



**Asia-Pacific  
Economic Cooperation**

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**2017/SOM2/SCSC/FSCF/PTIN/WKSP2/003**

**Expert Working Group on Harmonisation of  
Maximum Residue Limits of Pesticides Among  
ASEAN Countries**

Submitted by: Japan



**Workshop on Future Perspectives on  
Harmonisation of Import Maximum Residue Limits  
Ha Noi, Viet Nam  
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## Expert Working Group on Harmonisation of Maximum Residue Limits (EWG-MRLs) of Pesticides Among ASEAN Countries

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## Expert Working Group on Harmonisation of Maximum Residue Limits (EWG-MRLs) of Pesticides Among ASEAN Countries

1. ASEAN COMMUNITY BUILDING
2. ASEAN ECONOMIC COMMUNITY
3. HARMONISATION OF ASEAN MRLs
4. PRINCIPLE AND PROCEDURES
5. REVIEWS OF ENDORSED ASEAN MRLs
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# ASEAN

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## ASEAN Member Countries



MYANMAR  
 THAILAND  
 CAMBODIA  
 SINGAPORE  
 INDONESIA  
 LAOS  
 VIETNAM  
 MALAYSIA  
 PHILIPPINES  
 BRUNEI DARUSSALAM


➤ 4.4 million square km  
 ➤ 3% total land area of earth  
 ➤ 625 million people

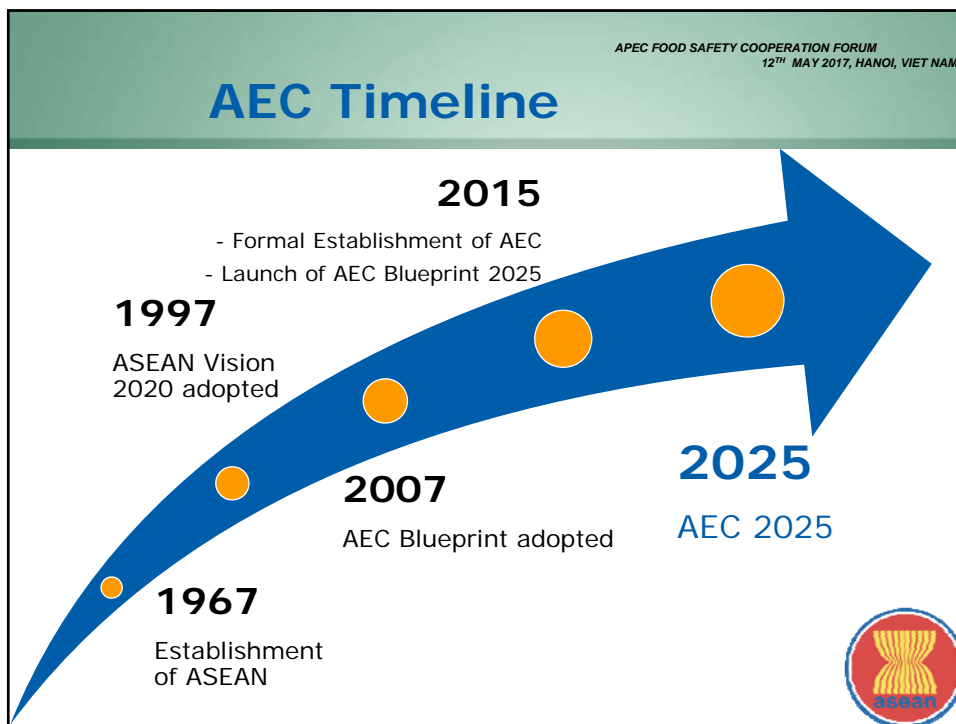


## ASEAN Community Building

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- A Community based on *three fundamental pillars* seeking to narrow development gap:
  - ASEAN Political and Security Community (APSC)
  - ASEAN Socio-Cultural Community (ASCC)
  - **ASEAN Economic Community (AEC)**
  - Initiative for ASEAN Integration (IAI)
- “Roadmap for an ASEAN Community 2015”.






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## AEC Blueprint 2025



- Adopted by Leaders at the 27<sup>th</sup> ASEAN Summit 22 Nov 2015
- Part of **ASEAN 2025: Forging Ahead Together**
  1. KL Declaration
  2. ASEAN Community Vision 2025
  3. APSC Blueprint 2025
  4. AEC Blueprint 2025
  5. ASCC Blueprint 2025




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## AEC 2025 Key Elements

Highly Integrated and Cohesive Economy	Competitive, Innovative, and Dynamic ASEAN	Enhanced Connectivity and Sectoral Cooperation	Resilient, Inclusive and People-Oriented, People-Centred ASEAN	Global ASEAN
<ul style="list-style-type: none"> <li>• Trade in Goods</li> <li>• Trade in Services</li> <li>• Investment Environment</li> <li>• Financial Integration, Financial Inclusion, and Financial Stability</li> <li>• Movement of Skilled Labour and Business Visitors</li> <li>• Participation in Global Value Chains</li> </ul>	<ul style="list-style-type: none"> <li>• Competition Policy</li> <li>• Consumer Protection</li> <li>• IPR Cooperation</li> <li>• Productivity-Driven Growth, Innovation, R&amp;D, and Tech Commercialisation</li> <li>• Taxation Cooperation</li> <li>• Good Governance</li> <li>• Regulations and Good Regulatory Practice</li> <li>• Sustainable Economic Development</li> <li>• Global Megatrends and Emerging Trade-related Issues</li> </ul>	<ul style="list-style-type: none"> <li>• Transport</li> <li>• Information and Communications Technology</li> <li>• E-commerce</li> <li>• Energy</li> <li>• <b>Food, Agriculture, and Forestry</b></li> <li>• Tourism</li> <li>• Healthcare</li> <li>• Minerals</li> <li>• Science and Technology</li> </ul>	<ul style="list-style-type: none"> <li>• Micro, Small, and Medium Enterprises</li> <li>• Strengthening the Role of the Private Sector</li> <li>• Public-Private Partnership</li> <li>• Narrowing the Development Gap</li> <li>• Contribution of Stakeholders on Regional Integration Efforts</li> </ul>	<ul style="list-style-type: none"> <li>• Strategic and coherent approach towards external economic relations</li> <li>• Review existing FTAs</li> <li>• Enhance economic partnerships with non-FTA Dialogue Partners</li> <li>• Engage with regional and global partners</li> <li>• Supporting the multilateral trading system and actively participating in regional fora</li> <li>• Engagement with global and regional institutions.</li> </ul>

\*New areas are highlighted



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## Food, Agriculture and Forestry Cooperation

### Vision and Strategic Plan for ASEAN Cooperation in FAF (SP-FAF) (2016-2025) - (approved by 37<sup>th</sup> AMAF, 2015)

**Vision**

- *A competitive, inclusive, resilient and sustainable Food, Agriculture, and Forestry (FAF) sector integrated with the global economy, based on a single market and production base contributing to food and nutrition security and prosperity in the ASEAN Community*

**Goals:**

- *Ensuring equitable, sustainable and inclusive growth*
- *Alleviating poverty and eradicating hunger*
- *Ensuring food security, food safety and better nutrition*
- *Deepening regional integration*
- *Enhancing access to global markets*
- *Increasing resilience to, and contributing to mitigation and adaptation of climate change, natural disasters and other shocks*
- *Achieving Sustainable Forest Management (SFM)*



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## Strategic Thrusts

- **Strategic Thrust 1: Enhance quantity and quality of production with sustainable, 'green' technologies, resource management systems, and minimise pre- and post-harvest losses and waste**
- **Strategic Thrust 2: Enhance trade facilitation, economic integration and market access**
- **Strategic Thrust 3: Ensure food security, food safety, better nutrition and equitable distribution**
- **Strategic Thrust 4: Increase resilience to climate change, natural disasters and other shocks**
- **Strategic thrust 5: Assist small scale producers and SMEs to improve productivity, technology and product quality, to meet global market standards and increase competitiveness in line with the ASEAN Policy Blueprint on SME Development**
- **Strategic Thrust 6: Strengthen ASEAN joint approaches on international and regional issues**
- **Strategic Thrust 7: Promote sustainable forest management**



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- **Strategic Thrust 1: Enhance quantity and quality of production with sustainable, 'green' technologies, resource management systems, and minimise pre- and post-harvest losses and waste**

1.5 Develop new and appropriate technologies, best practices and management systems to ensure food safety and address health/disease and environmental issues, particularly in the fast growing crops sub-sectors.

- *Develop regional agricultural standards and best practices: ASEAN Harmonised MRLs; ASEAN Standards for horticultural produce and other food crops; ASEAN Guidelines for the importation of priority crops etc.*



## HARMONISATION of ASEAN MRLs

### Objectives:

- To facilitate intra- and extra-ASEAN trade of agricultural commodities.
- To protect consumers' health.

**1996** - The Experts Working Group on the Harmonisation of Maximum Residue Limits (EWG-MRLs) of Pesticides among ASEAN Countries

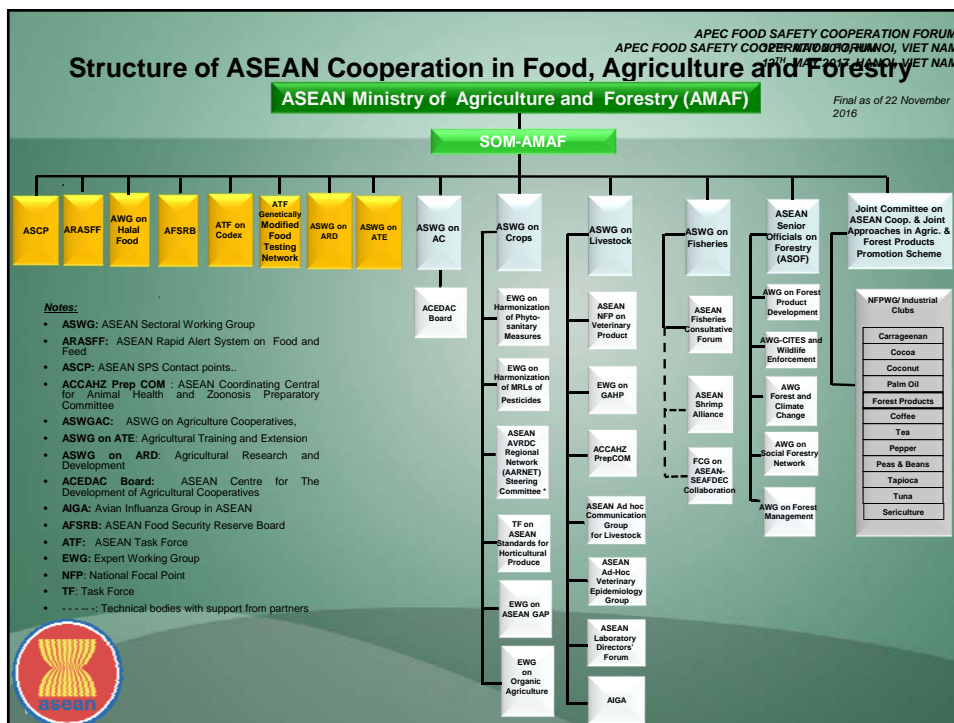
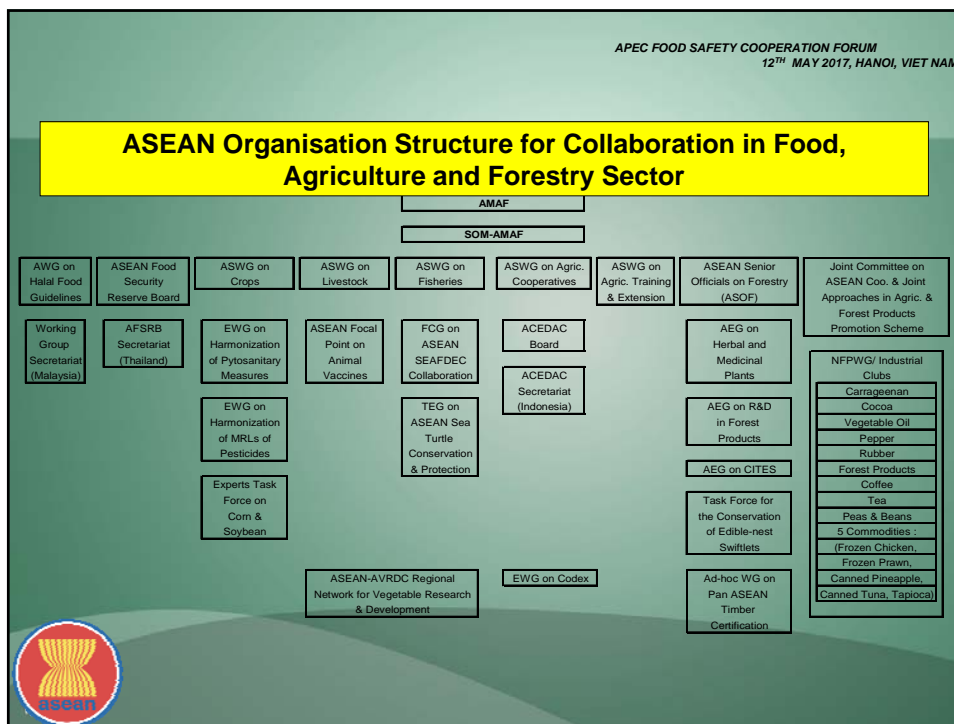
- *To establish maximum limits for pesticide residues in crop commodities for adoption as ASEAN harmonised MRLs.*
- *To prepare priority list of pesticide/crop combination for evaluation and subsequent harmonisation of MRLs at the Meeting.*
- *To adhere to a science-based protocol and procedure in the process of setting ASEAN harmonised MRLs in line with international procedures e.g Codex.*



## Jargons in ASEAN Organisation

1. EWG : Expert Working Group
2. ASWGC : ASEAN Sectoral Working Group in Crop
3. SOM-AMAF : Senior Official Meeting- ASEAN Minister of Agriculture and Forestry
4. AMAF : ASEAN Minister of Agriculture and Forestry
5. AWG : ASEAN Working Group







## ASEAN MRLs could be set up by 3 ways

1. Adoption from Codex MRLs → *early stage of EWG MRLs.*
2. Extrapolation from similar crops
  - *very few cases due to lack of information on crop grouping and representative crops in the region.*
3. Pesticides residue trials → *following Codex procedures*



## PRINCIPLES AND PROCEDURES

**A. Principles of Harmonisation of ASEAN-MRLs,**  
*Adopted by the 12<sup>th</sup> EWG-MRLs, 16-18 Jan. 2008,*  
*Makati City, Philippines*

**B. The “Revised Principles of Harmonisation of ASEAN-MRLs”,**  
*adopted by the 38<sup>th</sup> AMAF Meeting,*  
*6 October 2016, Singapore*



## A. Principles of Harmonisation

- Pesticide proposed must be registered in any ASEAN countries.
- ASEAN MRLs could be adopted from Codex MRLs, if available and applicable.
- If Codex MRLs are not acceptable, modification of MRL has to be supported with residue trial data and/ or risk assessment based on Codex procedures.
- If Codex MRLs are not available, establishment of MRL will follow Codex procedures using local residue trials and dietary risk assessment.



## The “Revised Principles of Harmonisation of ASEAN-MRLs”

- i. Where Codex MRLs are available and applicable, these should be adopted as harmonised ASEAN MRLs, Subject to the agreement of AMS.
- ii. Where Codex MRLs are available but not acceptable due to intake concern, modification of MRLs should be supported with residue trial data and/ or risk assessment based on Codex procedures.
- iii. Where Codex MRLs are not available, individual Member Countries could propose MRLs to be considered by the EWG-MRLs for harmonization. For such harmonization process, supporting data including residue trial data, GAP, food consumption data and/ or risk assessment need to be examined by the EWG-MRLs. Submission of residue trial data should follow the standard format as adopted by the EWG-MRLs. Further detail of the guiding principles



- iv. In generating regional data for harmonization process, minimum of four residue trials<sup>1</sup> are required for consideration and establishment of ASEAN harmonised MRLs.
- iv. Relevant data should be provided for setting EMRL (Extraneous Maximum Residue Limit) of persistent pesticides.
- vi. Pesticides proposed for setting up ASEAN MRLs should have registered uses in at least one ASEAN Country, and the pesticides commodity combination is important for trade among AMCs. The pesticides should have been completely toxicological evaluated by JMPR or OECD countries, otherwise toxicological evaluation have to be submitted to EWG-MRLs by the proposing country.



- vii. Harmonised ASEAN MRLs should be reviewed when it is needed in the situations.
- viii. The grace period should be applied for minimum 3 trials. The nomination of pesticide - commodity combinations for harmonisation of ASEAN MRLs made at or before the EWG MRLs 2017 is acceptable for 3 trials.

*Note 1: The grace period should be applied for minimum 3 trials.*

*The nomination of pesticide – commodity combinations for harmonisation of ASEAN MRLs made at or before the EWG MRLs 2017 is acceptable for 3 trials.*



## B. Data requirement for Harmonise ASEAN

### MRLs

Residue data from supervised trials in relation to national GAP.

- Dietary exposure estimate, based on food consultation data and food chemical concentration, using different data base for chronic exposure and acute exposure assessment



## Consideration of Residue Trials Field Report / Data

### Field Trial Report

- **General information – pesticide, formulation, trial number and type, commodity and variety, test location, soil characteristic, name of the person(s) responsible**
- **Application data for field trials – plot plan, size or number of plant per plot, replicate, method of application, number of application and dates, dose rate, climatic conditions, growth stage at (last) treatment.**
- **Sampling Data-growth stage at sampling, method of sampling sample portion, sample weight and preparation, control and treated sample, date of sampling with time interval between last application, storage conditions before transporting to laboratory**




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## Consideration of Residue Laboratory Report / Data

### Laboratory Report

- Details on the method used – full description or adequate reference, apparatus, chemicals and reagents, validation data, recovery data
- Preparation of sample – peeling, chopping, washing, drying
- Presentation of data- complete data should be provided, how residues are calculated, chromatographic and/or spectrophotometric evidence to support the analysis data must be submitted.



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## SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES

(Application on agricultural and horticultural crops)  
Responsible body for reporting (name, address):

Page :  
Country :

Date :

Pesticide (s) (common name) :  
CCPR No. (s) :  
Trade name (s) :  
Main uses e.g. insecticide, fungicide :  
Use Pattern :

1	2	3	4		6			7		8	9
Crop and /or Situation	Field Or Green House	Pest or Group of Pest Controlled	Formulation		Application			Application rate per treatment		PHI ( days)	Remarks
			Type	Conc. a.i. (%)	Method, kind	Growth stage	Number (range)	kg a.i. / hL	Water L / ha		



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# PART A

## REPORT ON PESTICIDE RESIDUE TRIAL. PART A FIELD REPORT

Page 1

1. Please type or use block capitals


### 1. RESPONSIBILITY

<sup>1</sup> YEAR		<sup>3</sup> Company or Organisation Name and Address	
<sup>2</sup> Trial identity or number			
<sup>4</sup> Person (s) responsible for (include signature)	a. Trial design .....		
	b. Application .....		
	c. Sampling .....		
	d. Analysis .....		

### 2. IDENTITY OF TRIAL

<sup>5</sup> Active ingredient (s) (common name)	<sup>6</sup> Class of pesticide of agricultural use	<sup>7</sup> Trade name (s) or Code number (s)	<sup>8</sup> Formulation		
			Type	Conc'n in SI units	Comm/ exper'l

Crop/ commodity		Location	
<sup>9</sup> Type		<sup>12</sup> Country/ region	
<sup>10</sup> Variety/cultivar		<sup>13</sup> Site or Map ref. (include address)	
<sup>11</sup> Codex commodity classification			
<sup>14</sup> Pests/ diseases			



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# PART B

## REPORT ON PESTICIDES RESIDUE TRIALS. PART B. ANALYTICAL REPORT

Person (s) responsible for the analysis \_\_\_\_\_

(Please type or use BLOCK capitals)

### IDENTITY OF SAMPLE

Crop commodity	Sample identity or number
Pesticides (s) on samples	

### CONDITION AND TREATMENT OF SAMPLE (S)

Date(s) of receipt in laboratory	Date (s) of analysis
Method of storage and condition of sample(s)	
Portion of sample(s) to be analysed	

### ANALYSIS

Method of analysis (or reference) and/or modifications	
Extraction: clean-up	
Method of determination and expression of residue	
Recoveries	
Limit of determination	


### RESULTS

Dosage rate	
Interval (Treatment to sampling)	
Residue* (Not corrected for recovery or control)	
Control (including standard deviation)	

nd. = <LOQ =      mg/kg

Other information e.g. stability of residues under storage conditions:

\* give mean values range and number of analyses



## D. Requirements for residue field trial to generate Harmonise ASEAN MRLs

- A minimum number of 3 trials (*before 2017*) and 4 trials (*after 2017*) are required in the region.
- This must be conducted under worst case scenario or critical GAP (e,g max no. of applications, highest rate etc.)
- In the case of increasing or reduction of application rate, the rate 25% rule is allowed.



## E. Rational for submission of proposal for harmonisation of ASEAN MRLs - The 17<sup>th</sup> Meeting of EWG-MRLs, 23-25 January 2013, Ho Chi Minh City, Viet Nam

- Agreed to the checklist form / General Information & Rationale for proposing field trials for setting up ASEAN Harmonised MRLs.
- The checklist should be submitted by the proponent countries when submitting new proposal, **starting 2014.**
- In cases that the checklist is not ready, AMSs shall submit the completed checklist within 2 months after the submission of new proposal to the ASEAN Secretariat for further circulation to AMSs.


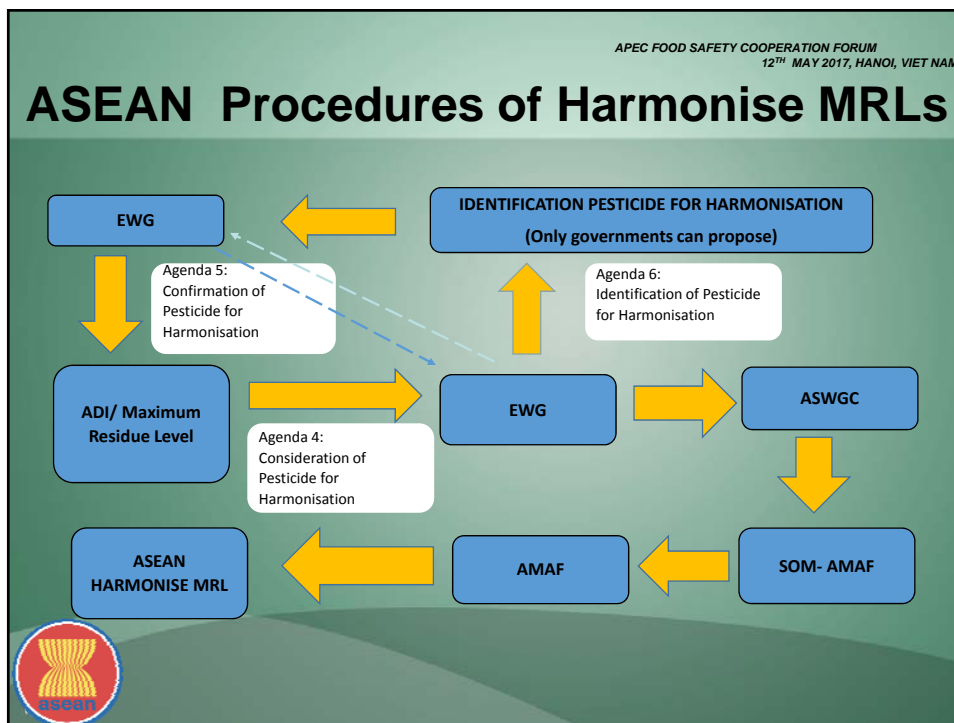


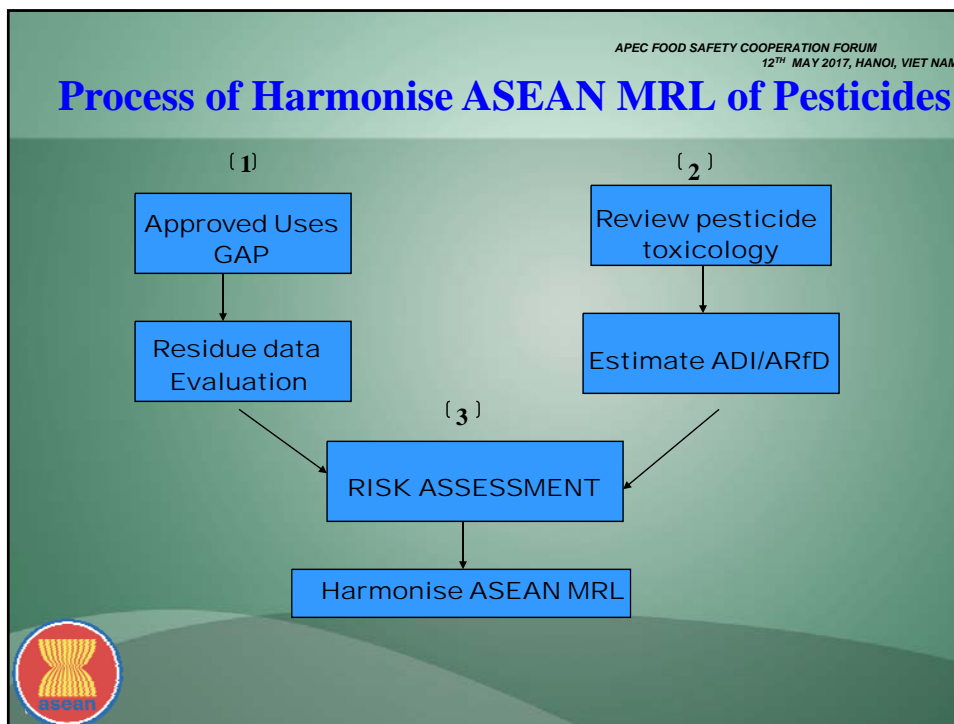


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### General Information and Rationale for Proposing Field Trials for Setting up Harmonized ASEAN Pesticide MRLs

Pesticide Common Name:	
WHO Hazard Classification	
Is the pesticide under Codex List? (Y/N). •If No, please specify the reason and provide explanation.	
ADI (including Year of Last Revision)	
ARfD (Year of Last Revision)	
Codex Residual Definition for compliance	
Codex Residue Definition for dietary risk assessment	
Crop(s) to be applied	
Formulation to be applied	
Targeted Pests	
National label available or to be available by year of .....	




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## Status ASEAN Harmonised MRLs (\*)

\* Total ASEAN Harmonised MRLs endorsed by AMAF (without review)

AMAF	ASEAN MRLs endorsed by AMAF
20 <sup>th</sup> AMAF, 14-16 September 1998, Hanoi	10
21 <sup>st</sup> AMAF, 28-29 October 1999, Bandar Seri Begawan	38
22 <sup>nd</sup> AMAF, 26-27 October 2000, Phnom Penh	122
24 <sup>th</sup> AMAF, 11 October 2002, Vientiane	94
25 <sup>th</sup> AMAF, 21 August 2003, Kuala Lumpur	105
26 <sup>th</sup> AMAF, 7 October 2004, Yangon	86
27 <sup>th</sup> AMAF, 29 September 2005, Tagaytay City, the Philippines	104
28 <sup>th</sup> AMAF, 16 Nov 2006, Singapore	117
29 <sup>th</sup> AMAF, 1 Nov 2007, Bangkok	99
30 <sup>th</sup> AMAF, 23 October 2008, Ha Noi	27
31 <sup>st</sup> AMAF, 10 November 2009, Bandar Seri Begawan	7
32 <sup>nd</sup> AMAF, November 2010, Phnom Penh	13
33 <sup>rd</sup> AMAF, 6 October 2011, Jakarta	8
34 <sup>th</sup> AMAF, 27 September 2012, Vientiane	12
35 <sup>th</sup> AMAF, 26 September 2013, KL	6
36 <sup>th</sup> AMAF, 23 September 2014, Nay Pyi Taw	73
37 <sup>th</sup> AMAF, 10 September 2015, Makati City	5
38 <sup>th</sup> AMAF, 6 October 2016, Singapore	4
<b>Total</b>	<b>930</b>



## Status as of November 2016

Total established ASEAN Harmonised MRLs:  
**959, involving 73 pesticides**, with the following status:

- ✓ Active : **902** MRLs
- ✓ Deleted: 57 MRLs (based on the result of reviews)



## REVIEW OF ENDORSED ASEAN MRLs

### A. Reason for reviewing ASEAN MRLs

- **Case 1** : The Codex MRLs have been amended to the different (higher or lower) value.
- **Case 2** : The Codex MRLs have been amended to the different (higher or lower) value on the different, but related, commodities.
- **Case 3** : The Codex MRLs remain the same value but have been established on the different, but related, commodities.
- **Case 4** : The Codex MRLs have been deleted on some commodities. The main reason for the deletion was that there were not enough residue data supported for the periodic re-evaluation by JMPR.
- **Case 5** : All Codex MRLs for specific pesticides have been deleted because of no data supported from manufacturer and countries



## B. Principles to review ASEAN MRLs - 10<sup>th</sup> EWG-MRLs 12-14 December 2005, Yogyakarta

- In case of Codex MRLs has been changed, the EWG would consider amending the ASEAN MRLs on case-by-case basis (Case 1 and 2);
- In case of Codex MRLs has been established for different, but related, commodities, the EWG would consider amending the commodity name according to Codex and add the synonym of crops in the annex (Case 3);
- In case of Codex MRLs has been deleted on some commodities, the EWG should retain the ASEAN MRLs, except the MRLs with acute intake concerns (Case 4);
- In case of Codex MRLs for specific pesticides has been deleted due to the lack of data supported from manufacturer and countries, the EWG should examine and consider to delete or to retain the ASEAN MRLs supported by residue trial data from the respective resources (Case 5).



## Review of ASEAN Harmonised MRLs

- **1<sup>st</sup> Review** (before 2008)
  - *Methamidophos on tomato, changed from 2 mg/kg to 1 mg/kg*
- **2<sup>nd</sup> Review** → Reviewed for 189 ASEAN MRLs endorsed by AMAF during the period of 1998 – 2002 and resulted on:
  - 52 MRLs were revised (case 1,2,3) (The 13<sup>th</sup> EWG MRLs, 13-15 January 2009)
  - 133 MRLs - case 4 & 5 (The 14<sup>th</sup> EWG-MRLs, 13-15 January 2010)
    - 56 MRLs deleted
    - 77 MRLs maintained
  - 1 MRL (carbofuran in potato) deleted (case 4) & 3 MRLs maintained (case 1) (The 15<sup>th</sup> EWG-MRLs, 12-14 January 2011)



- **3<sup>rd</sup> Review.** Thailand conducted review for ASEAN MRLs that were based on Codex MRLs and adopted by AMAF during 2009 – 2014. The result was those all ASEAN MRLs are in-line with updated Codex MRLs (*19<sup>th</sup> EWG-MRLs, 20-22 January 2015, Siem Reap, Cambodia*)
- **4<sup>th</sup> Review.** Review of ASEAN MRLs based on Codex MRLs and adopted by AMAF during 1998 – 2008 is in progress.



## Way forward


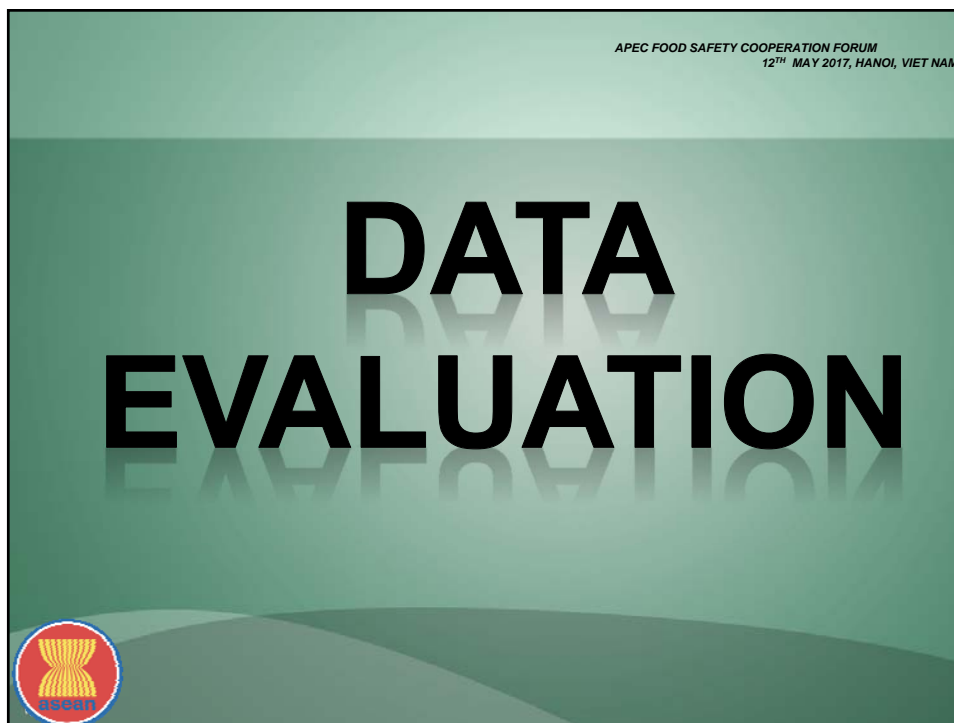
- Adoption of ASEAN MRLs to be part of AMS regulatory framework (35<sup>th</sup> AMAF, 26 September 2013).
- Submission of ASEAN Supervised Pesticides Residue Field Trials (SPRT) data to the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) to enable the recognition of ASEAN MRLs as Codex MRLs.



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## ASEAN HARMONISED MRLs


	PESTICIDE	COMMODITY	MRL
1	buprofezin	basil leaf	3
2	carbofuran	egg plant	0.05
3	carbosulfan	asparagus	0.06
4	chlorpyrifos	litchi	2
5	cyhalothrin	soybean immature	0.2
6	cypermethrin	shallot bulb	0.1
7	deltamethrin	asparagus	0.1
8	diazinon	garlic	0.1
9	dimethoate	Yard long bean	0.05
10	fipronil	basil leaf	0.6
11	imidacloprid	okra	0.1
12	Lamda-cyhalothrin	basil leaf	0.5
13	metalaxyl	pineapple	0.1
14	omethoate	Yard long bean	0.01

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## SUPERVISED TRIAL – DATA EXTRACTION & VALIDITY


- ✓ Most supervised trials are carried out by government agencies (nominee).
- ✓ The nominee must generate and provide such data and all the supporting information as part of the requirements for national pesticide registration.
- ✓ construction of the summary data tables is part of the evaluation process.
- ✓ The aim in constructing the summary tables is to produce a summary of valid data.
- ✓ interpretation of the data is difficult if questionable data are mixed with valid data.




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## EVALUATION OF SUPERVISED TRIAL DATA

- ✓ The data generation with the enforcement residue definition are needed for the estimation of the maximum residue limit while data with the risk assessment definition are needed for the STMR and HR.
  - ✓ This means that the sample from supervised residue trials should be analysed such a way as to cover both situations.
  - ✓ Ideally the parent compound and the relevant metabolites should be reported individually, so that the needs of the different residue definitions can be met.






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## Statistical Method – Estimation of Maximum Residue Levels

- Statistical methods for calculating MRLs directly from the results of supervised residue trials.
- The task of calculating MRLs from the results of residue trials is formidable .
  - Sets of residue trial are generally not designed for statistical calculation
  - A dataset are unlikely to be a random representative sample of crop that occur in commercial practice
  - The number of data points is limited, necessitating extrapolation beyond the range of observations
  - Data distributions are generally unknown
- Consequently, the situation is evolving with new methods and modifications to old methods appearing each year.
- JMPR recent years they tested a version of an OECD calculator.



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## MRL FOR COMMODITY GROUPS


- ✓ A group MRL can be achieved in the simplest case by satisfying two requirements.
  - ✓ The pesticide is registered or authorized on the crop group
  - ✓ Relevant and adequate residue data are available for at least one major commodity of the group
- ✓ The crop group with the registered uses corresponds with the commodity group with the MRLs
- ✓ Commonly adopted commodity group MRLs are citrus fruits, pome fruits, stone fruits, leafy vegetables, cucurbits fruiting vegetables.



## EXTRAPOLATION OF RESIDUE (PRECONDITIONS)

- ✓ Extrapolation of residue data for different crops presumes that the following are comparable.
  - ✓ Conditions of use with regard to the amount of active ingredient applied
  - ✓ the time of application
  - ✓ The number of application
  - ✓ The interval between application
  - ✓ Application method
  - ✓ Formulation used
  - ✓ Climatic conditions







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## MINOR CROPS

- A minor use crop may be defined as:  
“a crop that is grown on a small area and therefore uses amounts of pesticides that are too small to justify standard pesticide registration”
- MRLs may be obtained for pesticide residues on commodities from minor crops by:
  - I. Inclusion in a commodity group MRL
  - II. Extrapolation from pesticide uses on a relevant major crop
  - III. Evaluation of an adequate data package for the use on a minor crop
- Points to note
  - I. GAP for the minor crop must be the same as or similar to that of the major crop
  - II. GAP for the minor crop must be valid, e.g. on a registered label



APEC FOOD SAFETY COOPERATION FORUM  
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# *Thank you*

