MRL Risk Assessment Tool

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Background – MRL Exceedance Risks

Purpose

Produce and other commodities grown must comply with the maximum residue limits (MRL) for each country the product will be sold in. This tool will take you through the steps of assessing your risk of MRL exceedance.

The Risks Associated with MRL Exceedance

- Loss of credibility and business if testing by buyers or a governmental authority reveals MRL exceedance.
- Loss of exported product due to rejection based on testing in the destination country.

CB Annex 6 of GLOBAL G.A.P. CPCC identifies the following key reasons MRL exceedances may occur:

- Non compliance with good agricultural practices (GAP) and Plant Protection Product (PPP) label instructions, including improper or illegal use of PPPs.
- No proper quality assurance standard applied to check/validate production methods.
- Exceptional circumstances, where abnormal crop conditions, climatic events, or agronomic conditions are experienced.
- Differences in MRLs between the country of production (COP) and country of destination (COD), and other legal challenges in the application and communication of MRLs, such as occasional changes to MRLs midway through the growing season which fails to allow a producer to change his practices to ensure the final product complies with the modified MRL.

Instructions

- ✓ Complete a **"Crop MRL Risk Assessment" form/spreadsheet** for each crop grown to determine risk, one crop per tab.
    - It is important to be comprehensive and realistic when completing the form and to include all inputs with an MRL that are being used, or considered for use.
    - Use information on the product label to complete the spread sheet(s). US and International MRLs can be found at mrldatabase.com
- ✓ Review the table below and your crop risk assessments to get an idea of how much risk of MRL exceedance your operation has & Complete Page 2 "Actions to meet MRLs"
- ✓ Complete "Sampling Plan" page 4 for crop(s) and/or complete an attach documents for all requirement under "Qualifying for 'No Analysis'" page 6 for any crop that meets the requirements.
- ✓ Complete MRL Exceedance page 5 to describe your policies or the documents that address MRl exceedance.

Need to test	Inherent risk associated with each Plant Protection Product (PPP)
Minimal	0. Bio-pesticides that are registered and not restricted in country of origin and destination
Low-Moderate	1. Registered in country of origin and destination, US tolerance most restrictive
Moderate-High	2. Registered in country of origin and destination, one or more international tolerances more restrictive than US tolerance
Very High	3. Registered in country of origin, but not registered in one or more countries of destination

Actions to meet MRLs - WORKSHEET

Possible actions:

- If only selling domestically, applying PPP within the range of rates listed on the label for the crop and following "Days to harvest"/"Pre-Harvest Interval" (PHI) are actions that should result in product that complies with domestic MRLs.
- Regular calibration and maintence of spray equipment to ensure proper rates are applied.
- Application at minimal rates per the material (PPP) label. A lower risk would be associated if an operation applies a material at less than the max dose, due to for example agronomic conditions or target pest.
- When MRL crop tool shows destination market MRL is more restrictive than the US MRL for a PPP:
    - Discontinue use of a PPP. This action may be chosen when the tolerance is much lower in the country of destination for the product or the PPP is not registered in the destination market.
    - Change to a PPP with a lower risk of MRL exceedance with a significant amount of extra time, e.g. 90 days or 120 days prior to harvest. Each pesticide this is done for should be listed under action taken.
    - Through testing and use of pesticide degradation data a modified/extended PHI is determined and followed. The data used to determine the modified PHI needs to be available for review.

Please list below all actions taken to meet MRLs per crop.

Crop:	
Actions taken:	

Crop:	
Actions taken:	

Crop:	
Actions taken:	

Sampling Planning Guidance

Need to test	Producer-dependent risk factors	Independent factors
Minimal	0. Pesticide used only in quarantine zones on an as-needed basis. Application rates lower and preharvest intervals longer than labeled guidelines. Sufficient buffer zones and other drift management practices are in place.	0. There is no potential for cross contamination by pesticide drift during production. If there are nearby fields, they are either organic or under the same pesticide treatment program as my field(s). I can demonstrate the absence of risk for cross contamination of product under my ownership during storage or transport.
Low-Moderate	1. Pesticide applied minimally, early in the growing season on an as-needed basis. Application rates lower and preharvest intervals longer than labeled guidelines. Sufficient buffer zones and other drift management practices are in place.	1. There may be risk for cross contamination by pesticide drift, and similar food crops are grown nearby. Risk of drift is minimal and measures are in place to mitigate this risk. I can demonstrate minimal risk for cross contamination of product under my ownership during storage or transport.
Moderate-High	2. Pesticide applied regularly, but usually at frequencies and rates lower than maximum label use recommendations. Lengthened preharvest intervals may be (but are not necessarily) employed.	2. There is a significant risk for cross contamination by pesticide drift, and dissimilar food crops are grown nearby. Measures are in place to mitigate risk. I can demonstrate minimal risk for cross contamination of product under my ownership during storage or transport.
Very High	3. Pesticide applied regularly, usually at maximum rates and frequencies recommended on the label. Preharvest intervals are not typically extended beyond label guidelines. Postharvest treatments are sometimes required.	3. There is a risk for cross contamination by pesticide drift, but the significance of the risk is undefined or difficult to control. Non-food crops or dissimilar food crops are grown nearby. Measures are in place to mitigate risk of cross contamination via pesticide drift, or during storage and transport, but may not be totally effective.

Guidelines:

- If need to test is high consider a sampling frequency of more than 1 test per year per crop with that risk.
- The bigger the operation the greater the risk, consider more frequent sampling, or collecting a greater number of samples depending on the total acreage, or number of lots being exported.
- Increase the number of samples taken if pesticide applications vary widely between lots. One sample per lot may be appropriate for products going overseas.
- A note in CB Annex 6 states: “in many cases the value of the sampling + analysis is around 0.1-0.5% of the value of the crop.”
- The stricter the international MRL is compared with the country of origin, the greater the risk of violation.

List documents/evidence of

Sampling Procedures	
Lab Accreditation*	

*Laboratories must show evidence of participation in proficiency tests (e.g. FAPAS available). See Annex CB.5 Residue Analysis

Sampling Plan - WORKSHEET

Name/variety:	
Area cultivated and number of sites as applicable:	
Frequency of sampling:	
When to sample:	
Where to sample:	
Type of analysis:	

Name/variety:	
Area cultivated and number of sites as applicable:	
Frequency of sampling:	
When to sample:	
Where to sample:	
Type of analysis:	

Name/variety:	
Area cultivated and number of sites as applicable:	
Frequency of sampling:	
When to sample:	
Where to sample:	
Type of analysis:	

MRL Exceedance – WORKSHEET

☐ MRL Exceedance policy in place, possibly including procedures for sale/ release to alternate markets. Document/Policy:

☐ A Recall/Withdrawal or Hold and release procedure is followed. Document:

Qualifying For 'No Analysis' – WORKSHEET (if applicable)

List documents/evidence

A risk assessment resulting in no need to undertake residue analysis shall identify:	
A history of 4 or more years of analysis without detecting incidences (e.g. exceedances, use of non-authorized PPPs)	
No or minimal use of PPPs	
No use of PPP close to harvesting (Interval from time of spraying to harvest is much bigger than the PHI)	
A risk assessment validated by an independent third party (e.g. expert) or customer(s)	

Exceptions to these conditions could be those crops where there is no use of PPPs, environment is very controlled and for these reasons the industry does not normally undertake PPP residue analysis (mushrooms could be an example).	
Environment is very controlled:	
No use of PPP:	
Post harvest handling adds no risk or processing further residues risk(e.g. hulling):	

Operation Name:
Date:

ANNEX – CB 6 GLOBALG.A.P. GUIDELINE: CB 8.6.4 MRL EXCEEDANCE RISK ASSESSMENT

Background

Consumers are accustomed to a diverse variety of fresh and processed high quality food products, at affordable prices, available throughout the year. To satisfy this demand on a large scale, plants must be protected during growth against pests and diseases through the application of plant protection products (PPP). Depending on a variety of factors, toxic residues can sometimes remain on the surface of products all the way to the consumer. Maximum Residue Units (MRLs) are set so that farmers and regulatory agencies have an additional benchmark to include when analyzing a product's food safety.

It is in the interest of all persons working in agricultural production to take practical measures to ensure compliance with MRL standards. For GLOBALG.A.P., implementation of the GLOBALG.A.P. Standards is crucial to achieving certification. Despite following G.A.P. and local regulations, it is not always possible to eliminate PPP residues, however it is the responsibility of all in the food production chain to avoid exceedances of MRLs.

In order to deliver improved compliance to GLOBALG.A.P. protocols, producers must assess the risk associated with use of PPPs. The enclosed document provides examples of how MRL exceedances can occur so producers can modify their production procedures on farm during production.

Key Reasons Why MRL Exceedances May Occur

- Non compliance with good agricultural practices and label instructions, including improper or illegal use of PPPs
- No proper quality assurance standard applied to check production methods
- Differences in MRLs between the country of production (COP) and country of destination (COD), and other legal challenges in the application and communication of MRLs, such as occasional changes to MRLs midway through the growing season which fail to allow a producer to change his GAP. to ensure the final product complies with the modified MRL
- **Exceptional circumstances, where abnormal crop conditions, climatic or agronomic conditions are experienced**

I Producer Level (FIELD Level)

Cases that can be controlled by producers

- Failure to observe and comply with the on-label use instructions of PPPs:
    - Application method
    - Pre harvest interval

    - Handling and mixing
    - Errors in calculating concentration or spray volumes
    - Growing practices (covered vs. open production)
- Application of non registered PPPs (e.g. on minor crops)
- No proper use of additives or oils
- Application of illegal PPPs or use of formulation from non-authentic sources
- Failure to comply with general good agricultural practices (e.g. cleaning of equipment, discharge of spray mixture, management practices, including water management) and PHI
- Use of compost produced from treated plants
- Residues in the following (rotational) crops
- Sampling methods (by producer):
    - Cross contamination during sampling in field / pack-house
    - Incorrect sample taken due to human error in field / pack-house

Cases where control by Producer is minimal

- Rapid plant growth after application, leading to earlier harvest than foreseen and hence reduced PHI
- Spray drift from very closely planted neighboring crops

II Off Farm Level (Post farm gate)

Cases that can be controlled by producers

- Non-compliance with label instructions for post harvest-treatment used In downstream processing (e.g. pack houses) (see above)
- Poor management practices (e.g. failure to follow instructions and rules regarding hygiene/sanitation, safe storage and transport of PPPs which are designed to avoid direct contact of produce and PPPs).

No direct control by producer

- Lack of a complete set of globally harmonized MRLs
    - PHI not applicable to COD MRL (not relevant for produce of EU origin)
    - Lowering of MRL or withdrawal of all - combined with insufficient communication of changes
    - Different MRLs in COP and COD
    - Confusion regarding which MRL to comply with, given use of many several legal and private standards each with various MRL requirements
- Sampling methods (by third parties):
    - Cross contamination during sampling

        - In field
        - At depot
        - In store
    - Incorrect sample taken due to human error
        - In field
        - At depot
        - In store
    - Dry matter not divided homogenously in soil or plant material
    - Sample size too small
    - No harmonized sampling methods
- Testing and laboratory
    - Inherently large error margin to residue analyses
    - Wrong analytical method used
    - False positives (interference from plant-made actives, poor lab procedure, matrix effect)
    - Contrasting ability of certified and approved labs
- Statistical methods used, and conservatism in the way MRLs are set
    - According to EU Regulations MRLs are set based on a limited number of field trials using specified statistical methods, and in this context the ALARA (As Low As Reasonably Achievable) principle is employed
    - Due to the conservative way in which MRLs are set, and the statistical procedures that are in place, it is a mathematical inevitability that there will be a certain small percentage of MRL exceedances. The statistical possibility of such exceedances could only be eliminated by revising the legislation

Defining a Sampling Plan

Guidelines to Undertake a Risk Assessment to Define a Sampling Plan to Ensure Compliance with the MRLs

Background and Principles

- This risk assessment should conclude:
    - If PPP analyses are needed or not and how many
    - Where and when to take the samples
    - What type of analysis to perform
- The usual output of this risk assessment is a sampling plan that indicates the number, location, and timing that samples are to be taken and what type of analysis to perform
- The risk assessment should describe the reasoning and conclusions that led to the plan
- The sampling program should:

- Be a robust verification system of the GAPs implementation at farm and produce handling level
- Be a robust verification system that the residues in the product comply with the legal MRLs and customer specifications if applicable
- Control cross-contamination factors from neighbors, adjacent fields or though the environment (water, soil, application equipment, etc.)
- Ensure that only authorized products are used (i.e. only products registered for the crop are used in case the country of product has a PPP registration scheme or for organic product, that only products allowed in organic farming are used)

- The risk assessment should be done per crop (or group of similar crops, as can be the case of herbs), since the type of crop normally has a major impact on the risk
- The risk assessment shall be documented and reviewed annually

Number of Samples

- Factors to take into account to define the number of samples should include at least the following:
  - Crop: The type of crop can have a major impact on the risk. It is very different the risk in a mushroom production, a chestnut tree plantation or a table grape crop. In mushroom or chestnut tree plantation the risk assessment could conclude no residue analysis or minimal number of analyses is needed while in the grape it would be expected a much higher number of samples
  - Country of production: The country where the area of production is located can have an impact It should be know the historical data for each crop and country to assess the risk
  - Size: surface or tons of production. The bigger the size the bigger the risk
  - Number of PMUs (Production Management Units): The more PMUs the bigger the risk
  - **PPP** use Intensity: This factor is normally related to the type of crop (some crops require more PPP use than other), the location of the production are (in some areas there are more advanced IPM techniques, in other more pest pressure, etc.) and the skills and knowhow of each individual producer
  - Producer historical data: The historical data on PPP issues related to each individual producer should be taken into account

The number of producers, in addition to the factors above, should be taken as a crucial factor for producer groups. The bigger the number of producers the bigger the risk. The number of samples needs to be decides on a case per case scenario.

> Note: A thumb rule that could serve as a guideline: in many cases the value of the sampling + analysis is around 0.1- 0.5% of the value of the crop.

When and Where to Take the Samples

Once the number of samples is defined, it is important to decide when and where to take the samples.

- When: For each crop the most risky periods should be identified. To identify these periods' historical data for *that* crop and area should be considered. Also is important to have a good understanding of the crop agronomy and PPP use. In some cases it is useful to identify in which moments of the cycle there are more problems to comply with the pre-harvest intervals.
- Where to take the samples: this includes varieties and also locations
    - Crop varieties: Probably the risk of the different varieties is not the same. Some varieties tend to have more spraying than others; or PPP are applied closer to harvest; or are more sensible to pest or diseases
    - Sampling point: Should be considered if samples should be taken in the field, in the pack-houses, in transit, in destination, etc.
    - Origin of product: Also should be considered if some fields have bigger risks than others. Possible cross-contaminations from adjacent fields, previous crops, etc.
    - Field with more pest pressure; etc.

Type of Analysis

- There are multiple analyses available in the market and it is important to select those that are most appropriate and economically affordable. Considerations that should be made are:
    - If post-harvest treatments are used, these should also be covered by the analysis
    - The analysis should cover all (or at least most) of the active ingredients used as well as other active ingredients not used but that could be present in the environment (sprayed by the neighbor in another crop, cross-contamination, etc.).
    - *Active ingredients used that are not covered by the analysis due to technical or economical reasons should be identified and the risk of each one of these active ingredients should be assessed.*
        - It could be considered a low risk those active ingredients used at the beginning of the season, far away from harvest, that are not persistent and for which there has been no problems detected by the industry (laboratories, customers). In these cases the risk assessment could conclude that it is not needed to include the active ingredients in the analysis scope.
        - Other active ingredients with higher risks should be included in the analysis screening wherever possible. This could be done at origin in other laboratories, at destination by the customers, or in specific analysis undertaken not on a routine basis but just spot validation of the use of this PPP.