

Food Safety Cooperation Forum (FSCF)
Action Plan to Implement the APEC Regulatory Cooperation Plan
APEC Pesticide Maximum Residue Limits (MRLs) Roadmap

Introduction:

At the 4th APEC Food Safety Cooperation Forum (FSCF), held in April 2013, in Surabaya, Indonesia, the FSCF agreed to progress work on regulatory cooperation by endorsing an “FSCF Action Plan to Implement the APEC Regulatory Cooperation Plan.” It was agreed that the work would focus on two areas: Export Certificates and Pesticide Maximum Residue Limits (MRLs). The overall objective of the FSCF Action Plan is to promote alignment to relevant international standards wherever possible consistent with WTO obligations (the goal to which APEC Ministers agreed in 2011 and reaffirmed in 2012).

This paper will focus on the roadmap for MRLs. The MRLs roadmap outlines a way forward for consideration of regulatory cooperation on MRLs, building on the paper outlined and agreed to at the 3rd meeting of the APEC FSCF in Big Sky, Montana, 2011.

Background:

At the 3rd APEC FSCF meeting, a paper entitled *Recognition of Maximum Residue Limits (Appendix 1)* was delivered to the FSCF outlining issues relating to pesticide MRLs, including the effect on public health and trade facilitation amongst APEC member economies. At this meeting, an initial agreement on possible common approaches to pesticide MRLs was agreed to. This paper was developed following agreement at the 2nd APEC FSCF (2009) to address the FSCF goal of working towards food safety regulatory systems that are consistent with international standards, wherever possible. It was agreed at this meeting that an initial step could be to work towards aligning (regulatory convergence) MRL standards with Codex MRL or APEC MRL member economy standards.

Internationally, the Codex Alimentarius Commission sets MRLs for pesticide residues in foods and animal feed, providing a list of international standards for pesticide residues in foods. However, there are times when national MRLs for certain pesticide/commodity combinations are in place prior to the adoption of corresponding MRLs by the Codex Alimentarius. In these circumstances, the relevant government or chemical manufacturer may submit supporting data to Codex for development of an international standard. In other situations, national competent authorities may establish MRLs independently for the same pesticide/commodity combination, using different data sets due to different good agricultural practice (GAP) and/or methodologies, and different levels of protection.

The roadmap for regulatory cooperation on MRLs in APEC economies will allow the FSCF to facilitate, where practical and appropriate, the harmonization of MRLs across the region. This roadmap will also help ensure that this work is consistent with the APEC Leaders’ and the FSCF’s overall goal to promote alignment to relevant international standards.

Objective:

To develop a two year plan that will facilitate greater harmonization of pesticide MRLs between APEC member economies, with an initial focus on of MRLs for pesticides on wine grapes.

To achieve greater harmonization of APEC member economy MRL standards, it is proposed that, where feasible and consistent with domestic law, APEC member economies consider agreeing to and adopting, where practical and appropriate, a set of broad principles as follows:

1. participation in the development of MRLs in Codex Alimentarius;
2. incorporation of Codex compliant MRLs in domestic legislation;
3. work sharing, or exchanging data to support the establishment of pesticide MRLs by member economies, in order to encourage the adoption of Codex MRLs, in cases where there is no domestic equivalent for a member economy; and
4. unilateral recognition, where practical and appropriate, in domestic regulation of specific pesticide/commodity MRLs of trading partners on a case-by-case basis.

The key issue to consider in the promotion of harmonization of pesticide MRLs between exporting and importing countries in the APEC region, is whether APEC economies can be encouraged to recognise the MRL set by Codex Alimentarius (provided a suitable MRL exists in Codex). Alternatively, APEC economies could recognise the exporting economy's MRL, where there is no domestic equivalent MRL in the importing APEC economy, and where this lack of an MRL applying to the imported food results in a barrier to trade. For this to occur, it would be necessary to demonstrate that the dietary exposure assessment (both chronic and short-term) indicates no safety issue for the importing economy. An economy's decision to recognise another economy' MRL should also be based on the condition that the use in the exporting economy is consistent with that economy's GAP (if applicable); and is safe under the dietary exposure conditions of the importing economy.

Regulatory cooperation through recognition or harmonization of pesticide MRLs can also be advanced through data sharing and information exchange programs, which may assist in facilitating trade in safe food between APEC member economies, and where appropriate, reduce the burden of member economies in carrying out independent field trials and data generation in support of the establishment of pesticide MRLs.

Key Milestones:

1. Identify key issues, and consider an agreement on the above set of broad principles on harmonization of MRLs within the APEC region, and set priorities for the action plan. The principles could include the following elements:
 - a. Recognition that pesticides are used differently among production regions as product use patterns, pests and diseases and environmental factors differ internationally.
 - b. Recognition that member economies have the right to establish their own level of protection that they deem appropriate.
 - c. Where agreed upon by consensus, Member economies are encouraged to work together to establish Codex MRLs if it is determined that there is a need.
 - d. Where consistent with domestic law, importing APEC economies are encouraged to consider adopting an MRL established by the exporting member economy or by Codex, where no additional safety concerns are identified in the importing economy.
 - e. Where feasible, share work plans on future MRL development among APEC economies in order to increase transparency and awareness of MRLs that are scheduled to be reviewed or in a national registration process. Where

appropriate and consistent with domestic law, share data and information to allow for an improved process in considering the harmonization of pesticide MRLs. Data exchange will be beneficial in cases where an importing economy does not produce a particular product.

2. Review work undertaken by the World Wine Trade Group (WWTG) on of MRLs for pesticides on wine grapes:
 - a. Consider building upon the work being done in the WWTG to cover all APEC economies as a pilot project.
 - b. Assess the applicability of the WWTG work on of MRLs for pesticides on wine grapes to other commodities traded in the APEC region.

3. Secure the FSCF, SCSC and Trade Ministers endorsement for the broad principles for achieving greater harmonization of MRLs within APEC.

Process:

In order to achieve the stated objective, a working group was developed in the margins of the 4th APEC FSCF, with Australia and China leading this working group, and with the United States, Chinese Taipei, Thailand, the Grocery Manufacturers Association, and the Wine Regulators Forum as supporting economies and stakeholders. The working group would work predominantly out-of-session, but it is envisioned that there would need to be at least one (or perhaps two over a two year period) face-to-face workshop/meeting, perhaps the first in the margins of a SOM meeting in China in 2014, bringing together the APEC economy government and industry representatives, to:

- Convene the first meeting (e-meeting) of the pesticide MRLs working group to consider and, if possible agree, on the broad principles for greater harmonization of MRLs within APEC.
- Identify specific issues to be addressed and prioritise the schedule of work, including the pilot project on of MRLs for pesticides on wine grapes.

Work	Date	Other comments
Establish Working Group	2013	Surabaya
Present draft Roadmap to the Working Group	June-July 2013	
Present final Roadmap to the broader APEC FSCF for comment & endorsement	August 2013	
Monthly progress reports from issue leads (where appropriate)	August 2013 – August 2014	Monthly reports circulated to broader APEC FSCF
Agreement on broad principles for regulatory convergence of pesticide MRLs in APEC as per roadmap	September 2013	



Recognition of Maximum Residue Limits



Pesticide Maximum Residue Limits: Facilitating Trade and Protecting Public Health in the APEC Region

Purpose

The purpose of this paper is to introduce issues relating to pesticide maximum residue limits (MRLs) and their effect on public health and trade facilitation amongst APEC member economies. Recognizing that regulatory regimes and domestic legislation vary across APEC members, this paper advances concrete options for APEC economies to consider, consistent with domestic law, to protect public health and to reduce barriers to trade in the region. These options are (1) participation in the joint development and adoption of MRLs, including in Codex Alimentarius and (2) the unilateral recognition of specific MRLs of trading partners in domestic regulation.

Background

In 2009, the APEC Food Safety Cooperation Forum (FSCF) agreed to actively address the FSCF goal of achieving food safety regulatory systems that are consistent with international standards. It was agreed that an initial step in this direction could potentially be to work towards aligning standards, for example for maximum residue limits (MRLs) to be aligned with international standards.

A pesticide MRL may be regarded as the highest concentration of a chemical residue that is legally permitted, or accepted in a food at any time. The MRL does not indicate the actual amount of chemical that is always present in a food treated during production, but it does indicate the highest residue that could possibly result from the registered conditions of use of a particular pesticide on a specific crop in a country or region. Pesticide MRLs are used to monitor whether an agricultural chemical product has been used according to its registered use. MRLs act to protect public health and safety by ensuring that the pesticide(s) found on a commodity are at a level that is deemed safe through a scientific risk assessment and are as low as reasonably achievable to provide, effective control of pests and diseases.

Pesticide MRLs are also used as standards for international trade in food. If a limit is not listed in national regulation for a particular chemical/commodity combination, this often means there must be no detectable residues of that chemical in that commodity (known as “zero tolerance”). This general prohibition may mean that in the absence of the relevant MRL, the food may not be sold where there are detectable residues.

This Discussion Paper explores options to better align APEC member economy pesticide MRLs with those developed by other APEC economies; with those developed by Codex; or with those developed through collaborative or joint processes among APEC economies and proposes a number of recommendations for consideration.

Key Issues for consideration

Residues of pesticides are permitted in food where they are deemed safe and result from the legal use of registered pesticide products to control pests as permitted by the competent regulatory authority. In most countries, pesticide MRLs are set based on good agricultural

practice (GAP) and a human health risk assessment, including an assessment of dietary exposure. This reflects that a chemical must be safe for registered uses as specified on the pesticide label. Many countries will not have the same MRL for the same chemical or food combination because of specific environmental and use conditions and because regulatory approaches to MRL-setting and/or risk assessment methodologies may differ.

This lack of harmonization can lead to a barrier to trade for the exporting country, even in cases where the treatment of the crop in the exporting country has been undertaken using GAP and would not represent a health concern under dietary exposure conditions in the importing country.

Internationally, the Codex Alimentarius Commission sets MRLs for pesticide residues in foods and animal feed, providing a list of international standards for pesticide residues in foods. However, there are times when national MRLs for certain pesticide/commodity combinations are in place prior to the adoption of corresponding MRLs by the Codex Alimentarius. In these circumstances, the relevant government or chemical manufacturer may submit supporting data to Codex for development of an international standard. In other situations, national competent authorities may establish MRLs independently for the same pesticide/commodity combination, using different data sets due to different GAP and/or methodologies. This may result in divergent national regulatory standards.

Proposed Approach

To reduce unnecessary divergences across national regulatory standards, it is proposed that, where feasible and consistent with domestic law, APEC member economies consider undertaking one or more of the following options (1) participation in the development of MRLs in Codex Alimentarius; (2) adoption of Codex MRLs in domestic legislation; (3) work sharing or exchanging data to support the establishment of pesticide MRLs by member economies, in cases where there is no domestic equivalent for a Member economy; and (4) unilateral recognition in domestic regulation of specific pesticide/commodity MRLs of trading partners on a case by case basis.

Key issues to consider in the establishment of harmonised pesticide MRLs are whether to harmonise with a Codex MRL or trading partner MRL, dietary exposure assessments (chronic and short-term), and the approved or proposed uses of the pesticide in the country establishing the MRL. An economy's decision to harmonise should be based on the conditions that the use is consistent with good agricultural practice (GAP); and safe under the dietary exposure conditions of the importing country.

Greater harmonization can also be advanced through data sharing and information exchange programs and may assist in facilitating trade between member economies, and where appropriate, reduce the burden of member economies in carrying out independent field trials and data generation in support of the establishment of pesticide MRLs.

Recommendations

1. That a pilot project be initiated between APEC member economies for the purpose of promoting greater harmonisation of pesticide MRL standards. The pilot program involve the following steps:
 - (a) Recognition that pesticides are used differently among production regions as product use patterns, pests and diseases and environmental factors differ internationally.
 - (b) Consideration by APEC member economies to harmonize domestic standards with MRLs established by Codex or by a regulatory authority of an APEC member economy to facilitate trade in foods containing legitimate residues that do not pose health or safety concerns. Where issues are identified, APEC member economies may consider seeking relevant information from the exporting country relating to any established MRLs for pesticide residues in the relevant food.
 - (c) Where consistent with domestic law, an importing APEC economy may consider adopting an MRL established by the exporting member economy or by Codex, where no safety concerns are identified in the context of the diet of the importing country.
 - (d) Where feasible, share work plans on future MRL development among APEC economies in order to increase transparency and awareness of MRLs that are scheduled to be reviewed or in a national registration process. Where appropriate, share data and information to facilitate the adoption of harmonised pesticides. Data exchange may be particularly useful in cases where an importing country does not produce a particular product (e.g. setting of MRLs for tropical fruits in countries that do not grow tropical fruits.)
 - (e) Case-by-case assessment by APEC member economies will assist in facilitating trade.
2. The pilot will be subject to review and refinement by the FSCF within the next two years to ascertain whether it is delivering outcomes.