Regulatory Aspect of Food Additive in Asian Countries

Wilfred Feng
Keller and Heckman LLP
Shanghai Representative Office

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Definition of Food Additives

- May vary by countries
  - an additive in one country may be treated differently in another country
- Vitamins and minerals, processing aids, colourings and flavorings may defined and treated differently
- Use Singaporean definition as an example:
  - “all substances, which are components of foods, the intended use of which results or may reasonably be expected to result, directly or indirectly, in their affecting the characteristics of foods but does not include any foreign substance mixed with food as a result of contamination, or improper handling of the food during the preparation, processing, packing or storage of the food; and anti-caking agents, anti-oxidants, artificial sweetening agents, chemical preservatives, colouring matters, emulsifiers or stabilisers, flavoring agents, flavour enhancers, humectants, nutrient supplements, sequestrants and other general purpose food additives.
Three Groups of Asian Jurisdictions

• Based on how food additives are regulated:
  - Requiring pre-market clearance (or “Positive List”)
  - Setting general requirements/standards (or “Negative List”)
  - No regulating

There are countries in-between.
Three Groups of Asian Jurisdictions (cont’d)

• Requiring pre-market clearance:
  - China, Japan, Korea, Taiwan (partially, because of voluntary food formulation review system), Hong Kong (for colouring matters, artificial sweeteners and preservatives only), Malaysia, Singapore, Indonesia, Philippines, Australia/New Zealand

• Setting general requirement / standards
  - Hong Kong (anything other than coloring matters, artificial sweeteners and preservatives)

• Not regulating
  - The rest of the world
International Standards and Harmonization

• **JECFA**: Joint FAO/WHO Expert Committee on Food Additives
  - Evaluate the safety of food additives and develop principles for safety assessment

• **Codex Alimentarius Commission**
  - Adopt JECFA opinions and make them international code in the form of…

• **GSFA**: Codex General Standard for Food Additives

• **FCC**: Food Chemical Codex
  - Set industry standards on the specifications of food additives (currently edited by U.S. Pharmacopoeia), but widely accepted in global regulatory practice
Petition / clearance Procedure

• Risk-based Safety Assessment
  ➢ Toxicological studies
  ➢ Estimate potential exposure
  ➢ Justification of technical needs

• Administrative requirements
  ➢ Certificate of company’s good standing
  ➢ Free Sales Certificate

• Other considerations/requirements
  ➢ Global clearance status
  ➢ Local testing
More on Risk-based Safety Assessment

**Toxicological studies:**
- To answer “Is it toxic or harmful?”
  - Toxicological effects
  - Physiological effects
  - Allergenicity effects
  - Carcinogenicity possibility
  - GMO
- Endpoint of toxicological testing \(\rightarrow\) No-Observed-Adverse-Effect-Level (NOAEL), expressed in \(\text{mg/kg body weight}\)
- Safety factor
  - Difference between animal model and human: \(\times 10\)
  - Possible differences in sensitivity in human: \(\times 10\)
- Acceptable Daily Intake (ADI)
  - A JECFA concept
  - \(= \text{NOAEL} / 100\)
  - In case the safety level of an additive is sufficiently high, JECFA may opine “ADI not specified”
More on Risk Assessment

- Estimate potential exposure:
  - To understand “How much will be eaten?”
    - How much to be added in the target food?
    - How much food to be eaten in a day (food consumption)?
    - How much THE substance is there?
Food Consumption – How do we know?

- Different methods available
  - Food Consumption Surveys
    - “What We Eat in America” (USDA survey)
    - National Health and Nutrition Examination Survey (NHANES)
  - Food/Ingredient Disappearance Data
    - How much specific substance entered the food supply
  - Total Diet Study
    - Analytical results for 300 substances in the sampled foods
    - Plus national food consumption data
    - Focusing on nutrients and contaminants
  - Biomarker
    - Quantitative relationship between intake and remainder in human body
    - Still limited application so far

- Estimated Daily Intake (EDI), …more on this
- Sub-populations (“vulnerable populations”) may also be considered if necessary
Estimated daily Intake (EDI)

\[ EDI_x = \sum_{f=1}^{F} \frac{Freq_f \times Port_f \times Conc_{xf}}{N} \]

where:

F = Total number of foods in which substance "x" can be found
Freqf = Number of eating occasions of food "f" over "N" survey days
Portf = Average portion size for food "f"
Concxf = Concentration of the substance "x" in food "f"
N = Number of survey days
Justification of Technical Needs

• To address “Why Needed?”
  ➢ Functionality test
  ➢ Environmental or social justifications
Bottom-line Question

• *Is this additive safe to use?*
  
  ➢ Compare EDI with ADI
  
  ➢ If EDI is sufficiently lower than ADI, the additive is safe to use
A Typical Petition File May Contain

- Chemical information
  - May include impurity profile and/or specifications
- Manufacturer’s information
- Safety data
- Administrative supporting documents
There might be hidden rules, trivialities or other considerations

• Using China as an example…
  ➢ China will not approve a new food additive until, EU, or US approves or JECFA endorses it
  ➢ Some toxicological tests need to be repeated in a Chinese lab for validation purpose even such data have already been generated elsewhere
  ➢ Every page of petition file needs to be chopped with the company’s stamp
Labeling of Food Additives

• Labeling of food additives
  ➢ May be mandatory. Usually quite straightforward.

• Labeling of food additives in finished foods
  ➢ Requirements vary by countries
  ➢ Certain group of additives may be listed by generic names
Other Issues

- "Natural" claim
- Flavorings
  - Regulated off-line by industry groups (FEMA etc.)
- "Carry-over" principles
  - An additive may not need to be explicitly approved in certain food in order to be lawfully used in that food
- GMO derivatives
  - Separate GMO clearance may be needed
  - Substantial equivalence principle generally applicable
- Nano technology derivatives
  - Regulatory policies still evolving
Enforcement of Regulations

• Not just regulator’s job
  ➢ Government
  ➢ Industry
  ➢ Consumer
  ➢ NGO

• Things may still go wrong
We Know Things May Go Wrong: Melamine

• Safety crisis do happen, especially associated with food additives or contaminants, using China as an example…

• 2007 Crisis:
  - Melamine contaminated wheat gluten in pet foods
  - Diethylene glycol in toothpaste
  - Salmonella in spice ingredients
  - Unapproved drugs in seafood

• 2008 Crisis:
  - Melamine redux
Causes to the Melamine Crisis

• Unscrupulous Chinese operators cutting corners to reduce costs, without fear of real adverse financial consequences, motivated purely by greed

• But a major assist in the crisis has to be awarded to:
  ➢ Government
  ➢ The Dairy Industry
A bit elaboration

- **GOVERNMENT**, at all levels, failed to
  1. inspect and prevent,
  2. to act in a way that would deter the greedy perpetrators,
  3. to have a judicial system that would make all who facilitated the disaster financially responsible

- The **Dairy Industry**,
  - failed to realize the potential for contamination and to institute a rigorous testing program to prevent it.

- May not yet be over:
  - if milk and milk powder laced with melamine, why not eggs, soy, vegetable proteins: anything that can be diluted with water but where protein content is required

- Impact much broader
  - Not only in China
  - Not just dairy
The Solution to the Crises: Government

• First, require registration and inspection of all “risk” areas

• Recognize, however, that continuous inspection is not feasible

• Vigorous and prompt prosecution of perpetrators of intentional violations to act as a deterrent to others

• Establish judicial system that holds all stakeholders in the food chain accountable for significant financial damages. This will provide a deterrent effect not only to branded goods manufactures but to raw material suppliers as well.
The Solution: Industry Role

• First, to recognize that quality has a price, and that procurement at the lowest price is not always best.

• Second, to “think ahead” of the perpetrators as to other situations that might arise, and to plan for them.

• Finally, a “customer assurance program” to instill confidence in export customers and domestic consumers that their brands can be trusted.
Customer Assurance Program

Has three elements:

- Education
- Testing
- Audit
Customer Assurance: Education

- Food processors must learn the laws and regulations of the export markets, so they will be prepared for import country testing.

- Advice must be knowledgeable, experienced, and credible.

- Advice will vary from product to product. For example, all additives and processing aids used in the production of agricultural products and ingredients must first be evaluated to see if they are permitted in the country of import.
Customer Assurance: Education

• Determine if any pesticide residues present are in accord with the regulations of the import countries.

• A determination that the product meets relevant national and international standards for processed foods and for food additives.

• Where relevant, whether the product is free of pathogenic microorganisms.
Customer Assurance: Testing

• Next, product needs to be tested by an independent laboratory that has credibility in the country of import. The type of testing will depend on the product to be tested.

• To maintain credibility, the testing should be performed by an independent agent on a sample randomly selected from recent inventory or from an in-process sample.
  ● This is due to a concern, real or imagined, that some firms keep “clean” samples to give to testing labs that are not representative of production.

• Added assurance can be obtained by the agent selecting the sample also conducting an inspection of the processing facility, allowing him/her to observe hygiene and sanitary procedures, and to observe the presence of substances such as melamine which have no business being in a processing plant.
Customer Assurance: Audit

• After a thorough evaluation and adequate testing of representative samples, the producer will receive an audit report from a competent authority attesting to the compliance of a given product with the import country’s laws.

• Such an audit report should provide the assurance the customer needs.
Summary for Compliance Issues

• These crises will pass, and others will be prevented, if

  ● Government establishes a framework of deterrence and accountability
  ● Industry does its job in putting quality first and in establishing a Customer Assurance Program
  ● All sides base decisions on sound science and not politics
Customer Assurance Program Recap

• In short, the Customer Assurance Program is a three point program:

  ● **EDUCATION** of the producer to know what and what not to do

  ● **TESTING** of a truly representative sample of the product, which if satisfactory will lead to an

  ● **AUDIT REPORT** by a competent, credible third party organization with the requisite knowledge and high reputation22
General Advice to Regulatory Compliance

• Use cleared additives and within the limits
• Watch the specifications
• “Carry-over” principles may apply
• Label and list additives correctly
• Be careful to make claims
• Ask experts if necessary
• Use Customer Assurance Program when applicable
Thank You!

Wilfred Feng

Keller and Heckman LLP
The Bund Center, Suite 3604
222 Yan’an Dong Lu
Shanghai
China 200002
Tel. (86 21) 6335 1000
MP. (86) 139 1661 2772
Email. Feng@khlaw.com
http://www.khlaw.com