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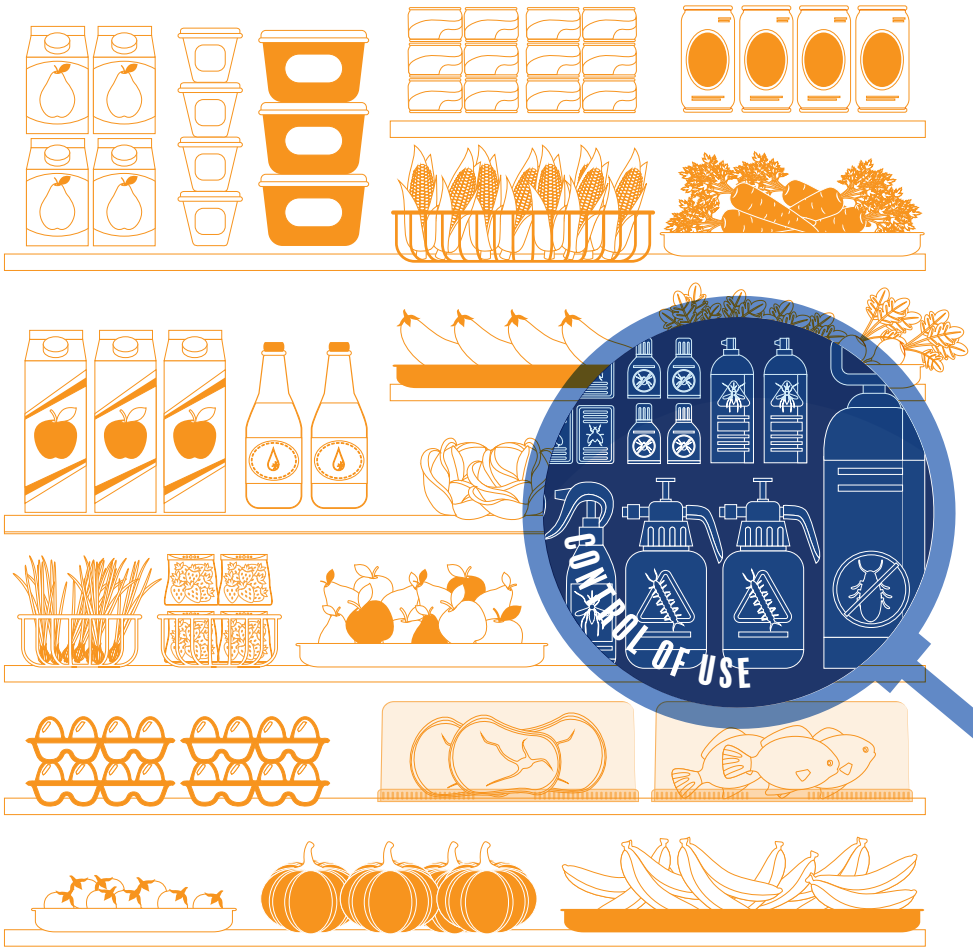

GUIDE TO DEVELOP AND STRENGTHEN NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMMES

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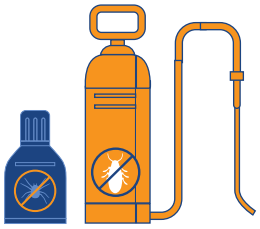

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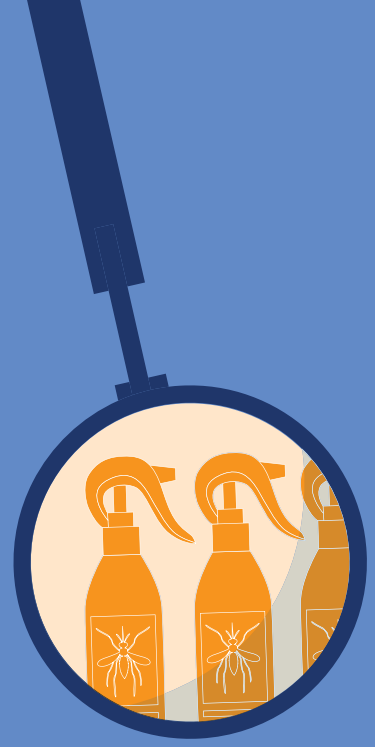

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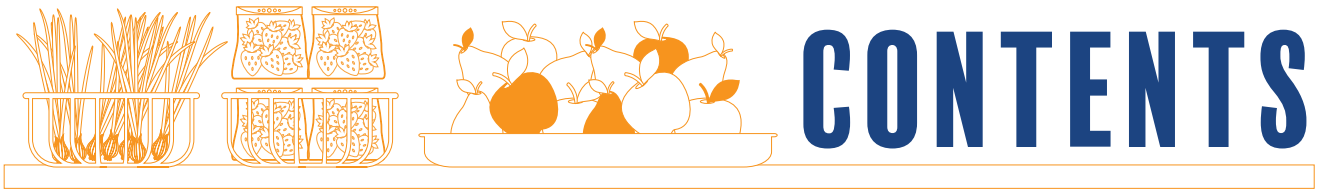
ABSTRACT

Countries in Asia and the Pacific region of the Food and Agriculture Organization of the United Nations (FAO) recognize the need to have a comprehensive framework for pesticide residue management through science-based risk assessment, management and communication. The framework incorporates a range of functions and activities including pesticide registration, Maximum Residue Limit (MRL) setting, approval of a pesticide product label, farmer education, pesticide control-of-use regulation, food traceability, verification of Good Agricultural Practice (GAP), national pesticide residue monitoring programmes, facilitation of trade and market access, traceback investigation and pesticide review. The frameworks tend to be operated as a continuum seeking ongoing improvement in good agricultural practice and enhancements to food safety.

A sound pesticide residue framework does not rely only on residue monitoring but importantly includes at the very least pesticide registration, chemical control-of-use, traceback investigation and a chemical review process. An increasing focus on harmonization of the pesticide risk management framework elements including the setting of MRLs is a key strategy to assist countries in the region. FAO received an official request from all ten countries participating in an FAO project entitled, "Support for Capacity Building for International Food Safety Standard Development and Implementation in Association of Southeast Asian Nations (ASEAN) Countries" to assist the countries in developing the basis for countries to implement effective pesticide residue monitoring systems which are in line with the overall framework of the ASEAN food safety policy.

Noting the broad spectrum of pesticide risk management frameworks present in the ASEAN countries, the ASEAN Health Cluster 4: Ensuring Food Safety (AHC4) committee and FAO worked collaboratively to develop this regional guide, which is based on an in-depth situation analysis of the ASEAN countries in terms of their capacities and knowledge levels. The present guide provides practical solutions and management options for countries at different capacity levels to develop or strengthen effective pesticide residue monitoring systems.

Keywords:
Risk analysis, pesticide residues, food safety, maximum residue limit, monitoring, regulation, compliance, ASEAN Health Cluster 4, FAO



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ACKNOWLEDGEMENTS

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ABBREVIATION AND ACRONYMS

ADI	acceptable daily intake
ARfD	acute reference dose
ASEAN	Association of Southeast Asian Nations
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GEMS/FOOD	Global Environment Monitoring System/Food Contamination Monitoring and Assessment Programme
IFIS	International Food Information Service
ILAC	International Laboratory Accreditation Cooperation
IMS	Information Management System
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
NPRMP	National Pesticide Residue Monitoring Programme
QA	quality assurance
WHO	World Health Organization
TAT	turn-around-time

1.
INTRODUCTION

1. INTRODUCTION

1.1 BACKGROUND

Pesticides are used worldwide in agriculture to control or prevent pests, diseases, weeds and other plant pathogens. In almost all countries, pesticide use is regulated and all pesticides must be registered by a national competent authority prior to launching in the market. During the process of the registration, most competent authorities establish the maximum residue limits (MRLs) as highest residue levels legally allowed on a specific commodity when pesticides are applied correctly in accordance with good agricultural practice (GAP).

The establishment of a national pesticide residue monitoring programme (NPRMP) is essential for a country to be able to confirm / verify that pesticides are used in accordance with GAP. While it may sound ideal to have a perfect pesticide residue monitoring system, it is not realistic to monitor each and every user of pesticide at the farm level as well as check the residue level of every single agricultural commodity. Many low- and middle-income countries would face a tremendous difficulty in meeting the requirements for resources. Therefore, it is recommended to develop a risk-based residue monitoring programme to have a specific focus in terms of the desired outcome of the residue monitoring system, in conjunction with implementation of GAP at the farm level so that the informed management decisions can be made in the limited-resource situations, while not posing unacceptable risks to consumers. Additionally, Codex Alimentarius Commission established a guideline entitled "Recommended methods of sampling for the determination of Pesticide Residues for Compliance with MRLs" (CXG 33-1999) as a reference for countries to enable the collection of a representative samples from a lot, for analysis to determine compliance with MRLs for pesticides.

However, a NPRMP is not the only approach for managing pesticide residues. Figure 1 explains the pesticide risk management framework adopted in many countries in the world, as a continuum of functions focused on GAP, food safety and market access. It can be seen that a sound pesticide residue management framework does not rely only on residue monitoring but importantly includes at the very least pesticide registration, chemical control-of-use, traceback investigation and a chemical review process. An increasing focus on harmonization of the pesticide risk management framework elements including the setting of MRLs is a key strategy to assist countries in the region.

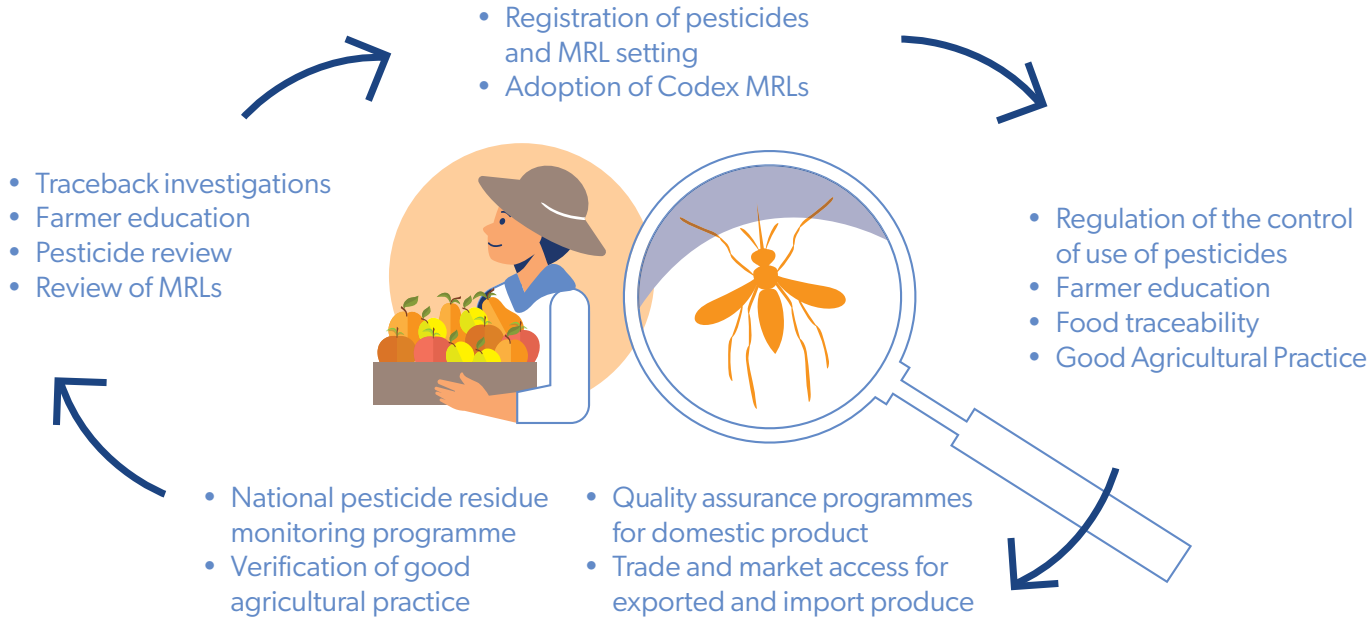


FIGURE 1. PESTICIDE RISK MANAGEMENT FRAMEWORK

FAO has received an official request from Thailand, on behalf of ASEAN Health Cluster 4: Ensuring Food Safety (AHC4), through a FAO project entitled, "Support for capacity building for international food safety and implementation in Association of Southeast Asian Nations (ASEAN) countries" to assist ASEAN countries in developing the basis for countries to implement effective NPRMPs which are in line with the overall framework of the ASEAN food safety policy.

Noting the broad spectrum of pesticide risk management frameworks present in ASEAN countries, the ASEAN Health Cluster 4: Ensuring Food Safety (AHC4) and FAO worked collaboratively to develop this guide, which is based on an in-depth situation analysis of the ASEAN countries in terms of their capacities and knowledge levels. The present guide provides practical solutions and management options for countries, not only with in the ASEAN region but also counties apart from this region, at different capacity levels to develop or improve effective pesticide residue monitoring systems.

1.2 OBJECTIVES

The principal purpose of this guide is to describe the essential elements and processes for developing and implementing effective compliance national pesticide residue monitoring programmes.
The guide has been developed as an aide for those aiming to develop or strengthen and implement a compliance programme and references the elements and functions which are critical to undertake this work.

The present guide considers that the key objective to develop or strengthen a national compliance pesticide residue monitoring programme are to:

- facilitate the design of an effective yet feasible compliance programme which identifies, verifies and promotes GAP;
- establishes a simple but effective framework for pesticide monitoring and implementation programme; and
- increase consumer confidence in food safety and public health aspects.

1.3 SCOPE

This guide encompasses several elements of the pesticide risk management framework which are essential to support a compliance NPRMP. At the very least, these should include a database of adopted MRLs, a system for pesticide registration, regulating the control-of-use of pesticides, food traceability, traceback investigation and farmer education.
For the purposes of this Guide, proposed compliance NPRMPs will involve the collection and residue analysis of plant products including grains, fruit and vegetables.

1.4 TARGET AUDIENCE

This guide has been prepared primarily for government authorities responsible for pesticide risk management frameworks and the establishment of compliance NPRMPs. They shall utilize the guide with the goal of implementing such a programme. Meanwhile, public sector officials serve as the main target audience of the guide. The information included in this guide may also be useful for other relevant stakeholders such as pesticide manufacturers, primary producers, food business operators, food importers / exporters and academia / researchers.

1.5 HOW TO USE THE GUIDE

Following the introductory section 1, section 2 provides a comprehensive description of the principal types of NPRMPs undertaken around the globe. Section 3 details general programme planning such as government approvals, resource allocations, consultation and risk assessment considerations which are common to all types of NPRMP. The remainder of the Guide with the main components is focused on compliance NPRMPs.

In order to assist those using the guide, some key elements of the guide provide both desirable and minimum requirements. The purpose of such tiered requirements is to assist those countries which self-assessed their capacity to undertake a NPRMP. However, those deemed as intermediate would be able to benchmark against the guide.

1.6 EXPECTED OUTCOMES

By reading and utilizing the guide, it is expected that the target audience will be able to:

- obtain a set of tools and knowledge to develop / strengthen and implement a residue NPRMP with a clear understanding of the minimum requirements;
- compare / verify existing NPRMPs against the guide with a view to enhancements to respective compliance programmes;
- determine where information sharing and exchange can be undertaken, with a better understanding of the desirable and minimum requirements for a NPRMP;
- execute continuous improvement of the pesticide risk management framework which is in line with the internationally or regionally harmonized guidelines and policies; and
- make, where appropriate, necessary adjustments to meet challenges in regard to free trade agreements and WTO / SPS obligations.

1.7 RELATED CODEX DOCUMENTS

Codex Alimentarius established the following set of standards and guidelines which can be references for the development of the national pesticide residue monitoring programme:

- Classification of Foods and Animal Feeds (CXA 4-1989)
- Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs (CXG 33-1999)
- Guidelines on Good Laboratory Practice in Pesticide Residue Analysis (CXG 40-1993)
- Portion of Commodities to which Maximum Residues Limits Apply and which is Analyzed (CXG 41-1993)
- Guidelines on the Use of Mass Spectrometry (MS) for Identification, Confirmation and Quantitative Determination of Residues (CXG 56-2005)
- Guidelines on Estimation of Uncertainty of Results (CXG 59-2006)
- Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups (CXG 84-2012)
- Guidelines on Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues in Food and Feed (CXG 90-2017)
- General Guidelines on Sampling (CXG 50-2004).

2. TYPES OF NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMMES

2. TYPES OF NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMMES

This section details the main types of NPRMP undertaken around the globe. These include compliance, quality assurance, export food monitoring, imported food inspection, dietary intake surveys and emergency incident responses. The primary objective of programme planning by respective countries for MRL compliance and food safety will be to determine which NPRMP is undertaken. Importantly, country-specific situations will influence the type of NPRMP to be developed and, as such, the NPRMP implemented may draw on various elements of the programmes described below.

2.1 COMPLIANCE PROGRAMMES

Compliance programmes are generally designed to verify GAP as an element of a pesticide risk management framework. Compliance programmes will have a regulatory element to, where required, provide enforcement capacity in certain cases where residue detected exceed the applicable MRL. In other cases where enforcement may not be necessary, education programmes may be implemented. Compliance programmes are generally supported by traceback investigation capability to determine the cause of the MRL exceedance. Risk-based approaches to compliance and enforcement will determine the focus of respective compliance NPRMPs.

In theory, the objective is for all type of commodities produced within a country to be sampled and analysed over a period of time. Each year, government authorities responsible for NPRMPs will identify commodities to be tested in a particular year. The number of samples to be collected and the analytical screen will be dependent on the specific commodities to be included in a particular year. Consideration may need to be given to data requirements to provide a statistical representation of pesticide residues present in the food supply.

Compliance programmes are normally undertaken with random sampling to a specified total sample number for each commodity. Given the number of farmers involved in the production of particular commodities, it would not be logistically and financially feasible to sample every farmer's produce. The random nature of the programme promotes GAP as a particular farmer will not be aware of impending sample collection until it occurs.

Where a residue-related issue has been identified, the compliance programme may incorporate a targeted sampling approach to either improve the understanding of the presence of high residue detection or to determine, on a regional basis, the source of the high residues. This approach may assist governments to identify residue problems including failure to comply with good agricultural practices, and to take necessary follow-up action to prevent or solve the problems.

2.2 QUALITY ASSURANCE

Quality assurance (QA) NPRMPs provide for integrated food assurance which covers all elements of crop production including pesticide use and residue management. In general, a farmer may attain GAP accreditation / certification following an audit / verification process. The audit will include provision of annual residue testing results for commodities produced.

A QA NPRMP would be developed to allow all farmers access to sampling and analytical services to obtain a specific residue testing report. The primary objective of a QA programme is to allow producers meeting QA / food safety requirements to trade freely within the domestic market. Generally, QA NPRMPs are managed by agricultural industry organisations and funded by farmers and fruit / vegetable wholesalers and marketers. In some cases, the QA programme may also support to export certification. A QA programme will not necessarily include a regulatory element for enforcement against MRL exceedances.

2.3 EXPORT COMMODITY / FOOD MONITORING

Most exported commodity / food monitoring will be conducted via full consignment testing, random consignment testing or bilateral monitoring plan in agreement with a trading partner to ensure compliance with the importing country's public health and safety requirements.

Consignment testing of exported commodity / food involves sampling at the point of origin immediately prior to export. At the commencement of trade, an exporting country may arrange for the sampling of all consignments. Should the residue testing results indicate high degrees of compliance with the relevant overseas MRLs, an exporting country may reduce the sampling rate to random status.
For all export monitoring, and consistent with the Codex Guidelines on Sampling, a representative sample must be collected from the consignment.

An export NPRMP may support export certification via a bi-laterally agreed monitoring plan with an overseas market. To achieve export certification for certain markets, an importing country may specify requirements for a NPRMP. The importing country may specify an export consignment testing programme for high-risk commodities and markets. However, in many cases, the importing country may request a NPRMP with specific sample numbers and analytical screens which for example ultimately demonstrates a 95 percent probability of a less than 1 percent MRL exceedance rate.

In this scenario, the importing country may expect 300 – 1000 random samples of a commodity to be collected throughout a 12-month period dependent on a number of risk factors. The exporting country would be required to notify the importing country of any MRL exceedances and provide an annual report in due course.

2.4 IMPORT FOOD INSPECTION

The key objective of an imported food inspection scheme (IFIS) is to verify that imported food products are compliant with an importing country's food standards and meets associated requirements for public health and safety.

Most IFISs take a risk-based approach to regulating imported food and involve the cooperation of an economies Agriculture and Health government authorities to monitor food entering the country at the point of entry. Given an IFIS requires sampling and analysis of products exported by an exporting country, it is customary for the programme to be supported by government legislation / regulation or written authority.

An IFIS operates in accordance with an agreed Monitoring Plan which stipulates the baseline rate of testing (e.g. 5 percent rate of testing for all consignments), the pesticide screen and the relevant MRL standards. The Monitoring Plan should be reviewed annually. The Monitoring Plan may include determinations on low, medium and high-risk consignments based on the commodity and exporting country.

The Monitoring Plan will also stipulate a protocol for non-compliant residue testing results. In non-compliance cases, international food safety incidents, post border domestic food safety incidents and high-risk consignments, an importing country may increase the inspection rates from the baseline of 5 percent to a higher rate of about 30 percent. A further non-compliance may result in a 100 percent inspection rate or market closure.

As an alternative, should an economy not have the capacity nor capability to conduct an IFIS, a country recognition agreements or food import compliance agreements may be established with exporting countries. These agreements involve:

- the exporting country documenting its food safety management systems including sampling and residue analysis of consignments to be exported. The exporting country would seek a mutual recognition agreement (MRA) which would be subjected to review periodically; or
- importers within the importing country demonstrating food safety systems through import compliance agreements. The importers would be regularly audited by the importing economy's Agriculture and Health departments.

2.5 DIETARY INTAKE SURVEYS

For the purposes of this guide, the likelihood of a country conducting a dietary intake survey in the first instance is relatively low. The key objective of a dietary intake survey is to monitor the food supply to ensure that existing food regulatory measures provide adequate protection of consumer health and safety. These surveys should be a comprehensive assessment of consumers' dietary exposure (intake) to pesticide residues, contaminants and other substances in food.

To achieve the most accurate dietary exposure estimates, a total diet study should be conducted where the food list should cover at least 90 percent of food intake and foods examined are representative of a typical diet in a particular country, with foods prepared as they are typically consumed prior to analysis. As a consequence, both raw and cooked foods are examined.

Dietary exposure for various age groups representing the general population are estimated by multiplying food chemical concentrations analysed in survey by food consumption amounts recorded in national food consumption survey, or if not available, in the most recent GEMS / Food. These estimated dietary exposures are compared to health-based guidance values (ADI or ARfD) to help characterise the risks for consumers. For the purposes of this guide, the likelihood of a country conducting a dietary intake survey in the first instance is relatively low.

2.6 EMERGENCY INCIDENT RESPONSES

For the purposes of this guide, the likelihood of a country conducting a emergency incident response programme in the first instance is relatively low. Responses to emergency residue incidents are highly variable. Reasons to implement an emergency incident response include:

- an identified or perceived domestic food safety issues;
- an identified food safety issue arising from imported food testing;.
- a report from a trading partner identifying a food safety issue arising from a consignment exported from a particular country.

For the purposes of this guide, the likelihood of a country conducting a emergency incident response programme in the first instance is relatively low.

3. PREREQUISITE PROGRAMME PLANNING

3. PREREQUISITE PROGRAMMME PLANNING

This section provides an overview of requirements for a NPRMP which are consistent across all types of programmes described in the section 2. The common requirements include government approvals, resourcing / funding considerations and assessment of programme and technical parameters.

3.1 GOVERNMENT ENDORSEMENT

Management commitment is the key starting point for development of a NPRMP[4]. Given trade / market access and food safety / public health sensitivities, all NPRMPs require the consideration and endorsement of the relevant government agencies.
It is expected that agriculture, health, food safety and trade departments or ministries will have a vested interest in NPRMPs. Government approval / endorsement would be preceded by interagency consultation between some or all of these departments.

Government endorsements / approvals should take into account:

- rationale for a residue monitoring programme including expected outcomes and benefit;
- the type of programme to be implemented;
- funding / resource requirements;
- responsible departments; and
- monitoring plan.

3.2 RESOURCES AND FUNDING

The development of a NPRMP and associated monitoring plan requires consideration of resource / funding arrangements. The type of NPRMP will determine whether resources / funding are derived from government, industry (farmers, packers), importers and / or exporters.

Governments may consider funding NPRMPs to seek improvement in pesticide risk management and in turn enhance trade and market access. Given NPRMPs focus on sound agricultural production and support food safety / public health initiatives, coordination between relevant government ministries / departments is essential. Suggested funding arrangements for each NPRMP are as follows.

Compliance
Compliance programmes generally involve random sampling on farm, packhouses and markets to support a country's pesticide regulatory scheme. These programmes require government endorsement / support and as such are likely to be government funded. However, programmes may also be funded through levies on industry or farmers. The Australian National Residue Survey is an example of a industry levy funded set of NPRMPs. The third option could be joint government – industry levy funded NPRMPs. The selection of an option will be largely dependent on government priorities in regard to its pesticide risk management framework.

[4] Endorsement mechanisms for a NPRMP will vary between economies with some taking a clear directive from Government while others conducting consultations between lead agencies (Agriculture, Health and Environment) before requesting in-principle government support / approval.

Quality assurance
QA programmes are designed to obtain certification to sell produce into the market. All farmers seeking to sell produce would be expected to participate by submitting relevant commodity samples for pesticide residue analysis. Accordingly, it is most likely that a QA programme would be organized by an industry body or a certification body supporting an industry body. In this case, programme funding would be derived from either an industry levy or a fee for service arrangement or both.

Export Programme
Export NPRMPs are designed to sample and analyse commodities at point of export. Although likely to be a government-based NPRMP, the funding source will again vary dependent on country's priorities in regard to maintenance of its trade and market access. Therefore, funding could be sourced from government, a relevant industry body or exporter / marketer or a combination of these sources.

Imported Food Inspection
Imported food inspection schemes are designed to sample and analyse produce at the port of entry. The objective is to ensure imported food meets importing country food standards. Programme funding could be sourced from local importers or government or both.

Dietary intake surveys
The expectation would be that respective governments organize and fund total diet / dietary intake surveys.

Emergency incident responses
An emergency incident response to a pesticide residue / food safety concern is likely be initiated and organized by a government along with provision of appropriate funding.

3.3 RATIONALE FOR A NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMME

3.3.1 Domestic pesticide use, public health and consumer concerns

Farmers in a particular country will have access to a range of pesticides for crop protection purposes based on decisions made by the government pesticide regulator or via regional arrangements. The range of available pesticides will be influenced by the variety of fruits and vegetables produced in a country. There are several variables including availability of pesticides, farmer's skills / knowledge, climatic conditions (rainfall, temperature, global zone etc.) and resultant plant pest pressures / pesticide use patterns which are likely to vary from country to country.

Consumer concerns should align with science-based regulatory decisions on pesticides and public health. However, in some cases, consumer concerns may arise where media focus has raised issues which are not necessarily science-based, e.g. glyphosate. The development of a NPRMP may need to consider these variables to assess pesticide residue risk potentials and public health risk to determine whether a NPRMP is required in the first instance. Other matters raised in this section will determine the objective, style and structure of a NPRMP.

3.3.2 Trade and market sensitivities

An exporting country will have trade / market access arrangements with a range of overseas markets. Each market is likely to have its own specific requirements and trading standards including MRLs. The exceedance of residue in exported fresh products may cause trade problems. With multiple overseas markets, an exporting country can either establish market access arrangements for each importing country or undertake a risk assessment against the strictest marketing requirements. For example, the country with the lowest MRLs and highest rate of imported food testing would be deemed to have the strictest marketing requirements. Decision making on an appropriate NPRMP will be dependent upon which approach is adopted.

3.3.3 Domestic concerns regarding food safety of imported produce

Importing countries are expected to communicate respective specific market requirements and trading standards to all prospective trading partners. Some exporting countries may conduct residue testing of respective export consignments while others may not. Some overseas countries may use pesticides which are not registered in the importing country. To address domestic public health / food safety concerns, an importing country should consider the establishment of an imported food testing scheme. Further details on Imported Food Testing Schemes can be found is Section 2.

3.3.4 Residue information from emergency incidence

Emergency incidents involving pesticide residues in food may occur for a variety of reasons which include ongoing high detections of unexpected residues in food during normal national monitoring, an identified food safety incident where residues are well above the MRL, the possibility of a specific pesticide residue detection such as glyphosate or a banned substance, and new pesticides made available to farmers for which previous monitoring has not occurred.

Incidents can be identified from several sources such as a regular residue monitoring programme, reports from imported food testing, and reports from trading partners.

Following an identified and confirmed pesticide residue incident, a specific emergency NPRMP should developed as soon as practicable.

The emergency NPRMP may be developed as an additional project to an existing NPRMP for efficiency and effectiveness by using existing operational systems such as sample collection, sample freight and laboratory capacity. If the emergency relates to a new pesticide, immediate steps should be taken to ensure laboratory capacity, capability and proficiency

3.4 ASSESSMENT OF NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMME TECHNICAL PARAMETERS

The assessment of technical parameters such as MRLs, food standards, pesticides to be included in the analytical screen for residue testing and the commodities to be selected for sampling require specific expertise and knowledge.

The lead departments (which may include Agriculture, Health and Environment) within a country would be expected to engage with the relevant agricultural industries, universities, agricultural research organisations to obtain expertise covering residue chemistry, pesticide physico-chemical properties, plant physiology and international food standards.

3.4.1 Difference in MRLs

Countries with a pesticide registration and management authority may, during assessment of pesticide dossier, establish MRLs. In other cases, Codex MRLs or regional standards such as harmonized ASEAN MRLs may be adopted. In a few cases, countries may adopt trading partner's MRLs. For example, some countries trading with the European Union will adopt EU MRLs to ensure agricultural products destined for the EU meet specific food standards. A major concern for all exporting countries is missing / differing MRLs applying in a trading partner's food standards.

During the development of a NPRMP, a formal decision is required on the MRLs to reference and compare to pesticide residue monitoring results. Below items can be used as a reference guide:

- compliance NPRMPs are expected to reference national MRLs which may have been established by the respective country, Codex MRLs or regional MRLs;
- export NPRMPs are expected to reference the MRLs applying in the export market; and
- import NPRMPs are expected to reference national MRLs unless a bilateral arrangement is established with the importing country using an import MRL.

3.4.2 Pesticides of concern

There are approximately 500 different pesticide active ingredients formulated into thousands of herbicide, insecticide, fungicide and other pesticide products, which are commonly used in agriculture. It is impractical from financial and analytical capability perspectives to consider a NPRMP which includes multi-residue analytical screens for all active ingredients.

In most cases, the pesticide use patterns on a particular commodity indicate that a subset of pesticides are registered or authorized for use on that crop. Therefore, a NPRMP could consider a multi-residue analytical screen covering only pesticides registered for a specific crop, for example brassicas. It may not be necessary to include pesticides registered for use on apples in the analytical screen . However, this approach may overlook situations where unregistered pesticides are used on a specific commodity. This is normally viewed as an 'off-label' use.

The pesticide's physico-chemical properties, environmental fate and degradation in the crop are also important factors in determining the selection of pesticides to be included the NPRMP's multi-residue analytical screen.

Pesticides of concern is also dependent on the type of NPRMP. For export-focused NPRMPs, some importing countries may specify, as a condition of market access, an analytical screen covering pesticides which may be registered for use on a commodity and a range of other pesticides for which trade sensitivities apply. The trade sensitive pesticides may include organochlorine pesticides (no longer registered around the globe), glyphosate (non-science-based consumer concerns) and organophosphate / synthetic pyrethroids / carbamates pesticides for which heightened awareness of hazards to public health apply.

Decisions on a multi-residue analytical screen should be made in consultation with respective agricultural industries, recognised pesticide residue experts and relevant government authorities (Health, Agriculture, Food Safety, Trade and Consumer Affairs). Other factors may be considered which include cultural sensitivities and country-specific agricultural issues.

3.4.3 Commodities of concern

The presence of residues in a food commodity should be weighted by a dietary exposure assessment which considers the amount of the commodity consumed and the health-based guidance values (ADI and ARfD) applying to the pesticide. High production volume staple foods such as rice, cabbage and mango form a significant proportion of the diet of the total population. Commodity production figures may be available (food consumption amounts may be recorded in a national food consumption survey, or if not available, in the most recent GEMS / Food) and provide a practical method of estimating consumption and thus potential human exposure to pesticide residues.

Some crops require relatively higher use of pesticides for plant protection and wider selection of insecticides, fungicides and herbicides. Pest pressures / biology, plant physiology, types of pesticides and climatic conditions may influence the volume of pesticides used.

The edible portion of fruit and vegetables will also influence the pesticide residue risk potential. The pesticide residue risk potential in situations where pesticides are applied directly to the edible portion of leafy vegetables and apple is likely to be higher than for banana and mango which are deemed to have inedible peel.

When selecting commodities to be included in a monitoring plan, these matters should be considered. However, noting the above, the selection of commodities to be sampled and analysed in your NPRMP is ultimately dependent on the type of programme to be undertaken.

While a compliance programme should include all commodities produced within a particular country, an export-focused programme will only need to cover those being exported. Similarly, an imported food testing scheme need only cover those commodities being imported into the country. As is the case with developing an analytical screen covering 500 active ingredients, the cost of a NPRMP covering all commodities produced in a country will be prohibitively high.

Moreover, the number of samples to be collected for each commodity requires close consideration and awareness of the type of programme to be undertaken particularly if statistical validity is a requirement. The capacity to make decisions on priority commodities will be restricted by the level of resourcing available for a NPRMP. The methodology / measures utilized by a country to make that decision may vary but still be based on food safety and verification of GAP.

Starting Point: prerequisite national pesticide residue monitoring programme planning

A proposal for a NPRMP must obtain government endorsement, relevant department authority approval and consider the level of funding / resources available. The issues raised in the pesticides of concern and commodities of concern are interlinked and thus should be cross-referenced and considered concurrently when developing a NPRMP. A country with limited funding and capability would consider a pilot programme for one group of commodities with the same plant classification and a pesticide analytical screen requiring a single multi-residue analytical method.

4. DEVELOPING AND IMPROVING A COMPLIANCE NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMME

4. DEVELOPING AND IMPROVING A COMPLIANCE NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMME

This section provides detailed guidance on the development of a Compliance NPRMP drawing on information provided in Section 3. Information on the development and implementation of other NPRMPs for quality assurance, exports and imports described in Section 2 may be drafted at a later stage. The process of the development of a compliance residue monitoring programme is provided as a flowchart at Appendix 2.

Section 5 of the Guide focuses on implementation of a Compliance NPRMP with detailed guidance on of the programme's operational requirements. For the purposes of this Guide, the development of a Compliance NPRMP relates to planning and scoping activities leading to the establishment of a Monitoring Plan, Sampling Plan, Logistics Plan and Information Management Plan. As countries have different capacity and capability, this guide also provides the fundamental requirements for each element as Appendix 3.

4.1 PROGRAMME OBJECTIVES

Verification of good agricultural practice should be the primary objective of a Compliance NPRMP. To be able to verify good agricultural practice, a compliance programme requires a set of MRLs with which to compare residue testing results. In many cases, countries defer to Codex MRLs or regional MRLs. Countries with a pesticide risk management framework including pesticide registration will set MRLs for pesticides in agricultural produce, particularly produce entering the food chain. These MRLs are set at levels that are not likely to be exceeded if the pesticides are used in accordance with approved label instructions, that is, good agricultural practice.

At the time the MRLs are set, the pesticide regulator will undertake a dietary exposure assessment to ensure that residue levels do not pose an undue risk to human health. Therefore, while an MRL is not specifically a food safety standard, the verification of GAP, which confirms residues in food are below the MRL, provides confidence to the community that food is safe to consume, and public health considerations are adequately managed. Thus, consumer confidence can be seen as a secondary objective.

A government-oversighted Compliance NPRMPs is expected to have a regulatory element to, where required, provide enforcement / education capacity in certain cases where residue detected exceed the applicable MRL. In the absence of legislation or regulation, government authorisation may be sufficient to adequately support the programme. Compliance NPRMPs are generally supported by traceback investigation capability to determine the cause and the source of the MRL exceedance.

In government discussions on resources and funding, a supporting argument for a Compliance NPRMP is to seek improvement of a respective country's pesticide risk management framework and in turn enhance good agricultural practice, trade / market access and consumer confidence in regard to pesticide use and food safety.

4.2 PROGRAMME APPROVAL

A compliance NPRMP will require government interagency coordination noting that at least two government authorities (agriculture and health) have responsibility for agricultural production, pesticide risk management, good agricultural practice, food safety and public health.

The initial compliance NPRMP proposal should identify purpose, objectives, outcomes, lead government agencies, resource / funding and potential collaborations which could include other agencies, regional economies and trading partners. Dependent on respective government roles and responsibilities, a lead government authority will be identified conduct coordination and consultation activities. The lead authority should seek agreement on:

- rationale for a residue monitoring programme including expected outcomes and benefits;
- the type of programme to be implemented;
- funding / resource requirements;
- responsible departments; and
- monitoring plan.

Once programme consultation / coordination is completed, the lead agency would present a proposed Compliance NPRMP to government for approval.

4.3 PROGRAMME CONSULTATION

Consultation and ordination between all vested interests in the Compliance NPRMP is essential. Consultation should occur at four levels as follows:

- relevant government agencies (e.g. Departments of Health, Agriculture, Environment, and Consumer Affairs) - inter-departmental consultation;
- government agencies with relevant agricultural industry bodies including marketers - government – industry consultation;
- regional coordination groups; and
- research institutions and analytical laboratories.

Inter-departmental consultation is required to ensure the Compliance NPRMP monitoring plan accurately reflect the objectives and desired outcomes of the programme. Topics for consultation would include programme scope, resources / funding, pesticides and commodities to be considered, roles and responsibilities, sampling plans, programme logistics and information management.

Government – industry consultation should continue throughout the development and implementation of the Compliance NPRMP. Stakeholders including, but not limit to, representatives of producers/farmers, market, trade, pesticide industries should have the opportunity to provide input to the development of the programme and the ability to comment on issues arising during implementation. Consistent with continuous improvement principles, all government and industry stakeholders would have the opportunity to comment on the compliance NPRMP and its performance.

4.4 SCOPE OF MULTI-RESIDUE ANALYTICAL SCREEN

The Guide assumes that the selected analytical laboratory has demonstrated requisite capability and capacity. This includes accreditation of analytical methods to be utilized and demonstrated proficiency using the accredited method.

A multi-residue analytical screen is developed through risk profiles of relevant pesticide-commodity combinations. The risk profiling considers:

- which pesticides are registered / authorised to be used on a particular commodity;
- likelihood of residues occurring in the product (potential for misuse; persistence in the crop, extent of use; use patterns);
- results of previous monitoring for the pesticide–commodity combination;
- availability of suitable sampling and analytical methods including limits of detection / quantification;
- perceptions of a pesticide–commodity combination as a possible public health hazard;
- relevant MRLs / food standards applying to the pesticide-commodity combination; and
- market access requirements of trading partners.

Where a limited programme budget applies, a subset of pesticides to be included in the NPRMP multi-residue screen may need to be established.

The first step is to establish a multi-residue screen based on the above risk profile. A quotation for this multi-residue screen should be obtained from the preferred analytical laboratories. If the quotation exceeds the programme budget for a defined number of samples, prioritisation of pesticides in the multi-residue screen is required. The cost of analysis will differ significantly for certain pesticides. The quotation must outline the costs for each pesticide or group of pesticides in the original multi-residue screen. For example, the analytical cost of analysis of, for example, the herbicides glyphosate and paraquat is significantly higher than for the analysis of certain organophosphate insecticides such as malathion and diazinon.

Keeping in mind the analytical costs, prioritisation can be undertaken by scoring each pesticide against the seven above elements of the risk profile. Weighting for each element would normally be dependent upon public health and consumer concerns along with a focus on those pesticides registered for use on a specific crop. Additional information is provided in Section 3.4.2: Pesticides of Concern.

4.5 AGRICULTURAL COMMODITIES

The selection of commodities to be included in the NPRMP needs to consider whether the produce will be sampled directly off farm, from a fruit / vegetable pack-house, markets or a port of departure / arrival.
This will help determine whether the sampled commodity will be raw produce or processed produce which may have been treated with post-harvest / storage pesticides and / or biocides. More detailed information is provided in Section 3.4.3: Commodities of Concern.

4.6 DEVELOP A PROGRAMME BUDGET

During the programme planning stage, a programme budget must be considered to take into account analytical costs, sampling costs, sampling equipment and freight costs and staff resources.

- *Analytical costs*: per sample to be determined. The selected analytical laboratory will provide a quote based on total number of samples and multi-residue analytical screen
- *Sampling costs*: sampling costs cover staff time and travel to obtain defined number of samples.
- *Sampling equipment*: inner sample bags, security satchel bags, ice packs, boxes, gloves and tape need to be costs.
- *Freight Costs*: a reliable national freight company should be contracted to transport samples safely from point of collection to the analytical laboratory within strict timeframes to ensure sample integrity is maintained.
- *Staff Resources*: 'time and materials' costing is required.

During the stakeholder consultation phase, other cost factors may be presented for consideration. It is essential that the proposed Compliance NPRMP sample numbers are a balance between available funds / resources and a reasonable representation of the commodity to be sampled at a national level. Once sound costings have been established, a programme budget can be finalised and the figures included in the Monitoring Plan, Sampling Plan and programme approval documents.

4.7 INFORMATION MANAGEMENT SYSTEM (IMS)

Residue monitoring information derived from the Compliance NPRMP must be entered and maintained in an electronic format available to the responsible agency, sample collector, analytical laboratory and any other official with an official role in the programme.

Web-based IMS is preferable to allow NPRMP managers, sample collectors, analysts and regulators to enter data. Accessible electronic database is also acceptable. The IMS allows storage of all relevant data and should contain a database of MRLs (domestic and relevant overseas). The IMS should allow data interrogation and reporting.

Alternatively, a paper-based system coupled with excel spreadsheets could be adopted. In this case, protocols are required to ensure that key officials involved in the programme have access to the residue monitoring information. An information management system developed for a Compliance NPRMP should include the following data fields:

- unique sample number
- commodity type e.g. apple
- sub product name e.g. granny smith
- nature of the sample, e.g. whole, cut peeled etc.
- name of commodity owner: farmer / pack-house
- contact details of commodity owner (physical address, phone etc.)
- sample collection date
- type of sample (refer Codex Guidelines on Sampling)
- location of sample collection e.g. farm, pack-house, market
- details of farm, pack-house, market
- sample analysis date
- analytical screen e.g. multi-residue screen
- pesticide residues detected plus result
- relevant MRL.

Starting Point: Information Management System

An electronic database such as an excel spreadsheet supported by a paper-based forms for sampling, freight and laboratory analysis is essential. A paper sample form is required to accompany the sample from point of collection to arrival at the analytical laboratory.

Coordination between the sample collector, analytical laboratory and the designated responsible department / lead agency is essential. The information technology solution must facilitate coordination and information sharing between the programme managers. The NPRMP's information management system should have a reporting capability. An excel spreadsheet should be sufficient to generate a range of reports including information to farmers and to conduct traceback investigations.

4.8 ANALYTICAL LABORATORY

This section focuses to the selection and involvement of the analytical laboratory in the NPRMP. The Guide does not include the requirements related to the method of analysis for pesticide residue. While sample integrity, traceability, supporting regulation and resourcing are some of the important elements of a robust NPRMP, the selection of the most suitably qualified analytical laboratory is critical to ensure a sound science -based approach which is defensible to the consumer and domestic / export markets.

The contracted analytical laboratory needs to be an integral part of the NPRMP to ensure sample integrity is maintained, chain of custody is upheld and the commercial-in-confidence status of sample information / residue results is assured. The selection of a preferred analytical laboratory will take into account availability of a government-managed central laboratory, ASEAN regional laboratory, or another laboratory with an accredited analytical method, demonstrated proficiency and preferred fee for service.

4.8.1 Accreditation of the laboratory and analytical methods

Laboratory accreditation (or international equivalent) is generally required by any analytical laboratory providing pesticides analytical services to government agencies undertaking a NPRMP. It is recommended that laboratory conducting analysis should be accredited and comply with ISO/IEC 17025. The analytical method includes sample preparation (pesticide residue extraction is dependent upon the type of pesticide and the commodity matrix and further chemical reactions including acid or alkaline hydrolysis) followed by application to the analytical instrumentation which also varies dependent upon the type of pesticide.
Laboratories are accredited for an identified range of tests and types of tests. The lead agency should only accept / endorse laboratory reports which contain residue testing data derived from accredited analytical testing.

Government agencies may recognise accreditation by bodies that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (often referred to as the ILAC Arrangement).

4.8.2 Analytical proficiency

The analytical laboratory is expected to have approached a proficiency scheme testing provider, as assessed against ISO/IEC 17043, to demonstrate analytical proficiency against the accreditation of the analytical method. For example, the laboratory which has been accredited for a multi-residue screen method to be used for the NPRMP must be able to demonstrate proficiency to international standards for the accredited multi-residue screen.

Analytical method accreditation and proficiency is generally commodity-specific and in some cases commodity group specific. For example, method accreditation for almonds may differ from macadamias given the differing oil content of the latter. Accreditation for canola testing is not comparable to wheat testing for the same reason. However, the analytical method for apples is likely to be comparable to the other pome fruits including pear.

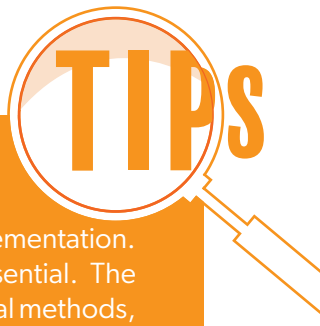
Documentation supporting the accredited multi-residue screen will specify limits of detection, limits of quantification and procedures for confirming false positive and false negative results.

4.8.3 Ongoing proficiency using 'blind samples'

While the analytical laboratory, prior to commencement of a NPRMP, will have demonstrated analytical method accreditation and analytical proficiency for that method, most NPRMPs will include the capacity to enter 'blind samples' into the sample collection system. Blind samples cannot be distinguished from normal samples submitted to the analytical laboratory. The blind sample will contain spiked residues at known concentrations which the laboratory must identify and quantify to specific standards. In doing so the laboratory will have demonstrated ongoing proficiency.

4.8.4 Analytical timeframes (turn-around-time)

Laboratory turn-around-times (TAT) refer to the time elapsed from sample receipt at the laboratory through to the presentation of a residue testing result. TATs are highly dependent on the type of NPRMP and the shelf-life of the commodity. A shorter TAT normally attracts a higher cost of sample analysis. This may need to be taken into consideration during programme planning. Export and import programmes are likely to need a shorter TAT to be able to quickly receive a residue testing result which allows the commodity to enter the exporting country or depart the exporting country.



Starting point: analytical laboratory

The foundation of any successful NPRMP is robust science-based development and implementation. Accordingly, access to appropriate analytical laboratory capacity and capability is essential. The selection of an analytical laboratory should take into consideration: accreditation of analytical methods, demonstrated proficiency using the analytical method and sound internal quality assurance.

4.9 TRACEBACK INVESTIGATION

Traceback investigations are an integral element of a country's pesticide risk management framework. A successful NPRMP will be supported by a country's pesticide risk management framework. The main objective of a compliance NPRMP is to verify good agricultural practice, that is to demonstrate farmers are adhering to the instructions on the pesticide product's label. Should detected pesticide residues exceed the MRL, a traceback investigation is essential to ensure the country's pesticide regulator can determine the cause and source of the MRL exceedance.

4.10 REPORTING

The management of residue testing results is dependent upon the type of NPRMP, the responsible authority and a particular country's commercial-in-confidence / privacy regulations. In most NPRMPs, the details of a farmer, exporter or importer will have been recorded against a commodity sample. This is a key component of traceability and chain of custody.

The relevant government authority, which is bound by privacy / non-disclosure laws, will be in receipt of the residue testing result and may only share the commercial-in-confidence information with other responsible government authorities and the specific importer or exporter. In the case of a compliance NPRMP, the same privacy provisions would apply with the specific farmer / packer being the only non-government recipient.

There are exceptions to the commercial-in-confidence approach to residue data management. Some countries have adopted a 'name and shame' approach whereby MRL exceedances are reported on government authority websites. Apart from reporting of commercial-in-confidence information from compliance NPRMPs, government authorities may produce periodic reports on a monthly or annual basis. Normally, these reports do not identify private persons or companies.

The choice of NPRMP reporting should be explained in detail during the consultation stages of the NPRMP development. Stakeholders from industry (farmers, marketers, exporters) should be made aware of how commercial-in-confidence information is handled.

4.11 DATA ARCHIVE, ANNUAL REPORTING AND COMMUNICATION

A web-based information management system which allows sample collectors, laboratories and regulators to enter residue testing data is highly desirable as it potentially allows programme managers to access, interrogate and generate data reports, trend analysis and forms of communication. An excel spreadsheet on an online shared space or other database is another acceptable option but the system is more reliant on manual data entry and data handling.

4.12 COMPLIANCE NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMME MONITORING PLAN

The Monitoring Plan should detail all agreed elements of the Compliance NPRMP. Compliance NPRMPs generally involve random or targeted sampling to a specified total sample number for each commodity.

Given the number of farmers involved in the production of particular commodities it would not be logistically and financially feasible to sample every farmer's produce. The random nature of the programme promotes good agricultural practice as a particular famer will not be aware of impending sample collection until it occurs.

Similarly, it would not be feasible to include every commodity in a Compliance NPRMP each year. Each year, government authorities responsible for residue monitoring programmes will identify commodities to be tested in a particular year. The number of samples to be collected and the analytical screen will be dependent on the specific commodities to be included in a particular year.

Where a residue-related issue has been identified, the compliance programme may incorporate a targeted sampling approach to either improve the understanding of the presence of high residue detection or to determine on a regional basis the source of the high residues.

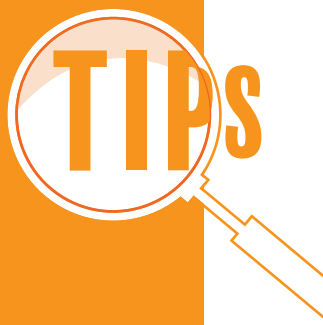
TABLE 1. MONITORING PLAN FOR A COMPLIANCE NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMME - EXAMPLE

PROGRAMME OBJECTIVE:	Verification of good agricultural practice[5]
OFFICIAL APPROVALS:	Departments of Health and Agriculture
FUNDING ARRANGEMENTS:	Government, industry or mix of both
ROLES AND RESPONSIBILITIES:	Department of Agriculture: lead agency for the NPRMP, responsible for sampling at farm levels. Department of Health: responsible for sampling at at the market and modern trade. (Agreement between participating government agencies at national and local level.)
COMMODITIES:	Example: leafy vegetables (attach list of commodities)
PESTICIDE SCREEN:	Accredited multi-residue screen covering insecticides and fungicides (attach list of pesticides)
SCOPE OF PROGRAMME:	Random sampling
ANALYTICAL LABORATORY:	The selection of a preferred laboratory will take into account availability of a government-managed central laboratory, ASEAN regional laboratory, or another laboratory with an accredited analytical method and demonstrated proficiency.
ANALYTICAL SCREEN:	Multi-residue pesticide screens covering selected insecticides, fungicides and herbicides
CONFIRMATORY TESTING:	For unusual results (criteria to be established), confirmatory analytical testing may be required. The archive retention sample should be sent to the laboratory.
SAMPLE PLAN:	Attach the sample plan which should include target sample numbers, sample collection locations, distribution of sampling, mode of collection, sampling equipment, sample handling and transport and operational performance targets.

[5] The summary of assessment of programme considerations (section 3.3) could be provided as additional supporting information.

SAMPLE TRANSPORT:	Formal arrangements for the transfer of samples from the collection point to the analytical laboratory taking into consideration handling of samples and chain of custody.
REPORTING:	To Department of Agriculture and further enter the results in the shared database. Agreed reporting frameworks for participants in the NPRMP including farmers. pack-houses, markets and consumers
TRACEBACK INVESTIGATIONS:	For compliance NPRMPs focused on verification of good agricultural practice, any samples with residues detected above the official MRL should be subjected to a traceback investigation. In these cases, investigations will be conducted by a government official. Where possible, the official will interview the farmer / producer and the fruit / vegetable market. The official will report to the responsible agency.
REGULATORY RESPONSE:	Investigation recommendations will include farmer education and advice, followed by a warning and, with ongoing contraventions, a financial penalty or market access block.

Starting point: a monitoring plan should detail all agreed elements of a compliance national pesticide residue monitoring programme.



Minimum requirement for a monitoring plan:

- Programme objective: verification of good agricultural practice
- Official approvals: Departments of Health and Agriculture
- Funding arrangements: government, industry or mix of both
- Roles and responsibilities: Agreement between participating government agencies at national and local level. This includes operational officers and requisite capacity, skills and capability.
- Scope of programme: Sample numbers, mode of collection, collection locations: e.g. farm, market etc.
- Commodities: Within the agreed budget, prioritise commodities on the basis residue potential, public health concerns.
- Pesticide screen: Within the agreed budget, prioritise pesticides to be included in the analytical screen. Alternatively, an accredited multi-residue screen may allow a broader screen to be utilized.
- Analytical laboratory: The selection of a preferred laboratory will take into account availability of a government-managed central laboratory, ASEAN regional laboratory, or another laboratory with an accredited analytical method and demonstrated proficiency.
- Sample Plan: sample locations, distribution of samples, sampling equipment, handling and treatment of samples.
- Sample transport: Formal arrangements for the transfer of samples from the collection point to the analytical laboratory taking into consideration handling of samples and chain of custody.
- Reporting: Agreed reporting frameworks for participants in the NPRMP including farmers. pack-houses, markets and consumers
- Traceback investigations: Agreed roles and responsibilities at national and local government levels for the conduct of traceback investigations when required and schedule of regulatory actions.

4.13 SAMPLING PLAN

In developing a sampling plan, the following Codex Guidelines should be referenced:

- Recommended Methods of Sampling For The Determination of Pesticide Residues For Compliance with MRLs (CAC/GL 33-1999);
- General Guidelines on Sampling (CAC/GL 50-2004); and
- Portion of the commodities to which maximum residue limits apply and which is analyzed (CAC/GL 41-1993).

However, as the Guide's objective is to provide assistance to those economies, which have assessed respective NPRMP capabilities and capacities as basic, an interpretation of the Codex Guidelines has been developed to present a simplified operational guide. A sampling plan is established to provide clear direction on sample numbers, location of samples, sampling timeframes, sampling distribution, sample handling and sample logistics.

4.13.1 Sample numbers

A decision on a Compliance NPRMP's sample number will be dependent on available funding for the programme and an assessment of a representative coverage of a country's production of a specific commodity. The assessment will consider the type of commodity, breadth of agricultural production across a country and production volumes.

4.13.2 Sample locations

Sample locations depend on the purpose of NPRMP. It can include directly on farm, fruit and vegetable markets, pack-houses, processing plants and supermarkets. Given the large number of farms, on-farm sampling is considered more difficult than sampling at a pack-houses or market which services large numbers of farmers in one location. Random sampling from markets and pack-houses should provide a reasonable spread of sampling across a particular commodity.

4.13.3 Sampling timeframes

Sampling timeframe for a specific commodity will be determined by the growing season and availability of product in the market or pack-house. In some cases where commodity is kept in cool stores to extend availability of a product to the consumer, the timeframe of availability of samples is lengthened.

4.13.4 Sample distribution

Sample distribution within a country will be determined on the basis of production seasons, regional production volumes, access to commodities and capacity to transport samples

4.13.5 Sample integrity

Sample integrity includes sample handling, sample logistics and chain of custody considerations. High degrees of sample integrity between point of collection and arrival for residue analysis is critically important for the following reasons:

- A compliance programme is generally supported by pesticide and food safety laws and regulations.
- The sample condition is maintained from collection to arrival at the laboratory.
- There is a chain of custody for the sample free from tampering and interference.
- Authorised and trained officials conduct the operational aspects of the programme.
- Appropriate sampling equipment is available to facilitate sample integrity.

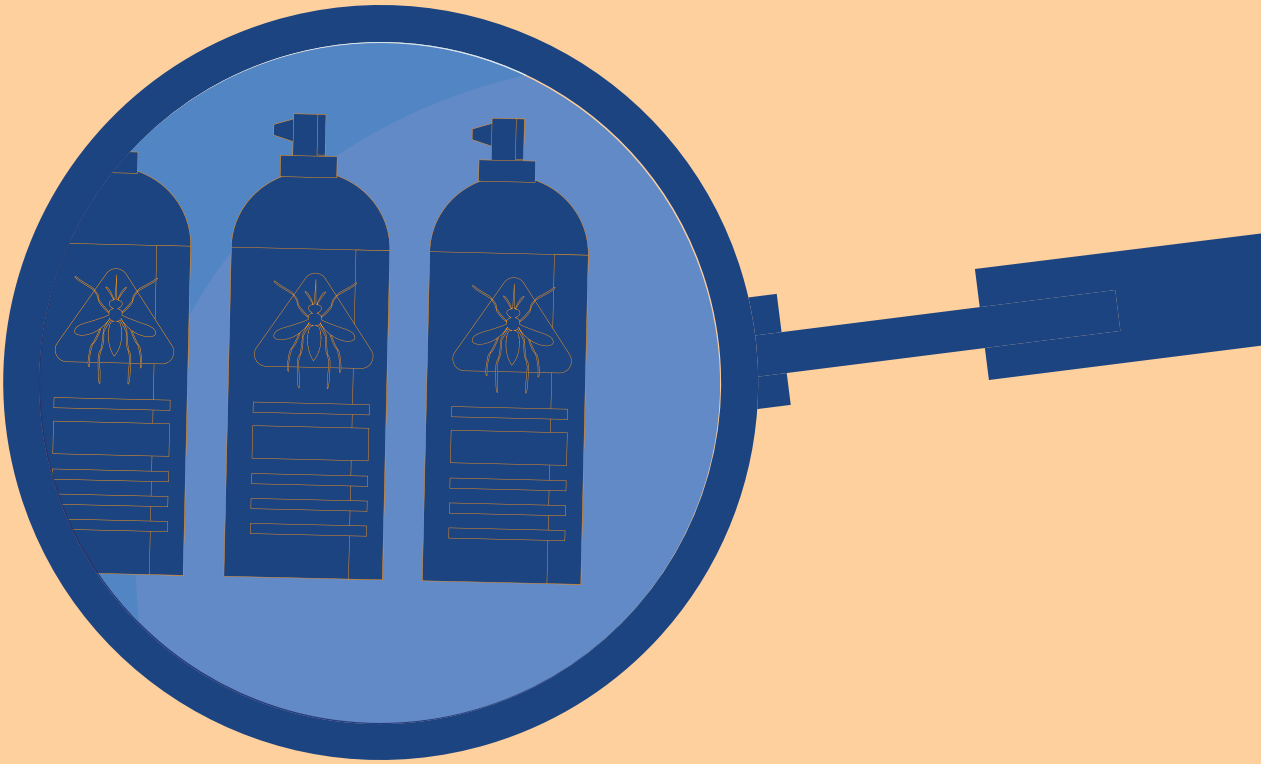
4.13.6 Sample traceability

Sample traceability is desirable to support the regulatory elements of a pesticide risk management framework and a compliance NPRMP. The sample plan should be developed to support traceability where this is possible.

Where practicable, when taking samples from a farmer, the sample collector should be able acquire sample identification details. However, where produce is aggregated before entering the market e.g. rice or fruit delivered from a farm cooperative, traceability to the farm may not be possible. Nevertheless, whether the samples are collected from a farm, pack-house or market, the sample collector should attempt to collect as much information as possible. The ability to collect farmer information, contact details and description of the commodity will allow the NPRMP managers the best opportunity to conduct a traceback investigation in cases where residue detected exceeds the MRL.

TABLE 2. SAMPLING PLAN FOR A COMPLIANCE NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMME - EXAMPLE

NUMBER OF SAMPLE	e.g. randomly select 300 samples of leafy vegetables
LOCATIONS	e.g growing regions are located in 5 of 10 provinces estimated number of leafy vegetable farmers is 1200 approximately 1 in 4 farmers will be randomly selected for leafy vegetable sampling
TIMEFRAMES	e.g. leafy vegetable growing season is July to November
DISTRIBUTION	e.g. production volumes have been obtained for each province Each province has a similar production volume thus will be allocated 60 samples each
EQUIPMENT	e.g. necessary sampling equipment (bags, security satchels, boxes, gloves etc) to be transported to provincial depots
INFORMATION MANAGEMENT	Paper-based sample form in triplicate
TRANSPORT	Sample freight arrangements
INTEGRITY	Chain of custody arrangements
TRACEABILITY	e.g. sample collection from identifiable farmers thus allowing full traceability



5. IMPLEMENTING A COMPLIANCE NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMME

5. IMPLEMENTING A COMPLIANCE NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMME

This section focuses on implementation of a Compliance NPRMP with detailed guidance on the programme's operational requirements. Section 4 of the Guide provides detailed guidance on the development of a Compliance NPRMP. The principal documents referenced to commence implementation of a Compliance NPRMP are the Monitoring Plan and Sample Plan prepared during the development stages. For the purposes of this Guide, it is assumed that the Compliance NPRMP involved samples taken directly off-farm.

5.1 PREPARE AN OPERATIONAL PLAN

The initial stages of implementation should involve preparation of an operational plan based om the NPRMP's Monitoring and Sample Plans. The operational plan will provide comprehensive details on steps taken from arrangements to visit a farm to collect samples, through sample arrival at the analytical laboratory to possible traceback investigation and regulatory response.

For the purposes of this Operational Plan, it is assumed that sample collection will be arranged in a district within a regional leafy vegetable production area. The essential pre-planning requirements are as follows:

- advise the analytical laboratory on forthcoming receipt of leafy vegetable samples;
- coordinate with sample freight company ensuring that adequate storage including refrigeration is available to maintain sample integrity;
- advise the district farmers of the official visit for sample collection. Forewarning ensures efficient well coordinated sample collection; and
- ensure that the sample collector adequately trained and has all requisite sampling equipment.

Starting point: operational roles and responsibilities

The Monitoring Plan will establish roles and responsibilities for sample integrity and chain of custody from sample collection to arrival at the analytical laboratory. Those responsible for sample freight will be accountable for sample integrity and chain of custody once the sample collector has delivered the samples to the aggregation point.

5.2 AUTHORIZED SAMPLE COLLECTORS

To ensure appropriate chain of custody and sample integrity, it is preferable for the sample collector to be authorized by the responsible government department to collect samples of fruit and vegetables. The sample collector will receive adequate training in the use of sampling equipment, taking representative samples, recording all necessary sample information, appropriate packaging of samples and preparing for freight to the analytical laboratory. The sample collectors will be provided sample collection instruction manuals.

5.3 SAMPLING EQUIPMENT

An officer within the lead government authority responsible for the NPRMP should be assigned responsibility for sampling equipment inventory management. Sample equipment is dependent on the type of commodity to be sampled. Commodities with short shelf-lives such as raspberries require careful handling to ensure the sample integrity is maintained. Large size commodities such as durian require sample equipment suited to accommodate the fruit. Leafy vegetables may need to be kept cool or frozen for the period between sampling and arrival at the laboratory.

For those commodities which need to be stored cooled or frozen in transit between sample collection and arrival at the laboratory, lined insulated boxes with chill sheets may be required. Noting the above, the equipment inventory manager will be required to ensure each sample collector has the requisite sampling equipment prior to commencement of each farm visit.

5.4 SAMPLE COLLECTION

The principal objective of sample collection is to ensure the selected commodity is representative of the lot whether it be directly off farm, from a box / carton, consignment of boxes / cartons or supermarket shelf. Given this is a guide for a Compliance NPRMP, it is assumed that fresh commodities refer to raw, whole produce (i.e., heads of lettuce, celery stalks, etc.). In the first instance, it is assumed that the prepared produce, such as salad mixtures, sliced carrots or chopped celery are not included. Items that are merely washed, brushed, or bagged are acceptable (i.e. leaf spinach, apples). However, the process of washing should be noted by the sample collector. The term delicate commodities refer to fresh produce (e.g., strawberries, raspberries, peaches, etc.) that are highly susceptible to bruising, crushing and/or deterioration during the sampling, packaging, and shipping process.

Random sampling involves the collection of number of samples (n) from a lot size (N) items in such a way that all possible combinations of n items have the same probability of being collected. The collection of samples is to be performed in a random manner, whenever possible during the loading or unloading of the lot. There is no mathematical relationship between n and N. Therefore, the sample collector should focus on taking a reasonable number of units (leaves, pieces of fruit etc.) from the lot to be sampled.

The type / size of sample to be collected is dependent on the type of commodity. For example, a reasonable sample of pome fruit would be 10 pieces weighing approximately 1.5kg and for spinach a bunch of 20 leaves. For additional examples, please see in table 3: suggested quantity of commodities to be collected.

The sample collector will prepare the representative sample by randomly taking a set number of items from the specified lot. For example, one spinach leaf could be taken from 20 bags of product to prepare a representative sample. If there are 60 bags of spinach, one leaf would be taken from every third bag and so forth. It is not desirable to take all 20 leaves from one bag.

When collecting more than one sample, the sample collector should ensure that cross-contamination does not occur. Wearing disposable sample gloves during the collection of a sample then discard prior to taking the next sample is preferable.

An example of how to collect representative samples is shown in Appendix 3.

The above suggestion is based on Codex Alimentarius Commission: Recommended methods of sampling for the determination of Pesticide Residues for compliance with MRLs, CAC/GL 33-1999 but simplified for this Guide.

Starting point: sample collection plan

Sample collectors should be provided with an authorized set of instructions covering the use of sampling equipment, how to collect a representative sample and appropriate packaging in preparation for transport to the laboratory.
Sampling equipment should include plastic sample bags which can hold between 1-5 kg of fruit and vegetable, security bags or boxes, official tape to seal bags and boxes, disposable gloves. For perishable commodities, lined insulated boxes and chill sheets are required.

5.5 SAMPLE PACKAGING

Each sample shall be packed by the sample collector. Sample collectors shall use precautions to prevent samples from being contaminated by compounds that will affect the analytical results. The next steps are dependent on the management of samples prior to arrival at the laboratory. Samples may be placed in boxed and prepared for shipment at the collection site, or transported to a local government office, shipping facility, or other location for packing.

At all times the samples must be kept at refrigerated temperatures in a cooled container until they are packed for shipment to the laboratory. This helps to maintain sample integrity. Frozen cold packs can be placed in the sample container to ensure refrigerated temperatures of the product during transit. Loose, wet ice is not an acceptable coolant material.

Sufficient room should be provided inside the shipping box so that samples are not squeezed, broken, bent, or bruised and there is no danger of rupturing sealed bags. The collector should use a sufficient amount of packing materials to prevent movement of the produce during transit, thereby protecting the samples from bruising or damage. These packing materials also help provide insulation.

If commodities have been grouped for collection, it is permissible for more than one commodity type to be placed directly in the same shipping container. However, when packaging more than one fresh commodity type, collectors should attempt to package together fresh commodities that have similar temperature, moisture, packaging, and shipping requirements to minimize product degradation. Demonstrated chain of custody is important. The sample collector should place guidance notes about sample handling on the sample container to ensure the transporter is aware of requirements.

5.6 SAMPLE TRANSPORTATION

Sample transportation may occur several times between sample collection and arrival at the analytical laboratory. Samples may be transported to aggregation points prior to final freight to the laboratory. The key objectives are to maintain the sample conditions established by the sample collector at all times, maintain chain of custody and ensure the samples is delivered to the laboratory within the shortest possible period of time. Freight of samples may occur via road, rail or air depending on the region and type of sample. It is preferable for one freight company to be engaged to transport samples from the point of collection to the analytical laboratory. Contracting one freight company may help with coordination and uniformity in sample handling, transport and management.

The freight company must be able to demonstrate competency in handling samples of agricultural produce from collection point to analytical laboratory. The freight company must ensure that the official samples are maintained in the pre-specified environment (temperature, physical characteristics). The freight company must have a system supporting chain of custody which could include barcoding.

5.7 SAMPLING PROCEDURE

Noting the operational guidance above, the following procedure is recommended.

1. The sample collector will survey the 'lot' (farm plot, container of fruit or vegetable or produce at a specific supermarket) and take units of produce from as many parts of the lot as is practicable to achieve a representative sample.
2. This could be a patch of spinach, an orchard of guava, a bin of apples, a box of cabbage or a tray of mangosteen. By surveying the lot, the sample collector can determine where in the lot, units of commodity can be selected to achieve a representative sample from the entire lot.
3. Separate samples should be sent for distinct lots of produce. Submit separate samples to the laboratory if you are dealing with: different fruits or vegetables, different cultivars or varieties; areas of crop which have had different pesticide treatments, or which have been sprayed on different days; produce sourced from different growers for repacking or processing.
4. Prepare your sample bags, sampling gloves and other equipment required to collect the sample.
5. Commence completion of the sample form. This will record the unique sample number, sample location and contact details (farm, pack-house, city market, distribution centre or supermarket), sample date, type of commodity and sub group (for example: apple – granny smith), spray diary availability (has the farmer kept records of pesticide use).
6. Commence selection of commodity units. For an example if sampling apples from a box, take 3-4 units from the top, from the middle and from the bottom of the container. If sampling a patch of spinach, take a leaf from 20 plants from the outer areas and inner areas. Avoid taking diseased or under-sized crop parts or produce at a stage when it would not normally be harvested.
7. It is preferred that whole fruit / vegetable samples are collected. However, this may not be possible. Therefore, the sample collector must record the nature of the sample, e.g. whole, cut, peeled etc. Take samples in such a way as to be reasonably representative of typical harvesting practice. Sample the parts of the crop that normally constitute the marketable produce.
    - For bulb, root and tuber vegetables, adhering soil should be removed to ensure a representative sample of the raw commodity. This may be done by brushing and, if necessary, gentle rinsing with cold running water. However, take care not to remove surface residues through excessive washing.
    - For vegetables like carrots, trim off tops and record details of any trimming should be recorded.
    - For Brassica vegetables, leafy vegetables, legume vegetables, fruiting vegetables and stalk vegetables, record any trimming of damaged leaves etc. and sample crops where the unit have been exposed to pesticide spray and not exposed to spray.
8. Place the units in a sealable plastic bag. Label the bag with the unique sample number on the corresponding sample form.
9. At the least, place the sample in a cooled container. Do not freeze fresh produce. As a general rule all samples, especially samples of perishable fresh produce, should be kept cool but not frozen. However, samples of already frozen foods should be kept frozen until they reach the laboratory.
10. If collecting a second sample, replace the sample gloves to avoid cross contamination and repeat the process.

5.8 ANALYTICAL LABORATORY – OPERATIONAL PLAN

5.8.1 Sample handling and integrity

As is the case with the sample collector, the analytical laboratory is responsible for the chain of custody of each sample upon arrival at the laboratory. In accordance with sample collection protocols, the sample collector will have recorded all requisite details relating to the sample. The laboratory will be responsible for ensuring these data are assigned correctly to the residue testing result. Quality control measures should be established to ensure the sample form and the sample are not mixed.

5.8.2 Data handling

The analytical laboratory will have similar access along with the sample collector and lead department to the shared excel spreadsheet containing all information relating to the NPRMP. Quality control measures will be in place to ensure the residue testing result is entered against the correct sample in the spreadsheet.

5.8.3 Analytical report

An analytical report of residue testing results should be generated by the laboratory and made available to the lead agency for all testing. All necessary information should be included in the report, as indicated in the example provided in Appendix 4. The analytical laboratory should retain a copy of the report for at least one year and retain relevant samples in a freezer for 3-6 months.

5.8.4 Data checking

All residue testing results must be checked to minimize the possibility of false positives and negatives or other unusual results. Over time, as residue testing data is accumulated and trend analysis can be undertaken. From this, data checkers have increasing capacity to assess data for false or unusual results. Quality control measures will cover the requirement to check a batch of residue testing results prior to submission to the lead department authority. In some cases, confirmatory testing may be required to verify an original result may be necessary to address residue testing results classified as unusual and false positives / negatives.

5.9 INTERPRETATION OF RESIDUE TESTING RESULTS

The lead department authority assesses each residue testing result against the relevant MRL / food standard and considers appropriate action in the case of a MRL contravention. The reference MRL will be stipulated by the lead department authority and will already be widely circulated to all agriculture stakeholders.

There are two decision points once a residue testing result has been received from the analytical laboratory. The confirmed residue testing result will be compared to the relevant reference MRL. If the residue level in mg/kg is higher than the MRL, the sample is deemed to be an exceedance or contravention. If the residue level is lower than the MRL, no further action is required at this stage. A MRL exceedance may occur where the chemical user (farmer):

1. did not follow the pesticide product label instruction relating to concentration of active ingredient in the spray mixture;
2. did not adhere to the withholding period (pre-harvest interval). The commodity was harvested within the withholding period;
3. did not adhere to the label instruction by applying more spray applications within a specific period of time than are authorised;
4. used a registered pesticide which is not authorised for use on a specific commodity. No MRL is set and therefore zero tolerance applies;

5. used an unregistered (possibly banned) pesticide on a specific commodity. No MRL is set and therefore zero tolerance applies; or
6. was subject to pesticide spray drift on their property as a result of a neighbouring farmer using a pesticide for a different crop.

For all exceedances, the lead agency will delegate a suitable government official to conduct a traceback investigation. The lead agency will need to consider thresholds for specific actions following an exceedance which may include farmer education, product recall, certification for market, suspension of market access or financial penalty.

For example, where the residue level is significantly higher than the MRL and the lead agency determines there is a potential food safety risk, a product recall and financial penalty may be appropriate.[6] In cases where the residue level slightly over the MRL (e.g. residue 1.1mg/kg and MRL 1.0mg/kg, the regulator may opt for a warning or farmer education.

5.10 TRACEBACK INVESTIGATION

For NPRMPs focused on verification of good agricultural practice, any samples with residues detected above the official MRL should be subjected to a traceback investigation by an government investigator. Refer to Section 5. 9 for likely MRL exceedance reasons. The investigation will seek to confirm why the MRL exceedance occurred, i.e. cause and source. A traceback investigation will involve an authorized investigator identifying the source of the residues and undertaking regulatory action consistent with the severity of the MRL exceedance.

The investigator will interview the farmer / producer and the fruit / vegetable market.
The investigator may need to interview neighbouring farms to take into account possible spray drift. This is particularly important if the farmer being investigated can demonstrate that a certain pesticide is not used in their farm.

Regulatory powers may determine that the specific sample contains 'illegal residues'. Accordingly, regulatory action will range from prosecution to an education programme but ultimately seek continuous improvement of pesticide use and minimization of future occurrences. A tiered approach to the regulatory action is recommended as follows farmer education and advice, followed by a warning and, with ongoing contraventions, a financial penalty or market access block. The inspector will have prepared a report on the investigation which explains all relevant detail about the residue incident along with regulatory action taken. The investigation report should be shared with each responsible government ministry / department.

Starting point: traceback investigation

In the event of a MRL exceedance, a traceback investigation should occur. The compliance NPRMP, which supports a country's pesticide risk management framework, should have the capacity to identify the owner of sampled fruit / vegetable to enable interaction between farmer and government authority.

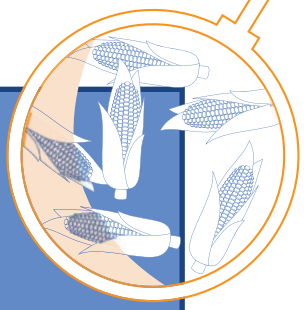
TABLE 3: SUGGESTED QUANTITY OF COMMODITIES TO BE COLLECTED[7]

COMMODITY	QUANTITY, METHOD OF COLLECTION
Citrus fruit, pome fruit, mango, papaya, litchi, avocado, guava,	10 fruit from 10 different trees. If the sample weight is less than 2 kg, take more fruit to yield a 2 kg sample.
Durian	Take 6 fruit and cut into half – sample to comprise 6 halves.
Jackfruit	Take 10 fruit from 10 different trees in the orchard
Grapes	10 bunches from 10 different vines to yield a 2 kg sample
Berries – currant, raspberry, strawberry other berries	A total of 1 kg from 10 different bushes or locations
Dates and figs	One kg sample from at least 10 trees
Pineapples	6 fruit from 6 different locations on the farm.
Bananas	10 fruit from 10 different bunches to yield a 2 kg sample
Coconut	6 fruit from 6 different locations on the farm.
Coffee	1 kg of beans from random selection of plants
Potato, taro, sweet potato	Take 10 tubers from 10 different plants located around the plot up to 2 kg sample
Carrot, sweet potato, celeriac, chicory and others	Take 10 units from 10 different locations around the plot up to a 2 kg sample
Leeks, onions, garlic, shallot	Take 10 plants from 10 different locations around the plot up to a 2 kg sample
Large brassica crops e.g. cabbage, cauliflower, kohlrabi	Take 10 plants from 10 different locations around the plot
Broccoli	Collect 1 kg from 10 different plants
Brussels sprouts	Collect 1 kg from 10 different plants
Cucumber, gherkin, squash, courgettes	10 fruits from 10 different plants
Melons, gourds, pumpkins, watermelon	Collect 5 units from 5 different locations around the plot
Aubergines	10 fruits from 10 different plants
Sweet corn	10 ears from 10 different plants
Mushrooms	1 kg from different locations around the plot
Tomato, pepper	At least 10 fruits from 10 different plants to a sample weight of 2kg
Lettuce	12 plants from different locations around the plot
Spinach, chicory leaves, kale	1 kg from 10 different plants
Grains: wheat, rice, peas etc.	1 kg from harvested crop with subsamples collected from various parts of the lot.
Herbs, spices, tea, hops	0.5 kg from various locations around the crop

[7] The information provided in Table 3 is derived from, and is an interpretation of, Appendix V of the FAO Manual on the Submission and Evaluation of Pesticide Residues Data. For further information, please see via http://www.fao.org/3/i5452e/i5452e.pdf.

FIGURE 2. DRAFT SAMPLE FORM

DRAFT SAMPLE FORM (IN TRIPLICATE: FARMER, COLLECTOR, LABORATORY)[8]



GOVERNMENT EMBLEM
DEPARTMENT OF AGRICULTURE / HEALTH

UNIQUE SAMPLE NUMBER: I23456A

SAMPLE:

Commodity type: sweet potato
Sample type: Raw, processed, treated
Nature of sample: whole, cut, peeled etc.

Variety name: okinawan
Sample size: 2kg
Sample treatment: light washing to remove soil before packaging

COLLECTION INFORMATION:

Date: 05 November 2020

Town / city: Chiang Mai

Collection location identification
Farmer ID: Frank Sinatra
Pack-house ID: Thai fruit company
Market ID: Bangkok fruit/vegetable market

Contact details:
physical address and email

ANALYTICAL LABORATORY:

Sample analysis date: Residue & Science Laborator
Analytical screen: 10 November 2020
Result: multi-residue screen
Signature of laboratory analyst: Pesticide residues detected plus result (attach certificate of analysis)

SAMPLE COLLECTOR:

Designation: Ms Elizabeth Taylor
Signature: Sample collection officer, Department of Health

FOR OFFICIAL USE ONLY:

MRL reference: Codex MRLs
Traceback investigation:
Action taken: Attach report where appropriate

[8] The draft sample form should be used as a possible example for compliance programme with some elements dependent on specific country situations.

DRAFT SAMPLE FORM: INSTRUCTIONS TO COMPLETE

(1) Each sample form will have a unique sample number prefilled.

(2) Record the sample details: commodity, variety, weight, etc.

(3) Record the collection date, sample location. The location should be as specific as practicable.

(4) Record the commodity owner and contact details. Record as many details as are available: physical address, phone number, email address. If the proposed sample is from unidentified commodity at a market, do not collect a sample. Traceability is important.

(5) One copy of the sample form should be packed with the sample before sealing the sample box or bag.

(6) Ensure the sample is cooled, chilled etc as per specifications related to the commodity.

(7) Arrange for transport of sample to the laboratory. Ensure instructions are placed on the sample box for the transport company to ensure the sample remains in the specified conditions upon arrival at the laboratory.

(8) The analytical laboratory will check the condition of the sample and commence analytical sample preparation. The date of analysis is recorded on the sample form.

(9) The laboratory records the analytical screen to be undertaken. Normally this would be 'multi-residue screen'.

(10) Once analysis is completed, the laboratory will record the residue result on the form, scan the document and email to the Department of Agriculture.

(11) The regulatory authority will review the result against the MRL and undertaken action as required (recorded on the form).

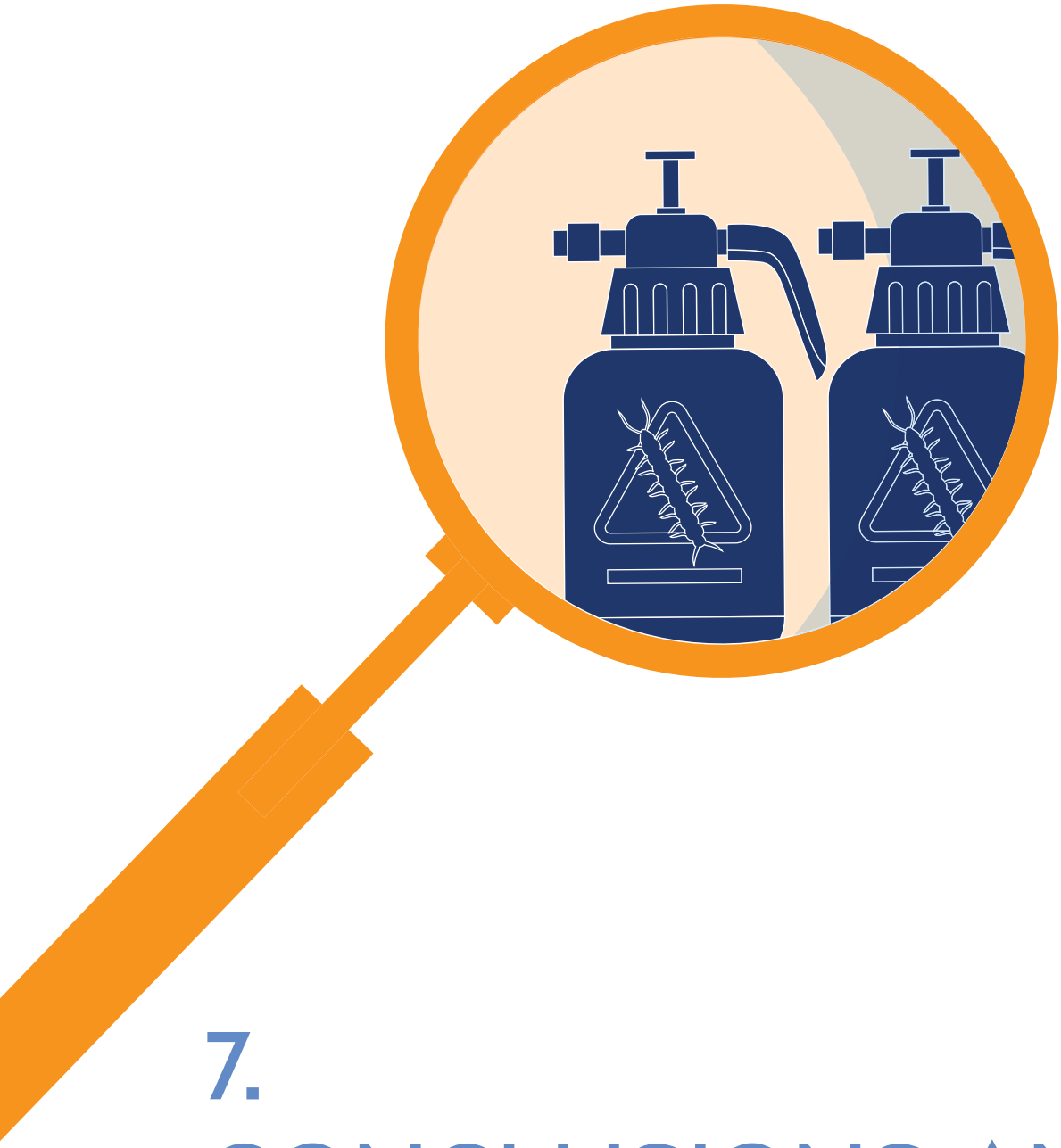
6. COMPLIANCE NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMME REVIEW AND EVALUATION

6. COMPLIANCE NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMME REVIEW AND EVALUATION

Prior to commencement of a compliance NPRMP, a table of review and evaluation topics should be prepared. All participants should, throughout programme implementation, have the opportunity to provide input where appropriate to the topics. The suggested topics to be included for review and evaluation are presented in the Table 4.

TABLE 4. TOPICS FOR PROGRAMME REVIEW AND EVALUATION

PROGRAMME OBJECTIVE	Require agreed performance indicators – were the stated objectives met? The objective can be assessed in follow up years where compliance trends become clearer.
PROGRAMME OUTCOME	Require agreed performance indicators
RESOURCES	Sufficient human resources allocated
FUNDING	Accuracy of programme budgeting
SAMPLE COLLECTION	Farmer understanding of process
SAMPLE COLLECTORS	Performance criteria
ANALYTICAL SCREEN	Non-screen pesticides detected
COMPLIANCE WITH MRLS	MRL compliance trends
TRACEBACK INVESTIGATIONS	Sufficient information, farmer interaction / understanding, investigator performance, quality of reports
REGULATORY ACTION	Statistics, MRL compliance trends
SAMPLE TRANSPORT	Performance of transport company – timeliness
SAMPLE INTEGRITY	condition of samples, samples lost
ANALYTICAL LABORATORY	Analytical performance, ongoing proficiency, quality of results (false positives / false negatives), Non-screened pesticides detected



7. CONCLUSIONS AND RECOMMENDATIONS

7. CONCLUSIONS AND RECOMMENDATIONS

A national pesticide residue monitoring programme (NPRMP) is one of the key elements supporting a pesticide risk management framework. As it is not realistic to monitor each and every user of pesticide for each commodity, it is recommended to develop a risk-based residue monitoring programme to specify pesticides-commodities to be included in the NPRMP.

This guide provides the essential elements and processes for developing and implementing effective risk-based compliance NPRMPs. The guide also provides the fundamental actions, as indicated in the "starting point" boxes, to be taken on the development of residue monitoring programme which would be feasible for some countries with the limited capacity.

Prior to the programme development stage, the current situation of pesticide residues (e.g. the occurrence of pesticide residues, the public's concern level) and the pesticide residue monitoring capacities in countries should be assessed and information gathered as valuable inputs to the NPRMP development.

Management commitment and the good collaboration between relevant stakeholders are the key starting point for development of NPRMP. The objective would be clearly set at the initial step of NPRMP development. To ensure effective NPRMP implementation, training and development of involved officers on all relevant aspects such as sampling is recommended.

The Guide has focused on development and implementation of a NPRMP without going into specific details on analytical methodology and laboratory performance. The authors recommend that a separate guide focus on analytical laboratories, methodology, procedures and proficiency.

GLOSSARY

Maximum residue limit (MRL)[1]

The MRL is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. MRLs are based on GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable. (Codex Alimentarius Vol. 2A)

Codex MRLs, which are primarily intended to apply in international trade, are derived from estimations made by the JMPR following:

a) a toxicological assessment of the pesticide and its residue; and

b) a review of residue data from supervised trials and supervised uses including those reflecting national good agricultural practices. Data from supervised trials conducted at the highest nationally recommended, authorized or registered uses are included in the review. In order to accommodate variations in national pest control requirements, Codex MRLs take into account the higher levels shown to arise in such supervised trials, which are considered to represent effective pest control practices.

Consideration of the various dietary residue estimates and determinations both at the national and international level in comparison with the ADI, should indicate that foods complying with
Codex MRLs are safe for human consumption.

Explanatory note: The MRL applies to the product when first offered in commerce, unless otherwise indicated. For commodities entering international trade the MRL is applicable at the point of entry into a country or as soon as practicable thereafter and, in any event, before processing.

Illegal residue

There are two instances when a pesticide residue is illegal:

(1) The country has established a MRL for that pesticide on the commodity on which the residue was found, but the level of the residue exceeds the MRL; or

(2) The country has not established any tolerance for that pesticide on the commodity on which the residue was found, and therefore any residue detection above the LOQ (LOD or a specified limit in some countries) is deemed to be an exceedance.

In both cases, health regulations should make it illegal to sell the commodity.

Limit of detection (LOD)[1]

The LOD is the lowest concentration of a pesticide residue or contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. (Codex Alimentarius, Vol. 2A)

Explanatory note: LOD has also been used as an abbreviation for "limit of detection," which may be confusing. JMPR has now adopted LOQ – see the following definition

[1] FAO Manual on the Submission and Evaluation of Pesticide Residues Data (http://www.fao.org/3/i5452e/i5452e.)

Limit of quantification (LOQ)[1]

The LOQ is 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.

Explanatory note: 'Limit of quantification' and 'limit of quantitation' are used synonymously and are abbreviated to LOQ. The FAO Panel estimates the LOQ of an analytical method for residues in specified substrates as being the lowest level where satisfactory recoveries were achieved. JMPR has used LOD (limit of determination) in the past with the same meaning as LOQ.

Lot[2]

A quantity of a food material delivered at one time and known, or presumed, by the sampling officer to have uniform characteristics such as origin, producer, variety, packer, type of packing, markings, consignor, etc. A suspect lot is one which, for any reason, is suspected to contain an excessive residue. A non-suspect lot is one for which there is no reason to suspect that it may contain an excessive residue.

Notes.

(a) Where a consignment is comprised of lots which can be identified as originating from different growers, etc., each lot should be considered separately.
(b) A consignment may consist of one or more lots.
(c) Where the size or boundary of each lot in a large consignment is not readily established, each one of a series of wagons, lorries, ship's bays, etc., may be considered to be a separate lot.
(d) A lot may be mixed by grading or manufacturing processes, for example.

Consignment

A consignment is a quantity of some commodity delivered at one time. It may consist in either a portion of a lot or a set of several lots.

Sample, sample size and unit[3]

One or more units selected from a population of units, or a portion of material selected from a larger quantity of material. For the purposes of these recommendations, a representative sample is intended to be representative of the lot, the bulk sample, the animal, etc., in respect of its pesticide residue content and not necessarily in respect of other attributes. The number of units, or quantity of material, constituting the sample.

A unit is the smallest discrete portion in a lot, which should be withdrawn to form the whole or part of a primary sample. For fresh fruit and vegetables, a unit is identified as follows: each whole fruit, vegetable or natural bunch of them (e.g. grapes) should form a unit, except where these are small. Individual fresh fruit or vegetables must not be cut or broken to produce units.

Representative sample

The representative sampling is a procedure used for drawing or forming a representative sample.
Random sampling involves the collection of n items from a lot of ***N*** items in such a way that all possible combinations of n items have the same probability of being collected. In order to avoid any dispute over the representativeness of the sample, a random sampling procedure should be chosen, whenever possible, alone, or in combination with other sampling techniques.

[2] Codex Alimentarius Commission: Recommended methods of sampling for the determination of Pesticide Residues for compliance with MRLs, CAC/GL 33-1999

[3] Codex Guideline – Codex Alimentarius Commission: Recommended methods of sampling for the determination of Pesticide Residues for compliance with MRLs, CAC/GL 33-1999

The collection of samples is to be performed in a random manner, whenever possible during the loading or unloading of the lot. If the lot is heterogeneous, a random sample may not be representative of the lot. In such cases, stratified sampling may be a solution. Stratified sampling consists of dividing the lot into different strata or zones, each stratum being more homogenous than the original lot. Then a random sample is drawn from each of these strata, following specified instructions which may be drafted by the Codex Commodity Committees. Each stratum can then be inspected by random sampling which usually includes from 2 to 20 items or increments per sample. (see the sampling plans of ISO 2859-1 of letter-codes A to F at the inspection level II). But before sampling, it is necessary, where appropriate, to refer to the specific instructions of the Codex Commodity Committees.

False positive result
Where a residue testing result reports detections of a pesticide which are unexpected and later via confirmatory testing are found to be false.

False negative result
Where a residue testing result fails to report a detection of a pesticide when there is a relatively high chance of a detection because a particular pesticide had been used during production.

Point of Entry
A location where produce from other countries enters a specific country including airports, seaports, and roadway border crossings.

Point of origin
A site where a country's grown produce is packed prior to shipment. The point of origin may be located at the production field for commodities such as lettuce, or at a packing shed for commodities such as citrus.

Good Agricultural Practice (GAP)
Good agricultural practice is a certification system for agriculture, specifying procedures that must be implemented to create food for consumers or further processing that is safe and wholesome, using sustainable certification methods. For the purposes of this Guide, GAP relates to a pesticide risk management framework which facilitates the production of fruit and vegetables which a safe to consume.

Acute reference dose (ARfD)
The estimate of the amount of a substance in food or drinking water, expressed on a body weight basis, that can be ingested in a period of 24 h or less without appreciable health risk to the consumer. It is derived on the basis of all the known facts at the time of evaluation. The ARfD is expressed in milligrams of the pesticide per kilogram of body weight.

Acceptable daily intake (ADI)
The ADI is the estimate of the amount of a substance in food or drinking-water, expressed on a body weight basis, that can be ingested daily over a life-time without appreciable health risk to the consumer. It is derived on the basis of all the known facts at the time of the evaluation. The ADI is expressed in milligrams of the pesticide residue ingested per kilogram of body weight (a standard adult person weighs 60 kg).

GEMS/FOOD
Since 1976, the Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme, commonly known as GEMS/FOOD, informs governments, the Codex Alimentarius Commission and other relevant institutions, as well as the public, on levels and trends of contaminants in food, their contribution to total human exposure, and significance with regard to public health and trade. WHO implements the programme in cooperation with a network Collaborating Centres and recognized national institutions located all around the world.

WHO developed an approach to describe the various diets around the world based on the analysis of per capita supply available from the FAO Food Balance Sheets. The GEMS cluster diets consist in national dietary patterns grouped by similarities. These 17 cluster diets updated in 2012 are commonly used by international committees for exposure assessment to food contaminants and pesticide residues. WHO and FAO also collect national individual food consumption data. At date individual data representing more than 40 percent of the world population were made available to WHO. The GEMS Food Programme supports the collection of food consumption data in ASEAN Countries as well as the harmonization of existing data.

International Laboratory Accreditation Cooperation (ILAC)

ILAC is the international organisation for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies including calibration laboratories (using ISO/IEC 17025), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189), inspection bodies (using ISO/IEC 17020), proficiency testing providers (using ISO/IEC 17043) and reference material producers (using ISO 17034).

Accreditation is the independent evaluation of conformity assessment bodies against recognised standards to carry out specific activities to ensure their impartiality and competence. Through the application of national and international standards, government, procurers and consumers can have confidence in the calibration and test results, inspection reports and certifications provided.

Accreditation bodies are established in many economies with the primary purpose of ensuring that conformity assessment bodies are subject to oversight by an authoritative body. Accreditation bodies, that have been peer evaluated as competent, sign regional and international arrangements to demonstrate their competence. These accreditation bodies then assess and accredit conformity assessment bodies to the relevant standards.

ISO/IEC 17025 enables laboratories to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work both nationally and around the world. It also helps facilitate cooperation between laboratories and other bodies by generating wider acceptance of results between countries. Test reports and certificates can be accepted from one country to another without the need for further testing, which, in turn, improves international trade.

APPENDIX 1: LINKS TO THE RELEVANT COMPETENT AUTHORITIES

Australian Imported Food Testing Scheme:
https://www.agriculture.gov.au/import/goods/food/inspection-compliance/inspection-scheme

Australian National Residue Survey:
https://www.agriculture.gov.au/ag-farm-food/food/nrs

Australian total diet survey:
https://www.foodstandards.gov.au/science/surveillance/Pages/australiantotaldiets1914.aspx

European Food Safety Authority:
https://www.efsa.europa.eu/en/data/chemical-residues-data

Japan Ministry of Health Labour & Welfare:
https://www.mhlw.go.jp/english/topics/importedfoods/index.html

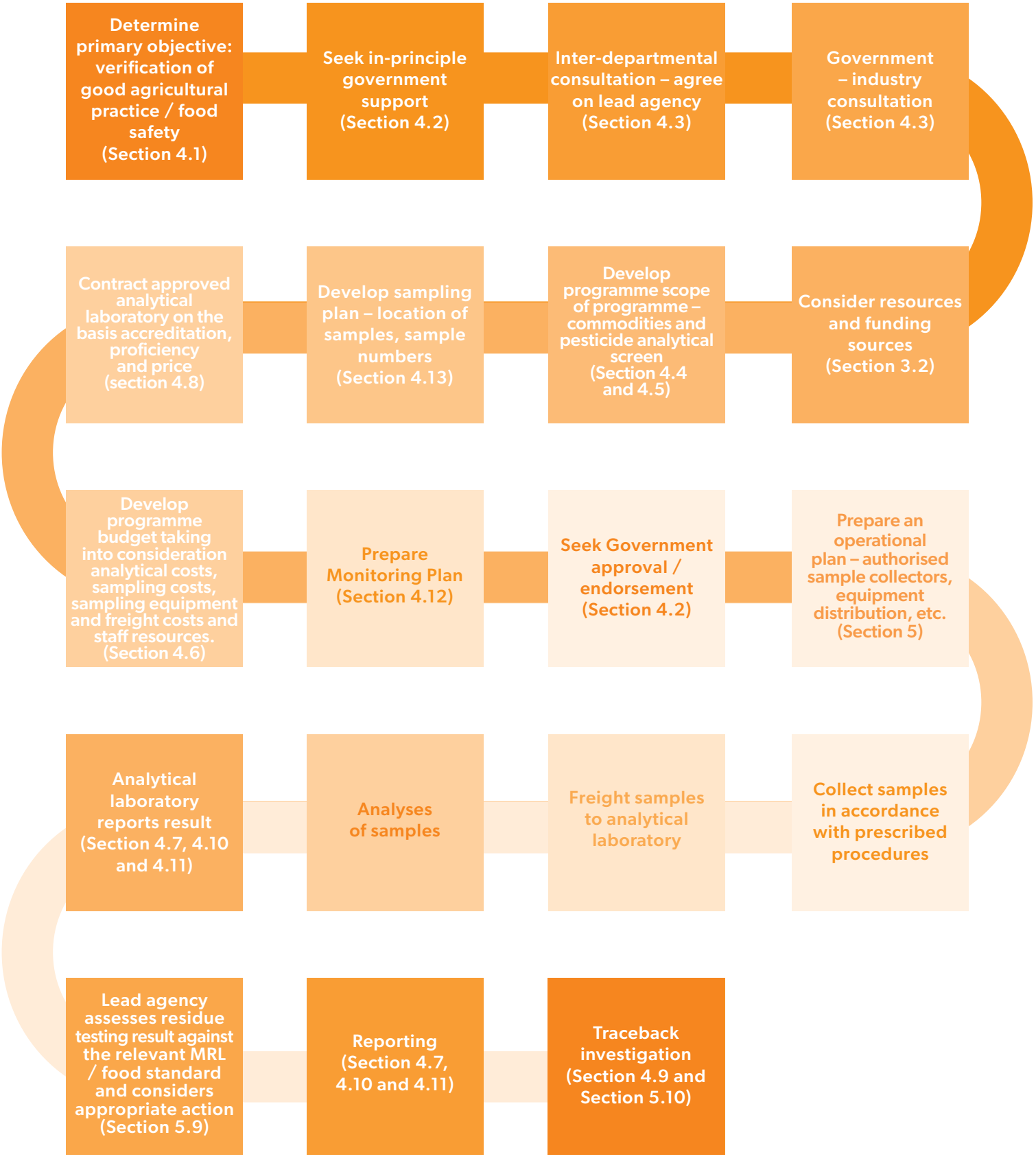
UK Pesticide Residues in Food:
https://data.gov.uk/dataset/5d5028ef-9918-4ab7-8755-81f3ad06f308/pesticide-residues-in-food

USA Food & Drug Adminstration (monitoring program):
https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-program-reports-and-data

USA Food & Drug Adminstration (total diet study):
https://www.fda.gov/food/science-research-food/total-diet-study

USA Pesticides Data Program:
https://www.ams.usda.gov › datasets › pdp › pdpdata

APPENDIX 2: FLOWCHART FOR THE DEVELOPMENT OF A COMPLIANCE NATIONAL PESTICIDE RESIDUE MONITORING PROGRAMME



APPENDIX 3: FLOWCHART FOR SAMPLE COLLECTION

Review sample plan and operational plan to ensure clear understanding of sample collection objectives.

Ensure authorised sample collectors and adequate sample collection equipment are available.

Review sample collection procedures.

Advise appropriate farmers and market managers of sample collection arrangements.

At the sample collection site, determine the best mechanism to obtain a representative sample.

Commence sample collection in accordance with the prescribed procedures.

Enter sample collection information onto a sample form which will have a unique sample ID.

Record the sample details: commodity, variety, weight etc.

Record the commodity owner and contact details for traceability purposes. Record as many details as are available: physical address, phone number, email address.

If the proposed sample is from unidentified commodity at a market, consider choosing another sample.

One copy of the sample form should be packed with the sample before sealing the sample box or bag. One copy is retained by the sample collector and another handed to the farmer or market manager.

Ensure the sample is cooled, chilled etc as per specifications related to the commodity.

Arrange for transport of sample to the laboratory. Ensure instructions are placed on the sample box for the transport company to ensure the sample remains in the specified conditions upon arrival at the laboratory.

Freight samples to analytical laboratory.

The analytical laboratory will check the condition of the sample and commence analytical sample preparation. The date of analysis is recorded on the sample form. The laboratory records the analytical screen to be undertaken. Normally this would be 'multi-residue screen'. Analyses of samples in accordance with accredited method.

Once analysis is completed, the laboratory will record the residue result on the form, scan the document and email to the lead agency.

Lead agency assesses residue testing result against the relevant MRL / food standard and considers appropriate action.

APPENDIX 4: DRAFT RESIDUE RESULT REPORT (EXAMPLE ONLY)

GOVERNMENT EMBLEM
LEAD AGENCY

UNIQUE SAMPLE NUMBER:
I23456A

SAMPLE:
Collection date: 5 October 2021

COMMODITY TYPE: sweet potato

VARIETY NAME: okinawan

FARMER / PACK HOUSE / MARKET DETAILS:

Farmer ID: Frank Sinatra
Pack-house ID: Thai fruit company
Market ID: Bangkok fruit/vegetable market

Contact details: physical address and email

Residue & Science Laboratory

ANALYTICAL LABORATORY:

Sample analysis date: 10 November 2020

Analytical screen: multi-residue screen

Result: Pesticide residues detected plus result (attach certificate of analysis)

RESIDUE	RESULT (MG/KG)	MRL (CODEX)
Chlorpyrifos	0.5	0.8
Malathion	1.5	1.0
Thiabendazole	3.6	5.0

LEAD AGENCY:

Name: Marlon Brando

Designation: Director – National Residue Survey
Lead Agency: Department of Agriculture

SIGNATURE:

Food and Agriculture Organization
of the United Nations

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