Tolerance limit of declared values on nutrition labelling

Legislative Proposal Relating to Formula Products and Foods Intended for Infants and Young Children under the Age of 36 Months in Hong Kong

3rd Technical Meeting with Trade
10 July 2013
Background

- Sources of nutrient information used to formulate the nutrition label vary from direct analysis and indirect analysis.
- Despite the method used, enforcement action would be based on test results obtained by the Government Laboratory.
- The test result is compared against the compliance limits (i.e., label value plus tolerance).
- Tolerance limits would therefore affect the compliance of nutrition labelling in terms of accuracy of the declared values.
Overseas situation

- There is no internationally recognized tolerance limits for declaration of nutrition information on food labels.
- Recommended tolerance limits have not been provided in relevant Codex standards.
- Guidelines on Nutrition Labelling (CAC/GC2-1985) recommends tolerance limits to be set in relation to:
  - public health concerns,
  - shelf-life,
  - accuracy of analysis,
  - processing variability and inherent lability
  - variability of the nutrient in the product,
  - whether the nutrient has been added or is naturally occurring in the product
Overseas situation

- Not every jurisdiction with a nutrition labelling scheme published the tolerance limits.
- Of those released, different approaches were identified in setting tolerance limits for different types of food products:
  - Specified range approach
  - “One-way tolerance” approach
a) Specified range approach

- The label value should fall within a specified range (e.g., ± 20% of the label value).
- Under the specified range approach, a tolerance limit of ± 20% of the label value of macronutrients is generally considered acceptable.
- However, the tolerance limits vary for other nutrients according to their nature.
b) “One-way tolerance” approach

- The label value should be equal/less than or equal/more than a maximum or minimum value.
- Nutrients that will bring a negative impact on health in case of imbalance intake (e.g., total fat, saturated fat, cholesterol, sodium, etc.) are generally set at ≤ 120% of the label value.
- Those that are positive to health (e.g., protein, dietary fibre, vitamins, etc.) are commonly set at ≥ 80% label value.
- Some jurisdictions also established a separate tolerance limit for added nutrients. Since the amount of nutrients added to the food can be precisely controlled by the manufacturer, the tolerance limit set for added nutrient is at the level of not less than 100% of the label value.
Tolerance limit for food for infant and young children

- Regardless of the approach being adopted, the tolerance limits applied to formula and foods for infants and young children may not be the same to those for other general prepackaged foods. E.g. -
  - USA:
    A set of “one-way tolerance”, similar to those for general prepackaged food, is applied to formula and foods for infants and young children
  - Mainland China and Taiwan:
    Different tolerance limits were established
<table>
<thead>
<tr>
<th></th>
<th>General foods</th>
<th>Formulae and foods for infants and young children</th>
</tr>
</thead>
</table>
| **USA**
(one way tolerance) | • added vitamin, mineral, protein, fiber, K: \( \geq \) declared value       | Infant formula:
• added vitamins, mineral, protein, linoleic acid, K: \( \geq \) declared value      |
• naturally occurring vitamin, mineral, protein, total CHO, fiber, other carbohydrate, PUFA, MUFA, K: \( \geq 80\% \) of declared value | • naturally occurring vitamins, minerals, protein, total CHO, K: \( \geq 80\% \) of declared value |
• calories, sugars, total fat, sat. fat, trans fat cholesterol, Na: \( \leq 120\% \) of declared value | • energy, fat, sodium: \( \leq 120\% \) of the declared value |
|                          | Similar to general foods                                                       | Other foods:
Similar to general foods                                                                    |
| **Mainland China**
(one way tolerance) | protein, vitamins, minerals, etc: \( \geq 80\% \) of labelled value; energy, sat. fat, sodium, sugar: \( \leq 120\% \) of labelled value | When declaring average value on nutrition label:
• Fortified/naturally existing nutrient: \( \geq 80\% \) of labelled value |
• Calories/ fat/ sat. fat/ cholesterol/ sodium which is claimed to be “low”:\( \leq 120\% \) of labelled value |
| **Taiwan**
(Specified range approach) | \( \pm 20\% \)                                                                 | • Energy and macronutrients: \( \pm 20\% \)  |
• Vitamins: 80%-180/250/300%*  |                                                                                           |
• Minerals: 80%-150/200%*       | (*) depending on the vitamin/mineral                                            |
Local situation

- Under the current Nutrition Labelling Scheme for general prepackaged food, depending on the type of nutrients, the declared values have different tolerance limits, which were described in the Technical Guidance Notes on Nutrition Labelling and Nutrition Claims—

<table>
<thead>
<tr>
<th>Energy/ Nutrients</th>
<th>Tolerance Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy, Total fat, Saturated fatty acids, Trans fatty acids, Cholesterol, Sodium, S</td>
<td>≤ 120% declared value</td>
</tr>
<tr>
<td>ugars</td>
<td></td>
</tr>
<tr>
<td>Protein, Polyunsaturated fatty acids, Monounsaturated fatty acids, Carbohydrates,</td>
<td>≥ 80% declared value</td>
</tr>
<tr>
<td>Starch, Dietary fibre, Soluble fibre, Insoluble fibre, individual component of</td>
<td></td>
</tr>
<tr>
<td>fibre</td>
<td></td>
</tr>
<tr>
<td>Vitamins and minerals (other than Vitamin A, Vitamin D and added vitamins and</td>
<td>≥ 80% declared value</td>
</tr>
<tr>
<td>minerals)</td>
<td></td>
</tr>
<tr>
<td>Vitamin A and Vitamin D (including added ones)</td>
<td>80% - 180% declared value</td>
</tr>
<tr>
<td>Added vitamins and minerals (other than Vitamin A and Vitamin D)</td>
<td>≥ declared value</td>
</tr>
</tbody>
</table>
For comments and discussion