interval between the last application of a pesticide to a crop and harvest. See also 'Withholding period' below.

Processing factor

The residue level in the processed product divided by the residue level in the starting commodity, usually a raw agricultural commodity. Also known as a concentration factor (when residue levels increase) and a reduction factor (when residue levels decrease) as a result of processing.

Processed food

The product, resulting from the application of physical, chemical or biological processes to a primary food commodity intended for direct sale to the consumer, for direct use as an ingredient in the manufacture of food or for further processing. Primary food commodities treated with ionizing radiation, chopped, washed, sorted or submitted to similar treatments that do not result in a cellular change are not considered to be 'processed foods'.

Residue

Any specified substance in food, agricultural commodities or animal feed resulting from the use of a plant compound. The term includes any derivatives of a plant compound, such as conversion products, metabolites, reaction products and impurities considered to be of toxicological significance.

Residue definition (compliance)

The definition of a residue (for compliance with MRLs) is that combination of the pesticide and its metabolites, derivatives and related compounds to which the MRL applies. This definition is based on the results of metabolism and toxicology studies, supervised residue trials, analytical methods and its general suitability for monitoring compliance with GAP.

Residue definition (intake estimation)

The definition of a residue (for estimation of dietary intake) is that combination of the pesticide and its metabolites, derivatives and related compounds to which the STMR and HR (highest residue) apply. This definition is based on the results of metabolism and toxicology studies and its general suitability for estimating dietary intake of the residue for comparison with the ADI and acute RfD.

Significant residue components

Compounds other than the active ingredient(s) that are present in the trade name product which may be toxicologically significant.

Supervised residue trials

Scientific studies in which agricultural compounds are applied to target host species according to specified conditions intended to reflect commercial practice after which harvested crops or tissues of slaughtered animals are analysed for residues. Usually specified conditions are those which approximate existing or proposed GAP.

Supervised Trials Median Residue (STMR)

The expected residue level (expressed as mg/kg) in the edible portion of a food commodity when an agricultural compound for agricultural use has been used according to maximum GAP (i.e. the acceptable use likely to result in the highest residue at harvest). The STMR is estimated as the median of the residue values (one from each trial) from supervised trials conducted according to maximum GAP conditions.

Trade name product

An agricultural compound containing one or more active ingredient(s), normally mixed with non-active ingredients (such as surfactants, solvents, diluents, suspending agents), intended for application, with or without dilution prior to use, and which is labelled with directions for use.

WHO

World Health Organisation.

Withholding period (WHP)

Minimum permissible time between the last application of an agricultural compound to a crop (including pasture) and its harvesting for human or animal consumption or grazing with livestock.

1.5 References

OECD GLP Guidelines:

Number 1 The OECD Principles of Good Laboratory Practice. Environment monograph No. 45, Paris (1992, as revised in 1997).

Number 6 GLP Consensus Document. The Application of the GLP Principles to Field Studies. Environment monograph No. 50, Paris (1992).

FAO. 2002. Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. FAO, Rome.

FAO. 1990. Guidelines on producing pesticide residues data from supervised trials. FAO, Rome.

Code of Federal Regulations, Section 40, part 160: Good Laboratory Practice Standards.

European Commission. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.

2 SUPPORTING DATA PACKAGE

The ‘Supporting Data Package’ must contain sufficient information about the plant compound and its residue characteristics in plants, animals and the environment for an assessment to be made on the composition and distribution of residues in food, and to estimate the potential dietary intake risks associated with these residues.

The data package should contain the full studies, detailed reports, or information waivers related to the submission; the Overview should contain data summaries and conclusions relating to the submission.

2.1 Overview

The Overview is a summary of the available information provided in the submission and the conclusions based on this information, referencing the relevant studies and preferably presented under the same section headings as used in the data package. Further details are included in Appendix 1.

Note that the submission of an electronic copy of the Overview, while optional, may facilitate the ACVM Group assessment process (in the preparation of assessment reports), and thus allow a more rapid response.

2.2 Supporting data

The data provided in support of any submission should be compiled under the following headings, and must include the full studies, detailed reports, or information waivers relating to the requested food clearance.

Identity and Properties

Information on the identity, composition and properties of each active ingredient and significant residue component in the trade name product.

Proposed Use Pattern

The proposed use of the trade name product must be fully specified together with explanatory information on growing and husbandry practices, and production techniques. Supporting statements or documentation on the efficacy of the proposed use and its relevance to Good Agricultural Practice.

Methods of Analysis

Methods of analysis for both trial purposes and for compliance. Residue stability studies in stored analytical samples.

Animal and Plant Metabolism

Studies that elucidate the metabolism of the compound(s) in animals and plants.

Supervised Residue Trials

The reports of the New Zealand supervised residue trials undertaken in accordance with these guidelines; or, in the case of overseas trials, summary reports that provide sufficient information to permit an assessment of the quality and relevance of the trials.

Processing Studies

Studies relating to the nature and concentration of residues present in foods that are normally processed before consumption.

Animal Transfer Studies

Studies on the nature, distribution and decay profile of the compound(s) and metabolites in animal tissues and products.

Environmental Fate Studies

Studies on the fate and behaviour of the compound(s) in soil, water and water/sediment systems.

ADIs and Acute Reference Doses

Information on Acceptable Daily Intakes and any Acute Reference Doses established in New Zealand, by WHO or by other national regulatory agencies, together with a summary of the relevant toxicology studies from which these ADIs have been derived and the rationale for any safety factors that have been used.

National MRLs (optional)

MRLs that are established, pending or proposed in New Zealand, by Codex or by other regional or national authorities.

2.3 Good Laboratory Practice (GLP)

For supervised crop residue trials submitted after 1 January 2003, the *analytical laboratory component* must be GLP compliant (i.e. all analytical laboratory work must be carried out by a GLP accredited laboratory and be in accordance with GLP principles), and the *field study component* must comply with the ACVM Research Standard.

GLP compliance for the field study component of a supervised crop residue trial is not essential, but the study must be done to GLP principles and the documentation must be sufficient to provide an equivalent level of confidence in the accuracy of the study reports.

In the case of the other studies submitted as supporting data (see 2.2 above), similar conditions apply, with these studies either being GLP compliant or conducted according to GLP principles (i.e. containing sufficient documentation to give an equivalent level of confidence in the accuracy of the study reports).

In all cases, where a particular study does not meet the above requirements, an information waiver must be obtained from the ACVM Group.

3 IDENTITY AND PROPERTIES

A detailed chemical characterisation of the compound should be provided, together with information on selected physical properties.

Characteristics and properties that need to be addressed include:

3.1 Product composition

This information is required to determine the need to assess the residue characteristics of any impurities, manufacturing byproducts or other components in the formulated trade name product. These data should identify and quantify:

- the active ingredient and its concentration in the trade name product, together with a description of the product formulation type;
- a clear indication of the identity of the active ingredient (e.g. the ISO common name, the IUPAC chemical name, CAS Registry number) and its structural formula;
- any impurities present in the technical grade material at a concentration of more than 10 g/kg (1%), preferably with reference to their CAS numbers for impurities, if available. Impurities present at 10 g/kg (1%) or less, which may be toxicologically significant (e.g. dioxins, PCBs or N-nitrosamines), must be identified, and quantified if possible;
- other additives and excipients present in the formulated trade name product, identified by their chemical/common name, CAS Registry number and common trade names.

3.2 Physical and chemical properties

Selected properties of the active ingredient are required to provide indicative information on the behaviour of the plant compound during and after its application on crops or animals, and to assess its possible movement and fate in the environment. These properties include:

- vapour pressure;
- solubility in water and organic solvents;
- partition coefficient (octanol/water);
- hydrolysis;
- photolysis;
- reference to any FAO specifications relating to the active ingredient.

4 PROPOSED USE PATTERN

The use pattern of a trade name product influences the level and nature of residues that will occur in food. It is essential, therefore, that submissions include the complete, detailed use pattern proposed for the product, to supplement the proposed label directions.

Of particular importance is the provision of information on the maximum application rates likely to be used in the field, in terms of active ingredient concentration(s) and rate(s) per hectare as well as the maximum number of applications per season and an indication of the intended or common GAP spray volumes used in commercial practice.

4.1 Use situation

The proposed crop or use situation should be clearly identified, including an indication of the crop growth stage(s) involved (e.g. pre-emergent, mid-season foliar spray, post-harvest), where appropriate, using recognised growth stage coding systems (e.g. BBCH).

If the proposed label claim is for use on crop groups (e.g. 'citrus' or 'cucurbits'), this should be expanded to identify the individual crops within the proposed crop group and preferably identified by reference to the commodity description and code given in the *Codex Classification of Foods and Animal Feeds*.

4.2 Application method

The intended treatment must be given in sufficient detail (e.g. the type of apparatus used and its output, such as low or high volume sprayer etc.). There is often a link between the type of treatment and specific formulations developed for such applications. Where different application methods are likely, identify the predominant method in common use.

4.3 Application rate

The dose rates in amounts of active ingredient should be expressed in grams or kilograms active ingredient per hectare and as dilution rates (in grams or kilograms active ingredient per 100 litres). Where relevant, details of acid equivalent application rates should be provided. The amount of diluted spray mix likely to be applied per hectare should also be specified, particularly the maximum spray rates generally recommended or in common practice. If there are likely to be significant regional or grower differences, these should be indicated, and the most common or predominant application practice should be noted.

Where the recommended application rates (dose rate per hectare or dilution) change during the crop life cycle, this should be specified.

Generally, for 'tall' crops such as orchard and vine crops, glasshouse tomatoes etc., for foliar-applied pesticides, where flat boom spraying is not common practice, the emphasis should be on the spray concentration (gai/100 litres) with a clear indication of the dilute spray rates being recommended per hectare at the various crop growth stages. For 'low' crops such as most vegetable crops, pasture and arable crops, where boom spraying predominates, application rates should relate to the rate of active ingredient applied per hectare, with supplementary information on anticipated water rates per hectare also being supplied.

Where the proposed use pattern is for spot treatment of weeds in pastures, it is recommended that the residue data be obtained for a broadcast rate equivalent to treating a hectare of the target weed using the necessary quantity of spray mix. For example, if the mixing rate is 10 g active ingredient per 100 L water and it takes 3000 L spray mix to treat 1 hectare of weed then the application rate for residue purposes is 300 g/ha. For the purpose of calculating animal intake of residues from treated pasture, information must also be provided on the anticipated maximum percentage of the pasture likely to be treated.

4.4 Application number and timing

In general most of the residues remaining at harvest are from the last one or two applications. The growth stages for each application should be recorded and any codes used to describe growth stages (e.g. BBCH, Zadoks) should be fully explained.

The minimum and maximum number of expected treatments per season, and the normal interval between applications in days should be stated. Because the treatment intervals are often linked to dose rates, any alternative treatment programmes should be indicated (e.g. dose A could be applied to a crop at 7 - 8 days interval or at a higher dose B at 10 -14 days intervals).

4.5 Proposed Pre-Harvest Interval (PHI)

The proposed Pre-Harvest Interval(s) should be indicated for all food or feed commodities concerned. If different PHIs are proposed for the same or similar commodity (e.g. for glasshouse or outdoor grown crops, cereal grains for human consumption or green feed cereals intended for animal feed), the particular circumstances should be clearly indicated.

Where the proposed PHI is related to a specific crop growth stage (e.g. when recommended for use up to a particular stage of the crop development, such as petal fall in apple and pears, pre-emergence for weed control etc.), information should be provided on the range of PHIs likely to occur.

4.6 Good Agricultural Practice (GAP)

The assessment of whether a proposed use pattern is Good Agricultural Practice is dependant on the submission of sufficient information to show that the product will be effective for its intended purpose when used according to the label directions.

This information must be relevant to the proposed use pattern, be of sufficient quality and quantity to show that the proposed label claim will be effective (without the excessive use of the product) and should comment on the relationship between the proposed use pattern and existing good grower practices commonly in use.

5 METHODS OF RESIDUE ANALYSIS

5.1 Analytical methods for trial purposes

The applicant must provide complete details of the analytical method(s) used for the determination of residues in the residue trials.

The methods should:

- possess a high degree of specificity for the compound in question and be able to show selectivity for each of the residue components identified in the plant, animal and environmental studies as being of toxicological significance;
- be validated in compliance with GLP;
- be substantiated by adequate evidence to show that the method is effective for the determination of the residues in the substrates analysed, and at the levels under consideration.

Where the analytical method involves an instrumental determination such as spectrophotometry, HPLC, or gas-liquid chromatography, specimen output charts showing blank determination and recovery determinations should be provided to assist in the evaluation of the method.

The individual methods should be summarised and clearly outline the compounds determined, the commodities for which the method is recommended, specificity, repeatability of the method, the Limits of Detection and Quantitation and the range of residue levels for which the method has been validated, the mean recovery and the relative standard deviation of recoveries at each fortification level including the Limit of Quantitation.

It is important to relate the residue analytical procedures used in a particular residue trial to those provided in the supporting documentation. It is therefore essential to identify the detailed method of analysis clearly with a distinctive reference number and to specify the appropriate reference number in each residue trial report. Each trial report should describe any modifications made to the method of analysis.

Situations can arise where proof of the accuracy of the residue analytical method is not entirely demonstrated by the formal method validation document. This is because incurred residues may be less 'extractable' than the same analytes simply added to a sample for recovery purposes. In such situations demonstration of the accuracy of a method using, for example, labelled drug in a metabolism study will be required if the applicant cannot otherwise demonstrate that the method results accurately reflect true sample residue content.

5.2 Analytical methods for compliance purposes

In some cases, analytical methods used in the determination of residues in the trials conducted for the purposes of risk assessment may differ from those available for routine monitoring and for regulatory control.

Where specific analytical methods for compliance exist, these must be provided and must be capable of determining all residue components identified in the MRL residue definition.

The major residue components should be determined individually as far as technically possible and should preferably involve a multi-residue procedure even if the recovery rate is not as good as that of a specific individual 'trials' method.

Any analytical method used for compliance purposes should be sufficiently sensitive to determine whether an MRL is exceeded or not. Generally this means that any Limit of Quantification (LoQ) should be at least five times lower than the MRL. However, where an MRL is set at 0.1 mg/kg or less (but not at the LoQ), the associated LoQ should be half the MRL.

5.3 Storage stability tests for analytical samples

The results of stability tests for residues in stored analytical samples of representative substrates should be provided. Typical matrices should be selected to include predominantly water, oil, protein or starch-containing materials. In the case of animal products, sample storage stability tests should include animal tissues, milk and eggs.

5.4 Residue definitions

Residue definitions are required to clearly establish the compound or compounds of interest when estimating dietary intake risks associated with the use of a plant compound, and also to provide a basis for monitoring for GAP compliance.

The two requirements are sometimes not compatible and, as a compromise, various definitions of residues are possible. For some compounds it may be necessary to establish separate residue definitions for MRL enforcement and dietary intake purposes.

The residue definition for dietary intake purposes should include metabolites and degradation products of toxicological concern irrespective of their source, whereas the residue definition for compliance with MRLs needs to be a simple residue definition, i.e. indicator molecule suitable for practical routine monitoring and enforcement of the MRL at a reasonable cost.

Although metabolites, degradation products and impurities are included in the definition of pesticide residues, this does not necessarily mean that metabolites or degradation products should always be included in the residue definition for enforcement (MRLs) purposes or for estimation of dietary intake (STMR). Inclusion of transformation products (metabolites and degradation products) in the residue definition depends on a number of factors, and the decision on whether they should be included is very complex. Decisions have to be made on a case-by-case basis.

This issue is discussed in some detail in the FAO Guidelines (*JMPR Manual*). If in doubt about the suitability of the residue definition for use in New Zealand, please consult the ACVM Group prior to conducting residue trials.

6 PLANT AND ANIMAL METABOLISM

The purpose of conducting metabolism studies is to determine the metabolic fate of the active ingredient. Many agricultural compounds undergo change during and after application to plants, soil, water and livestock. The composition of the terminal residue must therefore be determined before the analytical methodology can be developed and residues can be quantified.

The information should include documentation on the identity of the metabolites and the quantities present. Distinction should be made about the presence of metabolites in the different plant parts (surface, leaves, stems etc.), in different animal tissues (fat, muscle, kidneys etc.), and in different soil types. The rate of the formation and disappearance of metabolites in plants, animals and soil must also be investigated.

6.1 Plant metabolism

Plant metabolism studies provide information on the approximate level of total residues, identify the major components of the total terminal residue, indicate the route of distribution of residues and its mobility (uptake from soil, absorption by plants or surface residue) and show the efficiency of extraction procedures for various components of the residue.

These studies are usually required for a minimum of three diverse plants (unless the plant compound is to be used on only one or two crops). If the metabolism in three diverse crops is similar, then the metabolism in other crops is normally assumed to be similar. However, if the metabolism is different in different types of plants, a metabolism study is required for each type of crop groups (e.g. root vegetables, leafy crops, fruits, pulses and oilseed, cereals) for which use is proposed.

6.2 Animal metabolism

Animal metabolism studies are required where there is a potential for livestock to be exposed to residues, such as when a plant compound is applied to animal premises or housing, or where significant residues remain in crops or commodities used in animal feed, in forage crops, or in any plant parts that could be used in animal feeds or fed to livestock.

If original detailed toxicokinetic studies are performed using laboratory animals, it will be necessary to show that similar metabolic pathways are followed in livestock exposed to the chemical or its residues, and whose meat, milk and eggs are destined for human consumption.

Usually the most important metabolism studies are those involving ruminants and poultry. Normally lactating cows are used but, in the interest of economy, goats are acceptable alternatives. In the case of poultry, chickens are the animals of choice.

7 SUPERVISED CROP RESIDUE TRIALS

Supervised crop trials serve as the primary source of information for estimating maximum residue levels.

The *FAO Manual on the Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed (2000)*, and the associated *Guidelines on Producing Pesticide Residues Data from Supervised Trials (1990)*, are valuable references on the design and assessment of supervised residue trials. Both can be found on the FAO website (<http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Default.htm>). Click on the 'JMPR' link for the FAO manual (2002) and the 'FAO Pesticide Management Guidelines' for the link to the residue guidelines (1990).

7.1 Residue trial types

7.1.1 Residue decay studies

The most common type of residue trial in New Zealand is a residue decay study, where one or more (replicated) treatments are applied to a number of plots, with samples being taken at various intervals following the last treatment.

Decay curves for residues are valuable especially when a plant compound has been applied directly to the consumable part of a crop (e.g. to a half grown apple). In addition, decay studies allow a degree of interpolation to support use patterns (and Pre-Harvest Intervals) not directly equivalent to those used in the trials.

Samples should be taken at appropriate intervals after the last application, sufficient to demonstrate the decay profile of the plant compound. Generally this should involve **sampling on at least 4-5 occasions, up to and including harvest**. It is essential to sample at the proposed Pre-Harvest Interval.

For example, with most fruit and vegetable crops, if the intended Pre-Harvest Interval is 14 days, the first sample would normally be taken between 0 and 3 days after the last application, with subsequent samples being taken 7, 14, 21 and 28 days after the last treatment, i.e. at the proposed Pre-Harvest Interval and 2 points either side of this date. If 'zero-day' samples are taken, information on the number of hours between application and sampling must be provided. Note that while 'zero-day' samples are not essential, they do provide valuable information on the magnitude of the initial residue, and can assist in determining the acceptability of comparable residue trials from different regions or countries.

If the samples are analysed in date order, and if two consecutive samples show no detectable residues (i.e. less than the LoD), it may be acceptable to stop further analysis at that point (although the retention of any untested samples is strongly recommended).

'Reverse decline trials', where a number of different plots are treated on different dates (to reflect the different Pre-Harvest Intervals) and all the plots are sampled on the same date, are also acceptable if these studies are more relevant to the proposed use pattern. Such trials are recommended where the crop is growing or maturing rapidly over the proposed treatment period, and the crop growth stage at the time of treatment is a significant factor influencing residue levels present.

7.1.2 Single point tests

An alternative method of collecting residue data, particularly in situations involving clearly defined treatment and harvest times, is to take residue samples at harvest from a number of different trial sites that have been treated in accordance with the proposed label claim. Instances where single point tests may be appropriate include pre-plant soil incorporation treatments, herbicides used before the crop has emerged, and pre-flowering applications to deciduous fruit trees.

Single point tests may be more appropriate than decay studies in cases involving single (early season) applications and a clearly defined harvesting date.

7.2 Design of residue trials

Residue trials should aim at giving as accurate as possible a measure of the residues likely to occur in edible portions of the crop or in other food commodities such as products of animal origin (meat, milk, milk products, eggs).

7.2.1 Treatment frequency and timing

The frequency of application, the interval between applications, and field conditions should be the same as those being specified on the label. If the trial conditions differ from those likely to occur in practice, this should be highlighted in the commentary, and a reasoned argument should be provided to support the extrapolation of the data to field use.

7.2.2 Formulation and treatment rates

Trials should include treatment of the proposed (or similar) formulation at the maximum proposed rate. While the inclusion of a double-rate treatment is not normally required, the inclusion of such treatments in some of the submitted trials does provide the ability to extrapolate the results in future, should there be a need to increase the label application rate. Treatments should reflect the 'worst case' situation associated with the proposed use, i.e. the highest concentration or application rate and the shortest Pre-Harvest Interval.

Where commercial application equipment is not used, this should be noted. Comments on the relationship between the treatment method used in the trial and the method (equipment) commonly used in commercial practice should be explained.

7.2.3 Plot size and replication

Plot sizes should be sufficiently large to allow the use of application techniques that reflect commercial practice, and to provide representative crop samples for analysis, including duplicate samples that can either be bulked or analysed separately (see 7.6 below).

Because variations in residue levels between replicates at individual sites are generally less than the variability found in data from different sites, it is usually not necessary to replicate treatments at individual trial sites. However, it may be useful to include such replicate treatments (2 - 4) in at least one trial, in order to provide an estimate of 'within-site' residue variability.

7.2.4 Trial site selection

Trials should be designed to cover a representative range of growing or storage conditions. The sites of residue trials and the trial conditions (including, in the case of perennial crops, crop size and maturity) should be selected to reflect common commercial practice, so that the typical residue pattern likely to be encountered in the field may be determined. For crops with extended harvesting periods, more than 50% of the residue trials must involve early maturing varieties.

Where the crop management systems or growing conditions differ from region to region, the trial sites should be selected to reflect these different conditions and/or management practices.

7.2.5 Post-harvest trials

Where the product is applied to a harvested crop or a commodity in storage or transport, information is necessary on alterations to the amounts and nature of the residue that occur during the normal course of pre-sale storage and handling of the crop after treatment. In the case of a fumigant, for example, it is necessary to know how much is taken up by the foodstuff during treatment and whether and how quickly the plant compound is lost by ventilation.

Plant compounds used for pest control in stored products vary considerably in stability. In addition to the ambient temperatures, varying from tropical to temperate, moisture content and aeration can influence the rate of disappearance.

Application of plant compounds can vary from commodities stacked in sacks to automated systems in silos. In addition, the variability of residues within a store (i.e. intra-store variability) can be high, e.g. in situations such as fogged potatoes in box stores. For this reason, sampling procedures must be designed to obtain a sample representative of the lot.

7.3 Number of trials

The number of trials required (and the sampling methodology) is dependent on the variability of use conditions and the consequent scatter of the residue data.

Experience suggests that the minimum number of supervised crop residue trials listed in Appendix 2, spread over representative cropping areas or covering the predominant crop management practices and growing conditions, should be sufficient to provide an acceptable data base for a residue assessment.

Trials conducted at the same location will not normally be considered independent and thus ‘separate’ trials for the purposes of Appendix 2, unless there is convincing evidence that the additional trials are providing further independent information about the influence of the range of farming practices on residue levels.

7.4 Residue data from other countries

New Zealand residue data will normally be required for plant compounds. However, relevant data from residue trials carried out in other countries with similar crop management and growing conditions may replace some of the local trials, provided there is a clear rationale to show the relevance of the foreign data to the proposed New Zealand use pattern.

Factors that should be considered in this regard could include similarities in Good Agricultural Practice, crop production and management systems. However, in most cases, applicants will be expected to conduct confirmatory tests under typical conditions of use in New Zealand to indicate the levels of residues under local conditions, and to validate any extrapolation from the foreign data.

Appendix 2 provides more detailed guidance on the degree to which local trials can be replaced by foreign residue data and examples of where local trials may not be necessary.

7.5 Extrapolation within crop groups

Data on residue levels in one species of plant, or animal, do not necessarily represent the residue levels that might occur in distinctly different species.

Consideration will be given to the use of satisfactory data from several crops in a crop group to estimate the general residue behaviour for most, if not all, crops in that group, or even to a very similar crop in another group, provided use patterns are compatible.

The FAO publication *Codex Classification of Foods and Animal Feeds* provides guidance on crops and raw agricultural commodities considered essentially similar for the purposes of recommending MRLs.

Data on one crop within a crop group may be considered to represent the residue levels that can be expected to occur on crops within the same group, but in some cases, such as leaf (fancy) lettuce and head lettuce, such extrapolation may not be acceptable.

Residue data from other countries may also assist in the extrapolation from one crop when clearances are sought for an allied crop or a crop group. If these data show that residues are substantially similar for a number of crops within a crop group (as measured by the range of STMR values), this could provide a good case for extrapolating New Zealand data on one or two crops to all crops in that crop group.

Appendix 2 provides more detailed guidance on the trial data requirements needed to support a crop group extrapolation.

7.6 Sampling

Samples should be representative of the treated plot and the individual ‘units’ must be typical of those taken at harvest. Where immature or unripe samples have to be taken, these should be clearly noted in the trial report.

The *FAO Manual on the Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed (2000)* provides guidance on sampling methods in general, and includes advice on the number of units in a sample and the commodity portion to be analysed.

In addition, it is suggested that for crops having medium to large individual unit weights (e.g. more than 25 g/unit), at least three individual unit samples from at least one treated plot (preferably the one that approximates the proposed GAP label rate and Pre-Harvest Interval) should also be analysed and reported separately in order to provide some indication of the food unit variability within the composite sample.

Plot sizes should be sufficient to accommodate these multiple samples and provision should also be made for adequate sampling of controls or untreated crops.

7.7 Storage of samples

Samples should be analysed as soon as possible, but if it is necessary to store them before analysis then the method of storage and date of analysis should be given. In such cases it is recommended that the samples or subsamples be kept at -18 to -20 degrees C.

At most storage temperatures some changes in residues may still occur, so evidence should be provided on the stability of the residues in the sample under the storage condition used.

Where sample extracts have been stored for more than 24 hours prior to analysis, the stability of residues should be demonstrated with recovery studies performed under similar conditions.

7.8 Reporting of residue trials

In the full reports, all details of trial procedures must be provided, including data on variables that might influence the decline of residues. Each report must include details of the trial location, the specific trial site and design, together with comprehensive information on the application details, weather conditions, sampling methodology and analytical procedures and results. Any variations from documented protocols and methods must be identified.

The minimum data items that must be reported in any residue trial report are listed in Appendix 3, and the *FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (1990)* provides one example of a residue trial summary report.

8 PROCESSING STUDIES

The effects of industrial processing and household preparation on residues are required for commodities that may be further processed before consumption, in order to allow more realistic estimates of chronic or acute dietary intake of pesticide residues.

Processing studies are not normally required if:

- the plant or plant product is normally only eaten raw, e.g. head lettuce;
- only simple physical operations such as washing and cleaning are involved;
- significant residues (above 0.1 mg/kg) are not expected in the raw commodity (unless the pesticide concerned has a low acute RfD or ADI).

Processing studies should be conducted on representative commodities such as citrus fruits, apples, grapes, tomatoes, potatoes, cereals. By using core processing procedures and selecting representative crops, it should be possible to extrapolate to other crops processed by the same procedure. In cases where it is not possible to derive consistent processing factors or where a very low ADI is established, it may be necessary to conduct processing studies on every crop.

Procedures to be used in processing studies should correspond as closely as possible to those that normally occur in practice. Thus products of household preparation (e.g. cooked vegetables) should be produced using the equipment and preparation techniques normally used in households, whereas industrial items such as cereal products, preserves, fruit juices or sugar should be produced by procedures representative of commercial food technology. In some cases more than one commercial process may be routinely used (e.g. the different UK and US commercial practices in the production of potato chips). In such cases, reasons should be provided for the chosen process.

Processing studies should be designed so that processing factors can be derived. For consistent processing factors the results of more than one study are necessary.

The raw commodity used in the studies should be a field-treated commodity containing quantifiable residues, so that processing factors for the processed products can be determined. This may require field treatment at an exaggerated application rate to obtain sufficiently high residue levels. Processing studies with spiked samples are not acceptable unless it can be demonstrated that the residue in the raw commodity is entirely on the surface.

Generally, processing studies should be conducted on crops harvested at a reasonable interval after the last treatment (comparable with the proposed Pre-Harvest Interval) to allow ageing of the residue as expected in normal commercial practice.

9 ANIMAL TRANSFER STUDIES

In addition to the qualitative animal metabolism studies mentioned in 6.2 above, separate animal feeding studies (transfer studies), using unlabelled compounds, are required to establish the relationship between residue levels in feed and/or soil and the likely residues in food of animal origin (e.g. animal tissues, milk, honey and eggs).

These studies are required:

- if the chemistry or behaviour of an agricultural compound indicates a potential for residues to be transferred to livestock (e.g. fat-soluble pesticides); or
- where livestock metabolism studies indicate that significant residues (0.01 mg/kg or more) may occur in edible tissues and where significant residues (0.1 mg/kg or more in the total animal diet) occur in feed or feed crops (e.g. pasture, fodder crops, hay, silage), in crop wastes (e.g. kiwifruit, carrots, onions, potatoes, pumpkins and squash) or in the top 5 cm layer of soil; or
- there is a potential for bioaccumulation to occur; or
- where agricultural compounds are to be applied to livestock premises or other situations where there is a potential for residues to enter the animals (either by ingestion or skin contact).

Similar requirements exist where there is a potential for residues to occur in honey or propolis, generally from the presence of residues in pollen or nectar, or from the treatment of hives or honey extraction equipment.

Animal transfer studies may be necessary in both ruminants and poultry. The cow is the preferred ruminant species, but lactating goats are an acceptable model. Chickens are the preferred poultry species. A study on pigs may also be required if significantly different metabolites are present in ruminants, poultry and rats.

Further guidance on the conduct of animal transfer studies is provided in the *FAO Guidelines on Producing Pesticide Residue Data from Supervised Trials (1990)*, the *FAO Manual on the Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed (2000)* or in the *US EPA Residue Chemistry (Subdivision O) Guidelines*.

10 ENVIRONMENTAL FATE

Environmental fate studies are required to provide an indication of the general behaviour and fate of the compound in soil and water, and thus permit the assessment of the potential for residues to transfer from these compartments into food, feed or other agricultural commodities.

Studies on environmental fate in soil and in water/sediment systems are normally required for all plant compounds except those with specific restricted use (e.g. post-harvest application in storage). The availability of relevant studies is essential for the assessment of potential residues in food, feeds and drinking water arising from soil uptake/ingestion, irrigation or groundwater contamination.

The submitted data should address:

- metabolism and degradation in soils, identification of metabolites and degradation products, and an indication of their levels;
- persistence of the parent compound and its metabolites or degradation products in soils under aerobic and anaerobic conditions;
- mobility and partitioning of the parent compound and its metabolites in soils;
- adsorption by various soils;
- hydrolysis rate and products;
- photolysis on soil and plant surfaces and its products;
- crop uptake, bioconcentration and bioavailability of the compound and its metabolites;
- residues in rotational (subsequent) crops representative of those in New Zealand cropping systems.

11 ADIs AND ACUTE REFERENCE DOSES

Information is required on Acceptable Daily Intakes (ADIs) and any Acute Reference Doses (ARfD) established in New Zealand, by WHO or by other national regulatory agencies.

These intake levels are an essential component of all dietary intake risk assessments.

The ADI is required to estimate dietary intake residue levels that should not be exceeded in long-term (chronic) diets for various subpopulations, and the ARfD is used for the same purpose but for estimating short-term intake risks (generally over one meal or one day).

Supporting studies, from which the ADIs and ARfDs have been derived, should be summarised and the toxicological end-points clearly identified. If any safety factors have been used to account for intra-species variability, inter-species variability, special sensitivities of any subpopulations etc., these should be clearly indicated.

Where different ADIs or ARfDs have been established by different organisations or regulatory authorities, the rationale for these differences should be outlined.

12 NATIONAL MAXIMUM RESIDUE LIMITS

National or Codex MRLs should be reported exactly as they are published. The portion of the commodity to which the MRL applies should be specified and the relevant residue definitions should be given. Copies or extracts from the appropriate national legislation should be provided.

APPENDIX 1

SUPPORTING DATA PACKAGE – OVERVIEW CONTENT

RESIDUE DATA PACKAGE OVERVIEW FOR (TRADE NAME PRODUCT)

1 Identity and Properties

1.1 Product composition

- *A list of all active ingredients and impurities or contaminants present in the technical grade material/manufacturing concentrate at levels above 10 g/kg (1%), indicating their concentration and highlighting those considered to be of significance from a residue or toxicological point-of-view.*
- *A list of all compounds of toxicological significance (e.g. dioxins, HCBs, nitrosamines) present at levels of 10 g/kg (1%) or less, indicating their concentration and highlighting those considered to be of significance from a residue or toxicological point-of-view.*
- *A list of all other ingredients present at levels above 10 g/kg (1%) and their concentration in the trade name product.*

1.2 Physical and chemical properties

A description of the key properties of the active ingredient that are of relevance to its potential residue behaviour in plants, animal tissues, soil and water, and conclusions on the significance of these properties.

2 Proposed Use Pattern

- *A comprehensive description of the proposed use pattern, with comments on its appropriateness with respect to current production practices, and on any specific aspects of the proposed use that are novel or at variance with similar compounds or current practices.*
- *A brief overview of the target crop production systems (including the timing of the major crop growth stages) and commonly adopted pest management systems.*
- *A summary of the information submitted to support the proposed use pattern as being Good Agricultural Practice.*

3 Methods of Analysis

3.1 Analytical methods

- *Summarise the methods of analysis available for residue trial purposes, commenting on the specificity, limits of determination and quantitation, recovery rates and other method performance parameters.*
- *Summarise the methods of analysis available for compliance purposes, commenting on the specificity, limits of determination and quantitation, recovery rates and other method performance parameters.*

3.2 Storage stability tests

Summarise the available residue stability studies and indicate the degree to which residues in analytical samples are likely to decay during storage.

3.3 Residue definition

Indicate the proposed residue definitions for both compliance purposes (i.e. MRL-setting) and for dietary intake risk assessment purposes, together with the basis for proposing these definitions.

4 Animal and Plant Metabolism

Provide a summary of each of the available metabolism studies on representative plant species, laboratory animals and on livestock, identifying the metabolic fate of the active ingredient and the nature and distribution of the terminal residues.

5 Supervised Crop Residue Trials

- *In a table, summarise the results of each of the available crop residue trials data, including for each residue trial: the trial reference, application details, the Pre-Harvest Intervals and the associated residue levels found.*
- *Comment on the relevance of these trials to the proposed use and the level of consistency between the results.*
- *Identify and comment on any mitigating or confounding factors associated with the trials that may influence the assessment of the results.*

6 Processing Studies

Summarise the available processing studies and indicate an appropriate processing factor(s) to reflect the degree to which residues decline, increase or metabolise as a result of processing.

7 Animal Transfer Studies

- *Summarise the available animal feeding studies (transfer studies), indicating the nature and distribution of the parent compound and significant metabolites.*
- *Comment on the potential for residues to occur in animal tissues following the consumption of treated feeds or feed crops.*

8 Environmental Fate

- *Summarise the available studies on environmental fate in soil, water and water/sediment systems with comments on their relevance.*
- *Taking into account the key chemical and physical properties of the active ingredient, indicate the potential for residues to occur in subsequent food and feed crops, and in animal tissues as a result of soil ingestion or from residues in stock drinking water.*

9 ADIs and Acute Reference Doses

List any Acceptable Daily Intakes and/or Acute Reference Doses established in New Zealand, by WHO or other regulatory agencies, together with the toxicological endpoints from which these have been derived and a reference to the related study and the rationale for any safety factors that have been used.

APPENDIX 2

SUPERVISED CROP RESIDUE TRIALS

NATIONAL OR FOREIGN SUPERVISED RESIDUE TRIALS

New Zealand residue data are required for agricultural compounds whose use patterns or conditions of use in New Zealand are different from other countries, where the commodity is a major component of the New Zealand diet or animal feed, or where significant quantities of the treated produce are likely to be exported.

In some cases relevant data from residue trials carried out in other countries with similar crop management practices and crop growth characteristics may be included in the supporting data package to supplement or, in some cases, replace the New Zealand trials. In most cases, applicants will be expected to conduct confirmatory tests under typical conditions of use in New Zealand to indicate the levels of residues under local conditions, and to validate any extrapolation from the data from other countries.

In all cases where foreign studies are submitted to supplement or substitute for the listed New Zealand residue trials, the following conditions should apply:

- the foreign studies should have been conducted under conditions that reflect New Zealand crop management practices and crop growth conditions (with these similarities being clearly explained in the submission);
- the treatment regime used in the foreign studies should not differ from the proposed New Zealand use pattern (e.g. application rates, frequency, timing, PHI etc.) by more than 25% in total;
- the results of the entire data-set of trials should show similar residue behaviour patterns as measured by the range of the STMR values.

Foreign Trial Substitution Rule

Up to 50% of the specified New Zealand supervised field crop residue trials, and up to 75% of the specified New Zealand supervised glasshouse crop residue trials can be replaced by 'foreign' studies.

CROP GROUPS AND REPRESENTATIVE CROPS

Data on residue levels in one species of plant, or animal, do not necessarily represent the residue levels that might occur in distinctly different species.

Consideration will be given to the use of data from several crops in a crop group to estimate the general residue behaviour for most, if not all, crops in that group. The Codex crop grouping system, as described in the FAO publication *Codex Classification of Foods and Animal Feeds*, provides further information on this point.

Data on one or two ‘representative’ crops within the main group may be considered to represent the residue levels that can be expected to occur on crops within the same group but, in some cases, such as leaf lettuce and head lettuce, such extrapolation may not be acceptable.

Residue data from other countries may also assist in the extrapolation from one crop to another within a crop group. If these data show that residues are substantially similar for a number of crops within a crop group, this could provide a good case for extrapolating New Zealand data on one or two crops to all crops in that crop group. For example, if New Zealand data on cabbages show similar results to those from UK cabbage trials, and UK studies on Brussels sprouts and broccoli indicate a similar decay pattern, an argument could be made to extrapolate from the New Zealand cabbage data to include all horticultural brassica crops.

The listed crops within each crop group should be considered representative of the group, and a more extensive listing can be found in the *Codex Classification of Foods and Animal Feeds*. For specific crops not listed, the number of trials required should be based on the requirements listed under ‘Other’.

Crop Group Extrapolation Rule

The number of residue trials needed to support crop group clearances are listed in column 2 of the following table. Trials to support crop group clearances must involve the ‘representative’ crops listed in column 1, in proportion to the numbers listed for each specific crop. However, up to 25% of the trials can involve other crops within the crop group. Where claims are being considered only for ‘other’ crops, the required number of trials needs to be increased to the highest number listed for the representative crop (see example below).

Example

In the case of Vegetable Brassicas, four Broccoli trials are required to support a claim for use on Broccoli, and four Cabbage trials would be needed for a Cabbage claim. Similarly, if Cauliflower were the only use being proposed, then four Cauliflower trials would be needed, even though this is not listed as a ‘representative crop’. If a crop group clearance is being considered, a minimum of six trials is recommended, covering both flowering and leafy/head Brassicas. These trials could include:

- 3 Cabbage and 3 Broccoli trials (i.e. in proportion to the number of ‘representative crop trials’ -4:4); or
- if the 25% replacement option is chosen, 2 Cabbage, 3 Broccoli and 1 Cauliflower, Broccoflower or Brussels sprouts (‘other’) trial; or
- 3 Cabbage, 2 Broccoli and 1 Cauliflower, Broccoflower or Brussels sprouts (‘other’) trial.

Table A2.1: Crop Residue Trials Required for Plant Compound Trade Name Products

Crop Group and Representative Crops	No of NZ Supervised Crop Residue Trials	Notes and Comments
Residues less than the Limit of Detection	Reasoned argument plus 0-4 foreign trials at the proposed rate (or higher rates). Number of required trials decreases as the possibility of detectable residues decreases.	Situations where detectable residues would not normally be expected at harvest, but there is a small possibility that such residues could be detected at trace amounts. Examples could include the use of compounds on fruit crops just before or during flowering, use on immature vegetables (seedlings), early post-emergent soil treatments, treatment of food storage bins, packaging material, and food handling equipment etc. The reasoned argument must include sufficient technical justification and relevant studies to support the conclusion that no residues will occur at harvest.
Vegetable Brassicas Broccoli Cabbages Other	6 4 4 2	The selected crops should include both flowering and leafy/head brassicas.
Bulb Vegetables Onions Spring Onions Other	6 4 2 2	
Cucurbits (edible skin) Cucumbers Summer Squash Other	6 4 4 2	For protected (e.g. glasshouse) crops, up to 75% of trials can be substituted by foreign trials.
Cucurbits (inedible skin) Melons Winter Squash Other	4 2 2 2	For protected (e.g. glasshouse) crops and where trials on cucurbits (edible skin) have also been submitted, up to 100% of trials can be substituted by foreign trials; otherwise, up to 75% substitution can be considered.
Fruiting Vegetables (Solonaceae) Peppers Tomatoes Others	6 2 4 2	For protected (e.g. glasshouse) crops, up to 75% of trials can be substituted by foreign trials.
Leafy Vegetables Lettuce (head) Lettuce (fancy, leaf) Others	6 3 3 2	For protected (e.g. glasshouse) crops, up to 75% of trials can be substituted by foreign trials.
Legume Vegetables Beans with pod Peas shelled Peas with pod Other	6 4 2 2 2	

Crop Group and Representative Crops	No of NZ Supervised Crop Residue Trials	Notes and Comments
Root and Tuber Vegetables Carrots Potatoes Other	6 4 4 2	
Stem Vegetables Asparagus Celery Others	6 4 4 2	
Citrus Mandarins Oranges Other	6 4 4 2	
Pome Fruit Apples Pears Other	6 6 4 2	
Stone Fruit Cherries Peaches Other	6 4 4 2	
Bush Fruit Blueberries Others	4 2 2	
Cane Fruit Others	4 See notes	Includes blackberries, boysenberries, loganberries, raspberries, youngberries or hybrids of these, alone or in any combination.
Other Small Fruit Grapes (wine) Grapes (table) Strawberries Others	Not applicable 6 4 4 2	For protected (e.g. glasshouse) crops, up to 75% of trials can be substituted by foreign trials. Trials on wine grapes can be used as supporting data for field table grapes.
Other Fruit Avocados Kiwifruit Passionfruit Persimmons Others	Not applicable 2 6 2 4 2	

Crop Group and Representative Crops	No of NZ Supervised Crop Residue Trials	Notes and Comments
Pulses and Oilseeds Soybeans Others	6 4 4	
Cereal Grain Crops Barley grain crops Wheat grain crops Other small grain crops	6 4 4 4	
Fungi Mushrooms	Not applicable 2	
Herbs Basil Chives Parsley Others	Not applicable 2 2 2 2	For protected (e.g. glasshouse) crops, up to 50% of trials can be substituted by foreign trials.
Misc Crops Hops Maize/Sweetcorn Others	Not applicable 2 2 2	
Cereal Green Feeds Barley Maize Oats Wheat Other	6 4 4 2 4 2	
Fodder Beets Fodder beet Others	4 4 2	Can be replaced by any other fodder (root) brassica of regional significance.
Fodder Brassicas Swedes Others	4 4 4	Can be replaced by any other fodder (leafy) brassica of regional significance.
Grasses Pasture Ryegrass Other	6 4 4 2	
Legume Feed Crops Clovers Lucerne Other	6 4 4 2	
Post-harvest and Premises Treatments Stored grains Other	Not applicable Not applicable 4 2	Up to 75% of trials can be substituted by foreign trials.

APPENDIX 3

DATA ITEMS TO INCLUDE IN A SUPERVISED CROP RESIDUE TRIAL REPORT

1 Product identification

- 1.1 Active ingredient common name
- 1.2 Product trade name
- 1.3 Formulation and active ingredient content
- 1.4 Trial reference number
- 1.5 GLP status
- 1.6 Supervisor

2 Field data

- 2.1 Crop and variety/situation
- 2.2 Trial site and location
- 2.3 Plot size, layout and replication
- 2.4 Application details (dates, growth stages, dilution, area rates, intervals)
- 2.5 Application method and equipment
- 2.6 Other pesticide treatments
- 2.7 Climatic data

3 Sampling details

- 3.1 Sampling dates and growth stages
- 3.2 Field sampling codes
- 3.3 Days after last treatment
- 3.4 Days before/after normal harvest (or normal harvest date)
- 3.5 Number of sample units and their weight per sample
- 3.6 Details of sampling (sample selection, field preparation), packing, storage and transport

4 Laboratory details

- 4.1 Laboratory name
- 4.2 Principle investigator
- 4.3 Date and state of samples received
- 4.4 Storage details (duration and condition)
- 4.5 Crop part analysed
- 4.6 Sample handling, subsampling and preparation
- 4.7 Residue extraction and cleanup
- 4.8 Analytical method summary
- 4.9 Analytical method reference
- 4.10 Components detected
- 4.11 Method recovery
- 4.12 Degradation in storage
- 4.13 Residues in control samples
- 4.14 Result correction factor
- 4.15 Method sensitivity (LoD, LoQ)

5 Results

- 5.1 Lab and field sample codes
- 5.2 Pre-Harvest Intervals
- 5.3 Range of residues found and number of analyses (if multiple analyses)
- 5.4 Mean residue found (uncorrected for recovery or control)
- 5.5 Residues found in control samples

6 Attachments

- 6.1 Chromatograms
- 6.2 Supplementary information on methods of analysis