Micronutrient Fortification - regulatory status & challenges in SEA

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Outline of presentation ....

- Nutrient addition: voluntary and mandatory fortification of micronutrients
- Status of regulations in 7 SEA countries
  - Brunei Darulssalam, Indonesia, Malaysia, Philippines, Singapore, Thailand & Vietnam
  - Sources of data
- Regulatory status of voluntary fortification
  - Types of micronutrients permitted
  - Minimum and maximum levels (if any)
  - Permitted claims
- Regulatory status of mandatory fortification
  - Fortification programmes (food vehicles & nutrients)
- Concluding remarks
Micronutrient fortification

..... Voluntary & mandatory

- Food fortification refers to the addition of micronutrients to processed foods
- It is one of the generally recognised strategies for control of micronutrient malnutrition
- A valid technology for reducing micronutrient malnutrition as part of a food-based approach
- Can be a cost-effective public health intervention to improve micronutrient status
- Reinforces and supports other nutrition improvement programmes
  - part of a broader, integrated approach to prevent micronutrient deficiency
- Voluntary and mandatory fortification
Mandatory fortification

- Governments legally oblige food producers to fortify particular foods or categories of foods with specified micronutrients
- When supported by proper enforcement and information dissemination system, delivers a high level of certainty that the selected food(s) will be appropriately fortified and in constant supply
- Governments are responsible for ensuring that the combination of the food vehicle and the fortificants will be both efficacious and effective for the target group
  - yet safe for target and non-target groups alike

Examples of mandatory regulations most often applied to the fortification of food with micronutrients are
- iodine, iron, vitamin A, and increasingly folic acid
- Basic commodities are more suited to mass fortification
  - intended to reach the whole population
- In voluntary fortification, the food manufacturer freely chooses to fortify particular foods in response to permission given in food law
- Impetus stems from industry & consumers seeking to increase micronutrient intake
  - some times government provides the driving force
- Governments have a duty to ensure that consumers are not misled or deceived by fortification practices
- Must be satisfied that market promotion of fortified foods does not conflict with, or compromise, any national food and nutrition policies on healthy eating

- Need to regulate the range of foods eligible for voluntary fortification and on the permitted combinations of particular micronutrients and foods
- For any given population group there are several key considerations that together determine whether mandatory or voluntary fortification is likely to be the most appropriate option for the prevailing conditions
Scope of presentation and sources of references

- Both voluntary and mandatory micronutrient fortification programmes exist in countries in Southeast Asia, governed by specific regulations.
- This presentation provides an overview of the status of these regulations and challenges in implementing them.
- Source of information
  - ILSI SEA Region publication (2011)
  - as well as more recent documents from websites of the regulatory agencies.
ILSI SEA Region survey of regulatory status of micronutrient fortification in foods (2011)

- Survey covers regulatory status in:
  - Brunei Darussalam, Myanmar
  - Cambodia, Philippines
  - Indonesia, Singapore
  - Laos, Thailand
  - Malaysia, Vietnam

- Three types of fortification regulations
  a) addressing nutrient deficiencies (mandatory fortification)
  b) voluntary addition of nutrients
  c) related nutrient content claims
Regulatory status of voluntary fortification

- Malaysia allows addition of “nutrients” to food
  - to improve nutritional value of the food
  - positive list of permitted “nutrients”
  - including vitamins, minerals, amino acids, fatty acids, other food components
- Specific regulation for micronutrient fortification
  - for several categories of foods (bread, breakfast cereals, condensed milk, milk powder, malted milk powder, exact of meat, flour, other solid foods and liquid foods)
  - nutrients permitted for “fortification” claim:
    vitamins A, B1, B2, B6, biotin, pantothenic acid, niacin, C, D, E, folic acid, B12; calcium, iodine, iron, phosphorus
... regulation for micronutrient fortification
- a table stipulates minimum amount of the vitamin or mineral to be present to claim to have been enriched, fortified, vitaminised supplemented or strengthened or words of similar meaning
- maximum amount of the vitamins and minerals that may be present in daily servings stipulated in a separate Table

Malaysia is reviewing this regulation stipulating minimum and maximum levels for micronutrient fortification
- a positive outcome of a ILSI seminar and workshop on 10 October 2012
- these requirements (established in 1985) need to be reviewed/updated in accordance with current science
- an Ad Hoc Committee established comprising all stakeholders – government, academia, professional body, industry, ILSI
- expected to complete its task and recommend amendments to the regulations before year end
Malaysia permits Nutrient content claims –
high in, source of according to Codex criteria

- For claim of “source of”, at least 15% of NRV per 100g (solids) of 7.5% of NRV per 100 ml (liquids)
- For claim of “high in”, at least 2 times the values for “source of”
- Not permitted to claim “presence of”, “with”, etc for micronutrients added

*MOH (2012). Food Regulations Malaysia 1985 and associated amendments.*

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**Indonesia**

- Nutrient content claim for vitamins and minerals
  - for claim “source of”: must contain at least 15% ALG (Indonesian NRV) per 100 g for solids and 7.5% ALG per 100 ml for liquids
  - for claims of “high in” - must contain at least twice the value for “source of”
Indonesia

- Comparative claim of increased, more, extra, enriched, plus, fortified
  - a relative difference of at least 10% ALG for vitamins and minerals compared with reference food
  - an absolute difference that meets the criteria for claim for “source of” in nutrient content claim


Singapore and Brunei

- permit addition of “nutrient supplement” to improve or enrich the food
  - include any amino acid, mineral or vitamin
  - positive list of permitted nutrients
- Claim of presence of (or imply presence of) a vitamin or a mineral permitted if a reference quantity contains at least one-sixth of the daily allowance of that nutrient
- Claim that a food is enriched, fortified, ennobled, vitaminised or is an excellent source of one or more vitamins or minerals permitted if a reference quantity contains not less than 50% of the daily allowance
Singapore and Brunei

- Maximum permitted in per reference quantity
  - vitamin A < 750 mcg of RE
  - Vitamin D < 10 mcg of cholecalciferol
  - any mineral < 3 times the daily allowance


Philippines

- Under the Sangkap Pinoy Seal Program (SPSP) the DOH encourages the fortification of processed foods based on the rules and regulations of the DOH
Manufacturers may also opt to fortify their processed foods or food products but do not apply for registration under the Sangkap Pinoy Program

The addition of micronutrients to processed foods shall be based on DOH guidelines Administrative Order No. 4-A series of 1995 and such other necessary guidelines


Thailand

“comparative” claims are permitted – increased, more, added, fortified, enriched

products are only allowed to bear such claims when the difference in vitamin/mineral content in this food and the reference food is at least 10% of the Thai RDI

no maximum amounts of micronutrients that may be added to food

- Vietnam regulations permit
  - addition of several micronutrients to complementary foods and wheat flour
  - iron in fish sauce and vitamin A in margarine and sugar
  - minimum and maximum levels are stipulated for these fortification


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**Summary**

- Most countries have individual regulations permitting voluntary fortification with various vitamins and minerals
- However, considerable differences in the approach towards regulating voluntary addition of micronutrients in the 7 countries
- Significant differences in
  - food vehicle permitted
  - vitamins and minerals and forms permitted
  - minimum amount required
  - maximum permitted
  - nutrient content/comparative claims permitted
Regulatory status of mandatory fortification

- Mandatory micronutrient fortification programmes also vary in the region, depending on the prevailing nutritional problems
- One programme implemented in several countries is fortification of salt with iodine
  - Indonesia, Malaysia, Thailand and Vietnam
  - to combat iodine deficiency disorder
- Flour fortification with iron and other micronutrients in Indonesia, Philippines and Vietnam
  - to combat iron deficiency problem
- Fortification of sugar and cooking oil with vitamin A in Philippines
- No mandatory fortification of micronutrients in Brunei Darussalam and Singapore
## Mandatory nutrient fortification in SEA

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Food vehicle</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodine</td>
<td>Salt</td>
<td>All 10 countries, except Brunei, Singapore and some parts of Malaysia</td>
</tr>
<tr>
<td>Iron</td>
<td>Wheat flour</td>
<td>Indonesia</td>
</tr>
<tr>
<td></td>
<td>wheat flour and rice</td>
<td>Philippines</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>Condensed, evaporated &amp; filled milk; margarine</td>
<td>Malaysia*</td>
</tr>
<tr>
<td></td>
<td>Wheat flour, sugar, cooking oil</td>
<td>Philippines</td>
</tr>
<tr>
<td></td>
<td>Condensed milk, margarine</td>
<td>Thailand</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>Margarine</td>
<td>Malaysia*</td>
</tr>
<tr>
<td>Folic acid</td>
<td>Wheat flour</td>
<td>Indonesia</td>
</tr>
<tr>
<td>and B vitamins</td>
<td>Vitaminised rice</td>
<td>Thailand</td>
</tr>
<tr>
<td>Zinc</td>
<td>Wheat flour</td>
<td>Indonesia</td>
</tr>
</tbody>
</table>

### Codex Alimentarius

- addition of nutrients to foods
- nutrient content claim
GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS

- Review by Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) initiated in 2009
- At step 4 of the procedure; discussed at 34th session in December 2012
- Working document for 34 Session of CCNFSDU
Current draft text
- To provide guidance to National Authorities responsible for developing guidelines and legal texts for the rational and safe addition of essential nutrients to foods
- Essential nutrients means any substance normally consumed as a constituent of food, needed for growth and development and maintenance of life, and which cannot be synthesized in adequate amounts by the body
- Applicable to both mandatory and voluntary addition of essential nutrients
- Fortification means the addition of one or more essential nutrients to a food [whether or not it is normally contained in the food]

Concluding remarks