FOOD ADDITIVES SAFETY & MAXIMUM USE LEVEL

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Outline

1. Food additives → Chemicals
2. HOW are food additives regulated?
3. Maximum use level of food additive
Food Additive is a substance (intentionally) added to food to alter the properties and/or the appearance of the food.

As described by Paracelsus nearly 500 years ago, “All substances are poisons; there is none which is not a poison. The right dose differentiates a poison and a remedy”. This means that any chemical substance is likely to produce some form(s) of harmful effect, if taken in sufficient quantity.

More addition of a chemical in food does not itself make food unsafe, but the quantity used in food, quantity of that food consumed and bodyweight will decide the safety.
The Codex definition of hazard is “a biological, chemical or physical agent with the potential to cause an adverse health effect”.

The likelihood or risk of that hazard actually occurring in humans is dependent upon the quantity of chemical encountered or taken into the body, i.e. the exposure.

**WHY** do we need to regulate food additives?

These chemicals may be harmful to your health (if consumed above the safety margin level)

<table>
<thead>
<tr>
<th>Examples of types of adverse effect</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of toxicity</strong></td>
</tr>
<tr>
<td>Functional changes</td>
</tr>
<tr>
<td>Morphological changes (other than cancer)</td>
</tr>
<tr>
<td>Mutagenicity</td>
</tr>
<tr>
<td>Carcinogenicity</td>
</tr>
</tbody>
</table>

Benford, D. 2000, ILSI Europe

<table>
<thead>
<tr>
<th></th>
<th>Immunoxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitisation</td>
<td>(leading to hypersensitivity or allergy)</td>
</tr>
<tr>
<td>Depression</td>
<td>of the immune system</td>
</tr>
<tr>
<td>Embryotoxicity</td>
<td>(spontaneous abortion)</td>
</tr>
<tr>
<td>Teratogenicity</td>
<td>(fetal deformities)</td>
</tr>
<tr>
<td>Other developmental</td>
<td>effects</td>
</tr>
</tbody>
</table>

| Neurotoxicity        | Behavioural changes, deafness, tinnitus, etc.          |
| Reproductive toxicity| Impaired fertility                                     |

(If consumed above the safety margin level)
Food Additive (Codex Stan 192-1995)

• Any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging and transport.

• The term does not include contaminants, or substances added to food for maintaining or improving nutritional qualities.

Technological Function and Safety
### Traditional vs Modern Food Safety System

<table>
<thead>
<tr>
<th>Traditional Food Safety System</th>
<th>Modern Food Safety System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactive approach</td>
<td>Preventive approach</td>
</tr>
<tr>
<td>Main responsibility with government</td>
<td>Shared responsibility Addresses farm to table continuum</td>
</tr>
<tr>
<td>No structured risk analysis</td>
<td>Science based – used of structured risk analysis –</td>
</tr>
<tr>
<td>Relies on end product inspection and testing</td>
<td>Establishes priorities integrated food control Relies on process control</td>
</tr>
<tr>
<td>Level of risk reduction: not always satisfactory</td>
<td>Level of risk reduction: improved</td>
</tr>
</tbody>
</table>
What is Risk Analysis

A framework to view and respond to food safety problems in a **systematic, structured and scientific way** in order to enhance the quality of decision-making throughout the food chain.

Kerangka Risk Analysis Codex

**Risk Assessment**
- Hazard Identification
- Hazard Characterisation
- Exposure Assessment
- Risk Characterisation

**Risk Management**
- Risk Evaluation
- Option Assessment
- Option Implementation
- Monitoring & Review

**Risk Communication**
Interactive exchange of information and opinions concerning risks

Important step if we want to regulate food additives

Science based

Policy based

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Risk analysis is used:

- to develop an estimate of the risks to human health,
- to identify and implement appropriate measures to control the risks, and
- to communicate with stakeholders about the risks and measures applied.

What is required for successful Risk analysis?

- A well functioning food safety system
- Support and participation of key stakeholders (government, industry, academia, consumers)
- Basic knowledge about the three main components of risk analysis.
Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard

- Hazard is a fact
- Risk is a probability

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

How do we know the risk?
We need to know how much food (with hazard in it?) we eat

How are food additives regulated?
Globally Codex Alimentarius Commission
It is important to determine the margin of safety of your food additive consumption.

The Acceptable Daily Intake (ADI) is an estimate by JECFA of the amount of a food additive, expressed on a body weight basis (mg FA/kg BW), that can be ingested daily over a lifetime without appreciable health risk (standard man – 60 kg).

**ADI = Acceptable Daily Intake**

JECFA = Joint FAO/WHO Expert Committee on Food Additives
For contaminants, we use the term TDI (Tolerable Daily Intake) instead of ADI.

The Tolerable Daily Intake (TDI) is an estimate by JECFA of the amount of a contaminants, expressed on a body weight basis (mg contaminant/kg BW), that can be ingested daily over a lifetime without appreciable health risk.

\[ \text{TDI} = \text{Tolerable Daily Intake} \]

Note:

- The ADI is expressed in milligrams of the additive per kilogram of body weight.
- For this purpose, "without appreciable risk" is taken to mean the practical certainty that injury will not result even after a life-time's exposure (Report of the 1975 JMPR, TRS 592, WHO, 1976).
- The ADI is established over lifetime. A body weight of 60 kg is usually taken to represent the average weight of the population (Report of the 1988 JECFA, TRS 776 sec. 2.2.3. WHO, 1989).
Safety Evaluation

- Acute toxicity
- Short term toxicity
- Long term toxicity
- Mutagenicity,
- Carcinogenicity
- Teratogenicity
- Multigeneration
- Establishment of No Observed Adverse Effect Level (NOAEL)
- Acceptable Daily Intake (ADI)

How do we estimate ADI?

- Groups of animals (e.g. rats) are given daily diets containing different levels of the additive under examination.
- For example, levels of the additives in the diet could be: 0.1%, 1%, 2%, 5%. If a toxic effect is found at the 2% level and a "no toxic effect" at 1% level, the 1% level (expressed in mg/kg body weight) will be the "no-observed-effect level" (NOEL), and it is from this level that the extrapolation to humans is done.
- In this case, the no-observed-effect level (NOEL) lies between the 1% and 2% levels, and if no toxicological evaluations are done at intermediary levels (1.25%, 1.50%, 1.75%) the choice of the 1% level as the no-observed-effect level introduces already a first safety factor.
The extrapolation from the no-observed-effect level to an ADI is often done by using a safety factor of 100 (10 x 10) which assumes that humans are 10 times more sensitive than experimental animals and that there is a 10-fold variation in sensitivity within the human population.

This safety factor of 100 is based on the experience and common sense of toxicologists and therefore cannot be compared to a physical value such as the boiling point of a pure substance. More information regarding the no-observed-effect level and the use of safety factors can be found in "Principles for the Safety Assessment of Food Additives and contaminants in Food". (Environmental Health Criteria No 70, WHO, Geneva 1987, p. 77-79).
Acceptable Daily Intake "Not Specified"

A term applicable to a food substance of very low toxicity for which, on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background levels in food, does not, in the opinion of JECFA, represent a hazard to health.
Example: ADI (Acceptable Daily Intake) of several permitted preservatives

<table>
<thead>
<tr>
<th>Preservatives</th>
<th>Chemical Structure</th>
<th>INS No.</th>
<th>ADI (mg/kg BW)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoic and its salts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Benzoic acid</td>
<td>C₇H₆O₂</td>
<td>210</td>
<td>0 - 5</td>
</tr>
<tr>
<td>b. Sodium benzoate</td>
<td>C₇H₅NaO₂</td>
<td>211</td>
<td></td>
</tr>
<tr>
<td>c. Potassium benzoate</td>
<td>C₇H₅KO₂</td>
<td>212</td>
<td></td>
</tr>
<tr>
<td>d. Calcium benzoate</td>
<td>C₁₄H₁₀CaO₄</td>
<td>213</td>
<td></td>
</tr>
<tr>
<td>Nitrate and its salts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Sodium nitrate</td>
<td>NaNO₃</td>
<td>251</td>
<td>0 – 3.7</td>
</tr>
<tr>
<td>b. Potassium nitrate</td>
<td>KNO₃</td>
<td>252</td>
<td></td>
</tr>
</tbody>
</table>

Maximum level (ML)
The Codex maximum level (ML) for a contaminant in a food or feed commodity is the maximum concentration of that substance recommended by the CAC to be legally permitted in that commodity.

Maximum residue level (MRL)
The maximum concentration of residue in a food or animal feed resulting from use of a veterinary drug or a pesticide, (expressed in mg/kg or μg/kg on a fresh weight basis).

Acceptable daily intake (ADI)
An estimate of the amount of a substance in food or drinking water, expressed on a bodyweight basis, that can be ingested daily over a lifetime without appreciable risk (standard human = 60 kg). The ADI is listed in units of mg per kg of body weight.

Tolerable daily intake (TDI)
Analogous to Acceptable Daily Intake. The term Tolerable is used for agents which are not deliberately added such as contaminants in food.

Who determines ML, MRL, ADI, TDI in Codex?
The Codex Alimentarius Commission Executive Committee includes:

- **General Subject Committees**
  - Food Hygiene
  - Food Additives
  - General Principles
  - Food Labelling
  - Methods of Analysis and Sampling
  - Pesticide Residues
  - Residues of Veterinary Drugs in Foods
  - Food Import and Export Inspection and Certification Systems
  - Nutrition and Foods for Special Dietary Uses
  - Contaminants in Food

- **The Commission and its subsidiary bodies (risk managers)**
  - (CCFH)
  - (CCFA)
  - (CCGP)
  - (CCFL)
  - (CCMAS)
  - (CCPR)
  - (CCRVDF)
  - (CCFICS)
  - (CCNFSDU)
  - (CCCF)

- **The joint FAO/WHO expert bodies and consultations (risk assessors)**
  - JEMRA (Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment)
  - JECFA (Joint FAO/WHO Expert Committee on Food Additives)
  - JMPR (Joint FAO/WHO Meeting on Pesticide Residues)

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**Maximum Use Level of Food Additives**

- Maximum Level
- Average Usage
- Low
- High
- Low
- Maximum

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Codex General Standard for Food Additives (GSFA) Online Database

The “Codex General Standard for Food Additives” (GSFA, Codex STAN 192-1995) sets forth the conditions under which permitted food additives may be used in all foods, whether or not they have previously been standardized by Codex. The Preamble of the GSFA contains additional information for interpreting the data. Users are encouraged to consult the Preamble when using this database.

This database provides, in a searchable format, all the provisions for food additives that have been adopted by the Codex Alimentarius Commission.

Provisions are searchable by food additive (name, synonym, JIN number), by functional class and by food category, as described in Annex B of the Codex GSFA.

Please note that the summary and conclusions of recent JECFA meetings and other relevant information, such as call for data for future meetings, are available on the JECFA website and the WHO website. Other useful links:

- JECFA reports and toxicological monographs
- GSFA specifications

Click here to view the current version of the Codex General Standard for Food Additives.

Please note: The Codex General Standard for Food Additives is currently under development and it will be regularly updated to include additional food additive provisions adopted by the Codex Alimentarius Commission.

GSFA Online

Updated up to the 38th Session of the Codex Alimentarius Commission (2015)

FOOD ADDITIVE INDEX

This page contains an index of individual food additives or food additive groups (indicated in square brackets).

Clicking on an individual food additive or food additive group takes the user to a page with details on acceptable uses of the food additive.

Clicking on “Show synonyms” will display food additive synonyms.

Jump to:

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

- Acetamide (929)
- Acetanilide (929)
- Acetic acid, unsaturated (280)
- Acetamide, unsaturated (280)
- Acetylated diethylstilbestrol (1432)
- Acetylated diethylstilbestrol (1432)
## BENZOATES

The provisions that follow are defined at the additive group level, and thus apply to the total content of the additives participating in this group. Additives that make up this group are provided for reference only.

### Participating Additives
- **E 260** - Benzoic acid
- **E 261** - Calcium benzoate
- **E 262** - Potassium benzoate
- **E 264** - Sodium benzoate

### GSFA Provisions for BENZOATES

<table>
<thead>
<tr>
<th>Number</th>
<th>Food Category</th>
<th>Max Level</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>04.1.2.7</td>
<td>Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)</td>
<td>1,000 mg/kg</td>
<td>Note 13, Note 33</td>
</tr>
<tr>
<td>07.0</td>
<td>Bakery mixes</td>
<td>1,000 mg/kg</td>
<td>Note 33</td>
</tr>
<tr>
<td>04.1.2.8</td>
<td>Canned fruit</td>
<td>1,000 mg/kg</td>
<td>Note 33</td>
</tr>
<tr>
<td>06.5</td>
<td>Cereal and starch based deserts (e.g., rice pudding, tapioca pudding)</td>
<td>1,000 mg/kg</td>
<td>Note 13</td>
</tr>
<tr>
<td>05.2</td>
<td>Chewing gum</td>
<td>1,500 mg/kg</td>
<td>Note 12</td>
</tr>
<tr>
<td>14.2.2</td>
<td>Citrus and perry</td>
<td>1,000 mg/kg</td>
<td>Note 33</td>
</tr>
<tr>
<td>03.1.3</td>
<td>Cocoa based spreads, including fillings</td>
<td>1,000 mg/kg</td>
<td>Note 12</td>
</tr>
<tr>
<td>14.3.5</td>
<td>Coffee, coffee substitute, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa</td>
<td>1,000 mg/kg</td>
<td>Note 13</td>
</tr>
<tr>
<td>14.1.2.3</td>
<td>Concentrations for fruit juice</td>
<td>1,000 mg/kg</td>
<td>Note 91, Note 127</td>
</tr>
</tbody>
</table>

**Note:** The above values are maximum levels and may vary depending on the specific food category. Always consult the latest guidelines for compliance.
### Food Additive Details

**Sodium benzoate (211)**

#### Additive Group
- **BENZOATES**

Click to view provisions and details for this group.

*Functional Classes*
- Preservative

Click here to search the FAO/WHO database for the specifications of additive(s) with ENo. 211.

Click here to search the WHO/FACFA database for evaluation of additive(s) with ENo. 211.

#### Table: Food Category and Number

<table>
<thead>
<tr>
<th>Food Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dairy products and analogues, excluding products of category 02.0</td>
<td>01.0</td>
</tr>
<tr>
<td>Fats and oils, and fat emulsions</td>
<td>02.0</td>
</tr>
<tr>
<td>Edible ices, including sherbet and sorbet</td>
<td>03.0</td>
</tr>
<tr>
<td>Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds</td>
<td>04.0</td>
</tr>
<tr>
<td>Confectionary</td>
<td>05.0</td>
</tr>
<tr>
<td>Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares of food category 07.0</td>
<td>06.0</td>
</tr>
<tr>
<td>Bakery wares</td>
<td>07.0</td>
</tr>
<tr>
<td>Meat and meat products, including poultry and game</td>
<td>08.0</td>
</tr>
<tr>
<td>Fish and fish products, including mollusks, crustaceans, and echinoderms</td>
<td>09.0</td>
</tr>
<tr>
<td>Eggs and egg products</td>
<td>10.0</td>
</tr>
<tr>
<td>Sweeteners, including honey</td>
<td>11.0</td>
</tr>
<tr>
<td>Salts, spices, soups, sauces, salads, protein products</td>
<td>12.0</td>
</tr>
<tr>
<td>Foodstuffs intended for particular nutritional uses</td>
<td>13.0</td>
</tr>
<tr>
<td>Beverages, excluding dairy products</td>
<td>14.0</td>
</tr>
<tr>
<td>Ready-to-eat savouries</td>
<td>15.0</td>
</tr>
<tr>
<td>Prepared foods</td>
<td>16.0</td>
</tr>
</tbody>
</table>
### Food Category System (GSFA, 2005)

Check GSFA or national standards for ML of food additives in food

<table>
<thead>
<tr>
<th>No.</th>
<th>Name of Food</th>
</tr>
</thead>
<tbody>
<tr>
<td>01.0</td>
<td>Dairy products and analogues, excluding products of food category 02.0</td>
</tr>
<tr>
<td>02.0</td>
<td>Fats and oils, and fat emulsions</td>
</tr>
<tr>
<td>03.0</td>
<td>Edible ices, including sherbet and sorbet</td>
</tr>
<tr>
<td>04.0</td>
<td>Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds</td>
</tr>
<tr>
<td>05.0</td>
<td>Confectionary</td>
</tr>
<tr>
<td>06.0</td>
<td>Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses and legumes, excluding bakery wares of food category 07.0</td>
</tr>
<tr>
<td>07.0</td>
<td>Bakery wares</td>
</tr>
<tr>
<td>08.0</td>
<td>Meat and meat products, including poultry and game</td>
</tr>
<tr>
<td>09.0</td>
<td>Fish and fish products, including mollusks, crustaceans, and echinoderms</td>
</tr>
<tr>
<td>10.0</td>
<td>Eggs and egg products</td>
</tr>
<tr>
<td>11.0</td>
<td>Sweeteners, including honey</td>
</tr>
<tr>
<td>12.0</td>
<td>Salts, spices, soups, sauces, salads, protein products (including soybean protein products) and fermented soybean products</td>
</tr>
<tr>
<td>13.0</td>
<td>Foodstuffs intended for particular nutritional uses</td>
</tr>
<tr>
<td>14.0</td>
<td>Beverages, excluding dairy products</td>
</tr>
<tr>
<td>15.0</td>
<td>Ready-to-eat savouries</td>
</tr>
<tr>
<td>16.0</td>
<td>Composite foods - foods that could not be placed in categories 01 - 15.</td>
</tr>
</tbody>
</table>
Good Manufacturing Practices (GMP) for food additives

1. Lowest possible level necessary to accomplish its desired effect
2. The additive is prepared and handled in the same way as a food ingredient.
Example: Exposure assessment of Food Colorant

**Assumptions**
1. All the colors are used at permitted levels
2. A person consumes all the foods where these additives are added

**Food consumption data**
1. Food consumption data is taken nationally
2. Data is computed only on foods where the consumption data is available

**Body weight**
1. Average body weight used for ADI calculation
## Exposure assessment of Food Colorant

<table>
<thead>
<tr>
<th>No.</th>
<th>Food Colorant</th>
<th>INS</th>
<th>ADI (mg/Kg BW)</th>
<th>Percentage of ADI at mean value</th>
<th>Percentage of ADI at 95th percentile value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Erythrosine</td>
<td>127</td>
<td>0-0.1</td>
<td>96</td>
<td>537.6</td>
</tr>
<tr>
<td>2</td>
<td>Ponceau 4R</td>
<td>124</td>
<td>0-4</td>
<td>3.11</td>
<td>15.44</td>
</tr>
<tr>
<td>3</td>
<td>Carmoisine</td>
<td>122</td>
<td>0-4</td>
<td>2.4</td>
<td>13.44</td>
</tr>
<tr>
<td>4</td>
<td>Sunset Yellow FCF</td>
<td>110</td>
<td>0-4</td>
<td>2.4</td>
<td>13.44</td>
</tr>
<tr>
<td>5</td>
<td>Indigo carmine</td>
<td>132</td>
<td>0-5</td>
<td>1.92</td>
<td>10.75</td>
</tr>
<tr>
<td>6</td>
<td>Tartrazine</td>
<td>102</td>
<td>0-7.5</td>
<td>1.28</td>
<td>7.1</td>
</tr>
<tr>
<td>7</td>
<td>Brilliant blue FCF</td>
<td>133</td>
<td>0-12.5</td>
<td>0.7</td>
<td>4.3</td>
</tr>
<tr>
<td>8</td>
<td>Fastgreen FCF</td>
<td>143</td>
<td>0-25</td>
<td>0.38</td>
<td>2.15</td>
</tr>
</tbody>
</table>
Percentage of ADI used up for Tartrazine at mean intake of colored food

Percentage of ADI used up for Erythrosine at mean intake of colored food

Unused ADI 98.7%

Used up ADI 96%
Risk Management

• Food Colorant:
  – Erythrosine: permitted levels need to be reduced
  – Tartrazine: no action is required

Scientific Opinion on the re-evaluation Tartrazine (E 102)¹
EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)²,³

European Food Safety Authority (EFSA), Parma, Italy
ABSTRACT

The Panel on Food Additives and Nutrient Sources added to Food provides a scientific opinion re-evaluating the safety of Tartrazine (E 102). Tartrazine has been previously evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1966 and the EU Scientific Committee for Food (SCF) in 1975 and 1984. Both committees established an Acceptable Daily Intake (ADI) of 0-7.5 mg/kg bw/day. The Panel was not provided with a newly submitted dossier and based its evaluation on previous evaluations, additional literature that became available since then and the data available following a public call for data. New studies included a study by Sasaki et al. from 2002 reporting effects on nuclear DNA migration in the mouse in vivo Comet assay, a study by McCann et al. from 2007 that concluded that exposure to a mixture including Tartrazine resulted in increased hyperactivity in 3-year old and 8- to 9-year old children and studies on neurodevelopment by Tanaka. The Panel notes that Tartrazine was negative in long-term carcinogenicity studies and that the effects on nuclear DNA migration observed in the mouse in vivo Comet assay are not expected to result in carcinogenicity. The Panel also concurs with the conclusion from a previous EFSA opinion on the McCann et al. study that the findings of the study cannot be used as a basis for altering the ADI, and additionally considered that the Tanaka study can also not be used as a basis for altering the ADI. The Panel concludes that the present database does not give reason to revise the ADI of 7.5 mg/kg bw/day. The Panel also concludes that at the maximum reported levels of use, refined intake estimates are below the ADI. The Panel concludes that Tartrazine appears to be able to elicit intolerance reactions in a small fraction of the exposed population. The Panel also notes that sensitive individuals may react to Tartrazine at dose levels within the ADI.

Table 4  Summary of anticipated exposure to Tartrazine using the tiered approach (EC, 2001) in children and adult population

<table>
<thead>
<tr>
<th></th>
<th>Adult UK population (&gt;18 years old)</th>
<th>Pre-school UK children (1.5 to 4.5 years old, 15 kg body weight)</th>
<th>Children EXPOCHI population (1-10 years old, 25-30 kg body weight)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1  Budget method</td>
<td>8.1</td>
<td>13.1</td>
<td></td>
</tr>
<tr>
<td>Tier 2  Maximum Permitted Level</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Mean exposure</td>
<td>0.9</td>
<td>3.1</td>
<td>0.8-3.4</td>
</tr>
<tr>
<td>• Exposure 95th or 97.5th percentile**</td>
<td>2.1</td>
<td>7.3</td>
<td>0.8-9.4</td>
</tr>
<tr>
<td>Tier 3  Maximum reported use levels</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Mean exposure</td>
<td>0.3</td>
<td>0.85</td>
<td>0.2-1.9</td>
</tr>
<tr>
<td>• Exposure 95th or 97.5th percentile**</td>
<td>0.5</td>
<td>1.7</td>
<td>0.4-7.3</td>
</tr>
</tbody>
</table>

* For EU children, estimates are based on the EXPOCHI report, which gives the 95th percentile intake.
** For UK, estimates are based on the UNESDA report which gives the 97.5th percentile intake from beverages plus per capita average from the rest of diet (Tennant, 2006).
Risk Characterization

• JFCMP (Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme) membagi tiga kategori terkait paparan terhadap bahan tambahan pangan, yaitu:
  – Di bawah 30% ADI dapat dikategorikan bahwa penggunaan BTP tersebut aman untuk semua kelompok populasi.
  – Jika paparan terhadap BTP antara 30 – 100% ADI maka penggunaan BTP tersebut perlu menjadi perhatian terutama pada kelompok dengan risiko tinggi (seperti anak-anak).
  – Jika paparan melebihi 100% ADI maka penggunaan BTP termasuk tidak aman bagi seluruh populasi.
ESTIMATION OF THE SAFETY ASPECTS OF USE LEVELS - FOOD ADDITIVES WITH NUMERICAL ADI

Fractions of the ADI to be used for Solid Food and Beverages, Respectively

• If an additive is proposed for use in both solid food and in beverages the full ADI cannot be used for both for uses in solid food and uses in beverages.
• It is therefore necessary to allocate a fraction of the ADI to each of the applications. As a first approach, it may be appropriate to assume that one-half of the ADI is allocated to each solid and liquid foods.
• However, in special cases other fractions may be more appropriate as long as the sum of the fractions does not exceed the figure for the ADI (e.g. FS=1/4 and FB=3/4 ; FS=1/6 and FB=5/6), where FS is the fraction for use in solid food and FB is the fraction for use in beverages).
• If the additive is used only in solid food, then FS =1 and FB=0 and if the additive is used only in beverages, then FS=0 and FB=1.
CODEX STAN 192-1996

III (a) FOOD ADDITIVE USES IN SOLID FOOD (FS)

Guideline 5
Use Levels Below FS x ADI x 40
If the proposed use levels are below FS x ADI x 40, these food additive provisions could be suitable in food in general.

Guideline 6
Use Levels Below FS x ADI x 80
If the proposed use levels are below FS x ADI x 80 they are acceptable provided the daily consumption of the foods containing the additive will usually not exceed half of the assumed maximum total solid food intake (i.e. 12.5 g/kg bw/day).

Guideline 7
Use Levels Below FS x ADI x 160
If the proposed use levels are below FS x ADI x 160 they are acceptable provided the daily consumption of the foods containing the additive will usually not exceed one fourth of the assumed maximum total solid food intake (i.e. 6.25 g/kg bw/day).

Guideline 8
Use Levels Below FS x ADI x 320
If the proposed use levels are below FS x ADI x 320 they could be accepted provided the daily consumption of the foods containing the additive will usually not exceed one eighth of the assumed maximum total food intake (i.e. 3.13 g/kg bw/day).

Guideline 9
Use Levels Above FS x ADI x 320
If the proposed use levels are higher than FS x ADI x 320 they should only be accepted for products where calculation of potential intake from all proposed uses will show that exceeding the ADI is unlikely, or if estimation of the intake of the additive based on more exact intake estimates methods show that the use levels are acceptable (e.g. food consumption surveys).
III(b) FOOD ADDITIVE USES IN BEVERAGES (FL)

Guideline 10

Use Levels Below FL x ADI x 10
If the proposed levels are below FL x ADI x 10, the additive could be accepted for use in all beverages in general.

Guideline 11

Use Levels Below FL x ADI x 20
If the proposed use levels are below FL x ADI x 20 they could be accepted provided the daily consumption of beverages containing the additive will usually not exceed half of the assumed maximum total intake of beverage (i.e. 50 ml/kg bw/day).

Guideline 12

Use Levels Below FS x ADI x 40
If the proposed use levels are below FL x ADI x 40 they could be accepted provided the daily consumption of beverages containing the additive will usually not exceed a fourth of the assumed maximum total intake of beverage (i.e. 25 ml/kg bw/day).

Guideline 13

Use Levels Below FL x ADI x 80
If the proposed use levels are below FL x ADI x 80 they could be accepted provided the daily consumption of beverages containing the additive will usually not exceed an eighth of the assumed maximum total intake of beverage (i.e. 12.5 ml/kg bw/day).

Guideline 14

Use Levels Above FL x ADI x 80
Levels above FL x ADI x 80 should only be accepted for products where calculation of potential intake will show that exceeding the ADI is unlikely (e.g. strong alcoholic beverages).