# **Harnessing Efforts and Lessons Learnt in Harmonization of Approaches for Risk Assessment and Approval Process of Food Additives in ASEAN**

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Presented at "Seminar on Food Additives: Perspectives on Scientific Processes, Regulatory Development & Impact of Changes", Hanoi, Vietnam, July 11, 2017 and Jakarta, Indonesia, July 13, 2017

# **OUTLINE**

- Introduction
  - ASEAN Economic Community (AEC) 2015 at a Glance
  - ATIGA (ASEAN Trade in Goods Agreement)
- Approaches in Harmonization of Food Safety Standards (Food Additives) in the ASEAN
- Progress in Food Additive Standards Harmonization
- Risk Assessment to Support Food Safety Standards Harmonization
- Summary

Dedi Fardiaz Hanoi (July 11); Jakarta (July 13, 2017) Dedi Fardiaz Hanoi (July 11); Jakarta (July 13, 2017)

# **ASEAN ECONOMIC COMMUNITY**



# Membership: 10 states

- Brunei
- Darussalam
- Cambodia
- Indonesia
- Lao PDR
- Malaysia
- Myanmar
- Philippines
- Singapore
- Thailand
- Viet Nam

**Total Area:** 4,435,674 km<sup>2</sup>

**ASEAN Economic Community 2015** "establish ASEAN as a single market and production base with the goal of making ASEAN more dynamic and competitive."

Under the new Blueprint, a stronger AEC is envisaged by 2025 with the following characteristics:

- a. A Highly Integrated and Cohesive Economy;
- b. A Competitive, Innovative, and Dynamic ASEAN;
- c. Enhanced Connectivity and Sectoral Cooperation;
- d. A Resilient, Inclusive and People-Oriented, People-Centred ASEAN; and
- e. A Global ASEAN

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| ASEAN Economic Community 2025   |   |  |   |  |  |  |
|---|---|--|---|--|--|--|
| A Highly Integrated<br>and Cohesive<br>Economy  | A Competitive, Innovative, and<br>Dynamic ASEAN   | Enhanced<br>Connectivity and<br>Sectoral Cooperation | A Resilient, Inclusive<br>and People-<br>Oriented, People-<br>Centred ASEAN | A Global<br>ASEAN  |  |  |
| Trade in Goods  | Effective Competition Policy  | Transport  | Strengthening<br>the Role of<br>Micro, Small,<br>and Medium<br>Enterprises  | More strategic and coherent<br>approach towards external<br>economic relations   |  |  |
| Trade in Services   | Consumer Protection   | Information and<br>Communications<br>Technology      | Strengthening the<br>Role of the Private<br>Sector                          | Review existing FTAs   |  |  |
| • Investment<br>Environment   | Strengthening Intellectual<br>Property Rights Cooperation   | E-commerce   | Public-Private<br>Partnership   | Enhance economic<br>partnerships with non-<br>FTA Dialogue Partners by<br>upgrading and strengthening<br>trade and investment work<br>programmes/plans |  |  |
| <ul> <li>Financial Integration,<br/>Financial Inclusion,<br/>and Financial<br/>Stability</li> </ul> | Productivity-Driven Growth,<br>Innovation, Research and<br>Development, and Technology<br>Commercialisation | Energy   | Narrowing the<br>Development Gap  | Engage with regional and<br>global partners  |  |  |
| <ul> <li>Facilitating<br/>Movement of Skilled<br/>Labour and Business<br/>Visitors</li> </ul>       | Taxation Cooperation  | Food, Agriculture,<br>and Forestry                   | Contribution of<br>Stakeholders<br>on Regional<br>Integration Efforts       | Continue strongly supporting<br>the multilateral trading system<br>and actively participating in<br>regional fora                                      |  |  |
| Enhancing     Participation in     Global Value Chains  | Good Governance   | Tourism  |   | Continue to promote<br>engagement with global and<br>regional institutions   |  |  |
|   | Effective, Efficient, Coherent<br>and Responsive Regulations,<br>and Good Regulatory Practice               | Healthcare   |   |  |  |  |
|   | Sustainable Economic<br>Development   | Minerals   |   |  |  |  |
|   | Global Megatrends and<br>Emerging Trade-related Issues  | Science and<br>Technology                            |   |  |  |  |
|   |   |  |   |  |  |  |

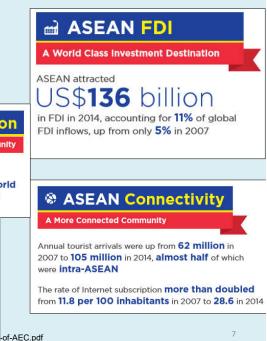
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Total trade increased by nearly

trade by partner.

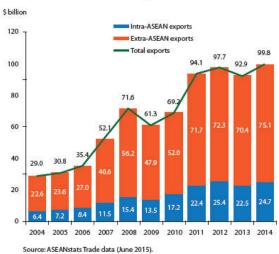
between 2007 and 2014, with intra-ASEAN trade comprising the largest share of ASEAN's total





# ASEAN TRADE Total trade, 2007-2014: increased by nearly US\$1 trillion Major Trading Partners, 2014 Intra-ASEAN trade comprises the largest share of ASEAN's total trade by partner 10% 9% 8% Source ASEAN Statistics

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ASEAN's Trade in Agro-based Products

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The objective of this Agreement is to achieve free flow of goods in ASEAN as one of the principal means to establish a single market and production base for the deeper economic integration of the region towards the realisation of the AEC by 2015

# CHAPTER 8 SANITARY AND PHYTOSANITARY MEASURES Article 79

The objectives among others are to:

- facilitate trade between and among Member States while protecting human, animal or plant life or health in each Member State
- strengthen co-operation among Member States in protecting human, animal or plant life or health

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ASEAN Trade in Goods Agreement
ATIGA

Food Safety Standards Harmonization is an Important Step to Support ASEAN Single

Market

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# CHAPTER 7 STANDARDS, TECHNICAL REGULATIONS AND CONFORMITY ASSESSMENT PROCEDURES Article 74 Standards

## 2 of 6 paragraphs

2 In harmonising national standards, Member States shall, as the first and preferred option, adopt the relevant international standards when preparing new national standards or revising existing standards.

Where international standards are not available, national standards shall be aligned among Member States

4 Harmonisation of the existing national standards and adoption of international standards into new national standards should be based on "Adoption of International Standards as Regional or National Standards", as contained in the ISO/IEC Guide 21 or its latest edition

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# Food Safety Standards Harmonization Efforts in the ASEAN

Since 2002, the ASEAN Food Safety Standards Harmonization Workshop Series sponsored by ILSI Southeast Asia Region have been used as a forum for regulators in the region:

- to facilitate the exchange of information and scientific updates in food safety and standards;
- to discuss and share potential mechanisms for the improvement of food safety standards in the ASEAN member states;
- to facilitate harmonization efforts towards Codex, where they exist; or towards scientifically-sound regional standards where Codex standards are not in place; and
- to identify gaps for exposure data development and risk assessment capacity building.

# How do we do it

The way we compared food additives (colorings) for the first time, 2002 S T V CODEX ADI P USFDA FSANZ 00 **Allura Red** 0 0-0.5 **Amaranth** 0 - 12.5**Brilliant Blue** 0 0 **Brilliant Black** 0 0 0 - 4Carmoisin 00 0 0 - 1.5 **Chocolate Brown HT** 0 - 0.1**Erythrosine** 0 0 - 4Ponceau 4R 0-2.5 **Tartrazine** 0 - 7.50 - 2.5**Fast Green FCF** 0 0 0 0 - 10 0 No ADI 0 Green S 0000 0 - 15 Chlorophyl- Cu complex **Indigo Carmine** 0-5 Red 2G 0 0 0 0-0.1 B = Brunei I = Indonesia M = Malaysia P = Philippines S = Singapore T = Thailand V = Vietnam

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# **GSFA Food Category System used as Harmonization Template**

- In the first three workshops, the Working Group agreed on the use of Codex General Standards for Food Additives (GSFA) as the basis for harmonization.
- GSFA Food Category System was used as template for comparing food additive standards similarities and differences among ASEAN member states.
- To further facilitate the harmonization efforts, an online database of ASEAN Food Safety Standards was developed and maintained by ILSI SEA Region. This database contains the national data which can be compared with Codex GSFA for harmonization process.

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#### **General Standard for Food Additives FAST GREEN FCF INS: 143 Function: Colour** М **Food Category** (mg/kg) Dairy-based drinks, flavoured and/or fermented 100 (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks) 01.7 100 Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt) Harmonized among AMSs and with Codex 02.1.3 Lard, tallow, fish oil, and other animal fats **GMP** 03.0 Edible ices, including sherbet and sorbet 100 04.1.2.4 Canned or bottled (pasteurized) fruit 200 Each AMS fills the column with ML of Food Additive (Fast Green FCF) 04.1.2.5 Jams, jellies, marmelades 400 permitted in each food category 04.2.2.3 Vegetables (including mushrooms and fungi, 300 roots and tubers, pulses and legumes, and aloe vera) and seaweeds in vinegar, oil, brine, or soy 04.2.2.4 Canned or bottled (pasteurized) or retort pouch 200 vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds Hanoi (July 11); Ja a **300**/ 05.3 De Chewing gum

# general Standard for Food Additives

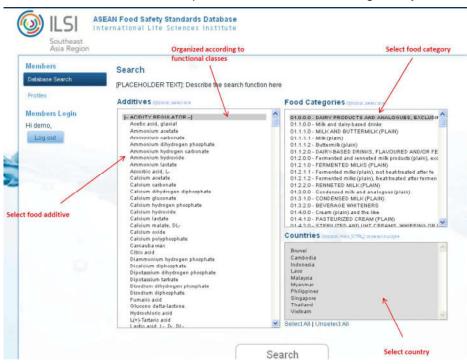
FAST GREEN FCF INS: 143 Function: Colour

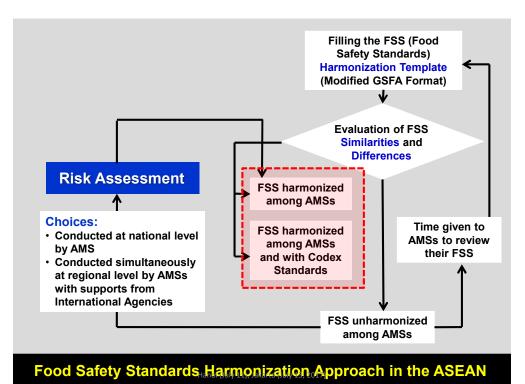
| Food Cat. No. | Food Category   | ML (mg/kg)    |
|---------------|---|---------------|
| 01.1.2        | Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)                                     | 100           |
| 01.7          | Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)  | 100           |
| 02.1.3        | Lard, tallow, fish oil, and other animal fats   | GMP           |
| 03.0          | Edible ices, including sherbet and sorbet   | 100           |
| 04.1.2.4      | Canned or bottled (pasteurized) fruit   | 200           |
| 04.1.2.5      | Jams, jellies, marmelades   | 400           |
| 04.2.2.3      | Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweeds in vinegar, oil, brine, or soy sauce             | 300           |
| 04.2.2.4      | Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds |               |
| <b>05</b>     | Chewing gum Hanoi (July 11); Jakarta (July 13, 2017)  | <b>300</b> .4 |



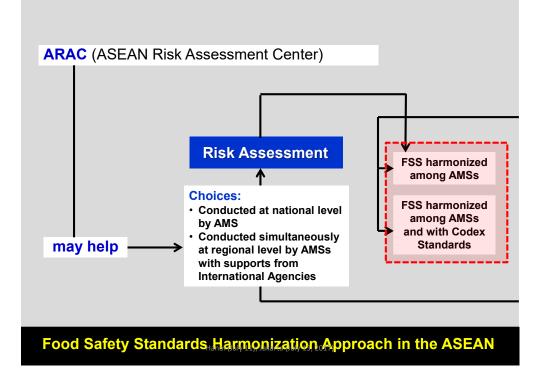
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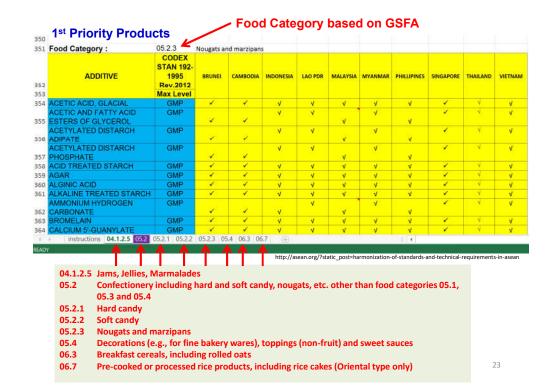




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### **Prepared Foodstuff**

- ASEAN General Standards for the Labelling of Prepackaged Food
- ASEAN Maximum Level for Food Additives for Prepared Foodstuff Products
- ASEAN Principles and Criteria for the Establishment of Maximum Level for Contaminants and Toxins in Food and Feed
- ASEAN Food Safety Policy
- ASEAN Principles and Guidelines for National Food Control Systems (CAC/GL 82 MOD)
- ASEAN General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.4 MOD)
- ASEAN Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26 MOD)
- ASEAN Guidelines for Food Import Control Systems (CAC/GL 47 MOD)
- Guidelines for ASEAN Food Reference Laboratories (AFRL)
- ASEAN Principles for Food Import and Export Inspection and Certification (CAC/GL 20 MOD)



#### ASEAN MAXIMUM LEVEL FOR FOOD ADDITIVES FOR PREPARED FOODSTUFF PRODUCTS

This Document sets forth the conditions under which food additives may be used in 1st and 2nd priority product for prepared foodstuff where maximum use levels have been harmonized among ASEAN Member States and agreed by ASEAN Consultative Committee on Standard and Quality – Prepared Foodstuff Product Working Group (ACCSQ PFPWG). Food additives listed in this document refer to Codex General Standard for Food Additives (GSFA) (Codex Stan 192-1995), which has been discussed and agreed by ACCSQ PFPWG. ASEAN Member States could use other food additives based on Codex and/or their national legislation. This document will be updated taking into consideration changes to the Codex GSFA and ASEAN Member States' proposal

The terms used in this document, such as food additives, Maximum Use Level, GMP, Functional Class, are referred to Codex Standards (Codex STAN 192-1995 & CAC/GL 69-1989)

1st and 2nd priority product for prepared foodstuff

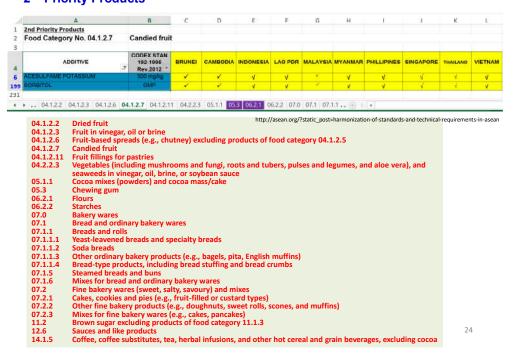
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• Food additives in GSFA (Codex Stan 192-1995)

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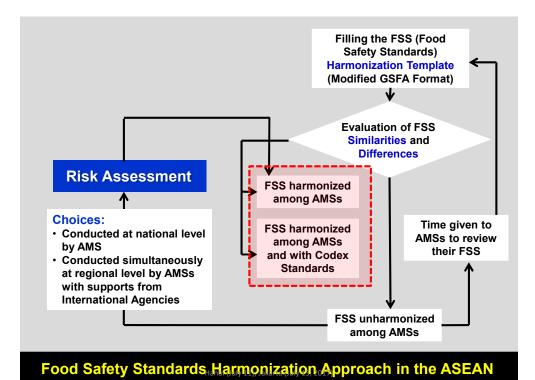
2<sup>nd</sup> Priority Products

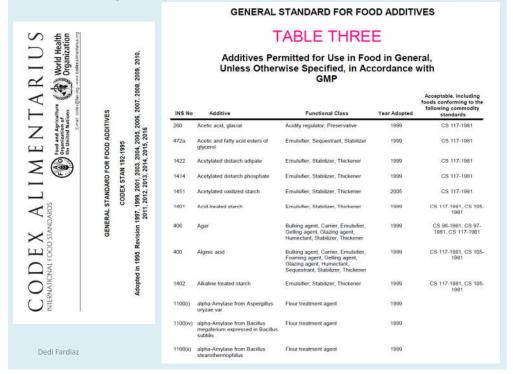


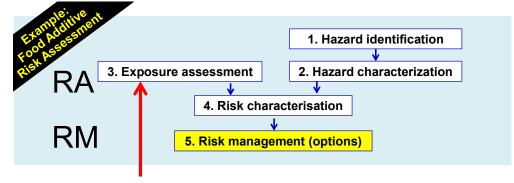
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|    | 2nd Priority Products                                       | ************************************** | SERVICE SERVICE |            |           |         |          |         |             |           |          |         |
|----|---|--|-----------------|------------|-----------|---------|----------|---------|-------------|-----------|----------|---------|
|    | Food Category No. 07.1.2                                    | Crackers, ex                           | cluding s       | weet crack | ers       |         |          |         |             |           |          |         |
|    | ADDITIVE  | CODEX STAN<br>192-1995<br>Rev-2012     | BRUNEI          | CAMBODIA   | INDONESIA | LAO PDR | MALAYSIA | MYANMAR | PHILLIPINES | SINGAPORE | THAILAND | VIETNAI |
| 6  | ACETIC ACID, GLACIAL  | GMP                                    | 1               | 1          | W.        | 1/      | V        | √       | ٧           | N         | V.       | ٧.      |
| ,  | ACETIC AND FATTY ACID ESTERS OF GLYCEROL                    | GMP                                    | 1               | 1          | 4         | ٧       | ٧        | ٧       | -           | N         | V        | ٧       |
| 3  | ACETYLATED DISTARCH ADIPATE                                 | GMP                                    | 4               | ¥          | V         | ٧       | V        | √       | V           | N         | V        | ٧.      |
| 9  | ACETYLATED DISTARCH PHOSPHATE                               | GMP                                    | -               | 1          | ٧         | ٧       | ٧        | V       | ٧           | V         | V        | V       |
| ı  | ACID TREATED STARCH   | GMP                                    | 1               | 1          | ٧         | ٧       | V        | √       | ٧           | V         | V        | ٧       |
| 2  | AGAR  | GMP                                    | 1               | 1          | ٧         | ٧       | ٧        | ٧       | ٧           | N         | V        | ٧       |
| 3  | ALGINIC ACID  | GMP                                    | -               | 1          | ٧         | √       | ٧        | ٧       | V           | N         | ¥        | V       |
| ı. | ALKALINE TREATED STARCH                                     | GMP                                    | 4               | 1          | V         | ٧       | ٧        | ٧       | V           | N         | V        | ٧       |
| ,  | ALPHA-AMYLASE FROM ASPERGILLUS<br>ORYZAE VAR.               | GMP                                    | 1               | 1          | 1         | ٧       | ٧        | 4       | V           | 4         | V        | ٧       |
| 5  | ALPHA-AMYLASE FROM BACILLUS<br>LICHENIFORMIS (CARBOHYDRASE) | GMP                                    | 4               | 1          | ٧         | ٧       | ٧        | ٧       | ٧           | Ŋ         | v        | ٧       |
| )  | ALPHA-AMYLASE FROM BACILLUS<br>SUBTILIS                     | GMP                                    | 1               | 1          | 4         | ٧       | ٧        | ٧.      | V           | N         | <b>V</b> | ٧       |
| 5  | AMMONIUM HYDROGEN CARBONATE                                 | GMP                                    | 4               | V          | ٧         | ٧       | ٧        | √       | V           | N         | y        | ٧       |
|    | BROMELAIN   | GMP                                    | 1               | 1          |           | ٧       | ٧        | V       | ٧           | V         | Ý        | ٧       |
|    | CALCIUM 5' GUANYLATE  | GMP                                    | 1               | -          | A.        | ٧       | V        | ¥       | ٧.          | V         | 4        | ٧       |
| 1  | CALCIUM 5'-INOSINATE  | GMP                                    | 1               | 1          | ٧         | ٧       | v.       | √       | ٧           | V         | V        | ٧       |
|    | CALCIUM ACETATE   | GMP                                    | V               | 1          | ٧         | √       | V        | V       | √           | N         | V        | √       |

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# **Risk Assessment of FA for harmonization in ASEAN:**

- 1. Calculation of the potential daily intake.
- 2. Comparison of the potential daily intake with the ADI.
- 3. Recommendation of approved uses and use levels which ensure that the potential daily intake is less than the ADI.

**Need Dietary Exposure Assessment Data** 

# **Developing Common ASEAN Food Consumption Data for Dietary Exposure Assessments**

1st Workshop on 'ASEAN Food Consumption Data and Exposure Assessment', October 10-13, 2011, Kuala Lumpur, Malaysia

Organized Jointly by ILSI Southeast Asia Region, FAO and Food Safety & Quality Division, Ministry of Health, Malaysia

# **Objectives:**

- Discuss availability of food consumption data in ASEAN
- Discuss food consumption survey methods
- · Identify steps to enable existing food consumption data to be used for dietary exposure assessment purposes among ASEAN countries Hanoi (July 11); Jakarta (July 13, 2017)



http://www.ilsi-guidea.org

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# **Developing Common ASEAN Food Consumption Data for Dietary Exposure Assessments**

2nd Workshop on 'ASEAN Food Consumption Data and Exposure Assessment', November 19-21, 2013, Kuala Lumpur, Malaysia

Organized Jointly by ILSI Southeast Asia Region, FAO and Food Safety & Quality Division, Ministry of Health, Malaysia

# **Objectives:**

- Discuss finalization of common food categories for the ASEAN Food Consumption Database
- Discuss challenges in transferring national data into the common template

GUIDANCE FOR DIETARY INTAKE OR EXPOSURE ASSESSMENTS Current and best practices of dietary intake or exposure assessments described by practical examples

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# **Harmonized Food Categories for ASEAN Food Consumption Data** (ILSI Southeast Asia Region, 2014)

| No | Food Category                                 | No | Food Category                            |
|----|---|----|--|
| 1  | CEREAL & PRODUCTS (4 sub-cat)                 | 11 | SUGAR, SYRUP & CONFECTIONARY (3 sub-cat) |
| 2  | PULSES, NUTS, SEEDS & PRODUCTS<br>(4 sub-cat) | 12 | CONDIMENTS, SPICES & SAUCES (4 sub-cat)  |
| 3  | STARCHY ROOTS, TUBERS & PRODUCTS (2 sub-cat)  | 13 | BEVERAGES: ALCOHOLIC (3 sub-cat)         |
| 4  | FRUITS & PRODUCTS (9 sub-cat)                 | 14 | BEVERAGES: NON-ALCOHOLIC (8 sub-cat)     |
| 5  | VEGETABLES & PRODUCTS (13 sub-cat)            | 15 | SNACKS NOT ELSEWHERE SPECIFIED           |
| 6  | MEAT & PRODUCTS (7 sub-cat)                   | 16 | SWEETENERS & SUGAR SUBSTITUTES           |
| 7  | FISH, SEAFOOD & PRODUCTS (6 sub-cat)          | 17 | FOODS FOR INFANTS & BABY FOODS           |
| 8  | EGG & PRODUCTS (2 sub-cat)                    | 18 | SPECIAL PURPOSE / FUNCTIONAL FOODS       |
| 9  | MILK & PRODUCTS (3 sub-cat)                   | 19 | FOOD SUPPLEMENTS & NATURAL EXTRACTS      |
| 10 | FATS & OILS (3 sub-cat)                       | 20 | COMPOSITE FOOD                           |

# Potential Uses & Benefits of the ASEAN FCD

- Could be used to conduct dietary exposure assessment at both the national level and regional level
- Countries that do not have specific data (e.g. no FCD for children or no data for certain foods) can use data of other countries to calculate exposure estimates (using appropriate assumptions)
- Countries that do not have any national FCD could use data of other countries in the ASEAN FCD to calculate exposure estimates ('surrogate data' especially if dietary patterns considered similar, i.e. Lao & Thai)
- Could also be used to calculate what are 'ASEAN exposure estimates' to a particular hazard
- Also relevant to the work of ASEAN WGs such as PFPWG in relation to harmonization of food safety standards, as described in the PFPWG's "Decision Tree for Harmonizing **Divergence on Food Safety Standards**"

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## **EXAMPLE OF EXPOSURE ASSESSMENT METHOD**

- 1. Determination of Food Groups, and Sub-Food-Groups
- 2. Preparation of Portion Size Measurement Tools











- 3. Determination of Targeted Respondents
- 4. Preparation of Sampling Framework
- 5. Determination of Survey Locations
- 6. Preparation of Questionnaire for 24-hour dietary intake (24-hour Recall) interview
- 7. Training of Surveyor
- 8. Implementation of the Food Consumption Survey
- 9. Data processing for Risk Characterization
- 10. Recommendation of Risk Management

| Harmonized Food Category for ASEAN Food | l |
|---|---|
| Consumption Data                        | l |

- 1. Cereal & Products
- 2. Pulses, Nuts, Seeds & Products
- 3. Starchy Roots, Tubers & Products
- 4. Fruits & Products
- Vegetables & Products
- 6. Meat & Products
- 7. Fish, Seafoods & Products
- 8. Egg & Products
- Milk & Products
- 10. Fats & Oils
- 11. Sugar, Syrup & Confectionary
- 12. Condiments, Spices & Sauces
- 13. Beverages: Alcoholic
- 14. Beverages: Non-Alcoholic
- 15. Snacks Not Elsewhere Specified
- 16. Sweeteners & Sugar Substituttes
- 17. Foods for Infants & Baby Foods
- 18. Special Purpose/Functional Foods
- 19. Food Supplements & Natural Extracts
- 20. Composite Foods

| Food<br>Consumed (g) | Food<br>Consumed/person/<br>day (g/day) |                             |
|----------------------|---|-----------------------------|
|                      |   |                             |
|                      |   | We can calculate            |
|                      |   | FA consumed/<br>person/day  |
|                      |   | (mg/person/day or mg/kg BW/ |
|                      |   | day)                        |
|                      |   | Compare with ADI            |
|                      |   |                             |
|                      |   |                             |
|                      |   |                             |
|                      |   |                             |

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# **SUMMARY**

- ASEAN Economic Community has been established as a single market and production base with the goal of making ASEAN more dynamic and competitive.
- Food Safety Standards Harmonization is an Important Step to Support ASEAN Single Market.
- Efforts to harmonize food safety standards in the ASEAN have been made since 2002, through the ASEAN Food Safety Standards Harmonization Workshop Series sponsored by ILSI Southeast Asia Region
- ASEAN Maximum Level for Food Additives for Prepared Foodstuff Products has been harmonized in ASEAN Member States for the 1<sup>st</sup> and 2<sup>nd</sup> priority products. Food additives listed in the document refer to GSFA (Codex Stan 192-1995)
- To continue support the harmonization of food additive standards, Risk Assessment (exposure assessment in particular) of food additives is required, started by conducting national or regional food consumption data collection.



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