Regulations on Food Additives in Vietnam

Mr. Nguyen Xuan Truong
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REGULATIONS ON FOOD ADDITIVES IN VIETNAM

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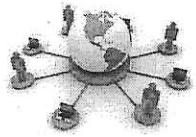

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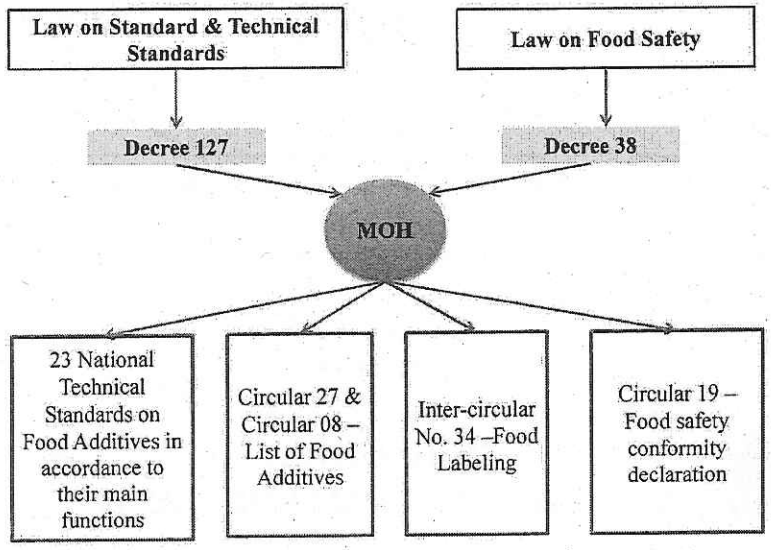
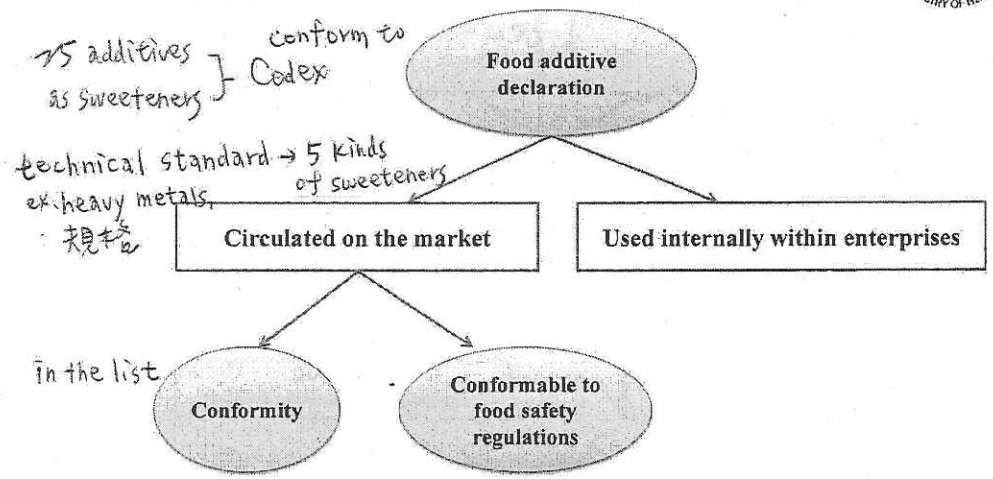


LEGAL FRAMEWORK ON FOOD ADDITIVE MANAGEMENT

23 National Technical Regulations on food additives according to the main functions of additives	Technical requirements coloring substances sweeteners Testing methods purity
Circular 27 & Circular 08 – List of food additives	List of Food Additives allowed to be used in food 407 additive Maximum limits
Inter-circular No.34 – Food labelling	Labelling food additives
Circular No.19 – Food safety regulation conformity declaration.	Order, Procedure, required documents Clause 2 Article 8

VFA不一定依Codex or 其他國家standard, declaration

FOOD ADDITIVE DECLARATION PROCEDURE



Order, Procedure, Dossier for declaration of conformity to food safety regulation
(for additives to be circulated on the market)

➡ Lodge online dossier at:

http://congbosanpham.vfa.gov.vn/HomePage.do

Within 07 working days from the time of receiving the proper dossier, VFA shall grant the Receipt of Declaration of Conformity to technical regulation.

Order, Procedure, Dossier for declaration of conformity to food safety regulation
(for additives to be circulated on the market)

❖ **Declaration of conformity to technical regulation:** Article 5, Decree 38

- Declaration of conformity to technical regulation;
- Product Specification ;
- Testing results within 12 months by a testing agency meeting the required standards;
- Quality control plan;
- Periodic monitoring plan;
- Conformity assessment report;
- Certificate of Business registration;
- A certificate of HACCP, ISO 22000 or equivalents (if any)

有的 validity time 5年 → need to test sample once/year
沒有 3年. → need to test sample twice a year

Order, Procedure, Dossier for declaration of conformity to food safety regulation
(for additives to be circulated on the market)

❖ **A dossier for food safety conformity declaration shall include the followings** (according to Article 6, Decree 38)

- A declaration of conformity to food safety regulation;
- Detailed specification of the product;
- Testing results within 12 months by a testing agency meet the required standards;
- Periodic monitoring plan;
- Sample of product label as circulated in the origin country and supplementary label in Vietnamese
- Sample of finished products only for the products that first time imported into Viet Nam;
- Business registration certificate;
- Certificate of satisfaction of food safety conditions;
- A certificate of HACCP or ISO 22000 or equivalent (if any)
- **Within 15 working days from the time receiving the food safety conformity declaration dossier, VFA shall grant the Certificate of Conformity to food safety regulation.**

Order, Procedure, dossier for declaration of conformity to food safety regulation
(for food additives to used internally within enterprises)

❖ **A dossier of food additives to be used internally within enterprises includes the followings** (according to Clause 1, Article 6, Circular 19/2012/TT-BYT).

- Product declaration;
- Certificate of Business registration;
- The results of testing product within 12 months.

ONLINE PORTALS FOR LEGAL DOCUMENTS ON FOOD ADDITIVES

1. Online portal of Vietnam Food Administration:

http://www.vfa.gov.vn

2. Online portal of the Ministry of Health

http://www.moh.gov.vn

3. Online database on food additives: allow and maximum limit

http://tracuuphugia.vfa.gov.vn/phuGiaAction.do?page=timkiem

THANK YOU VERY MUCH

Regulation on Sweeteners in Malaysia

Ms. Norhidayah Othman
Ministry of Health
Malaysia

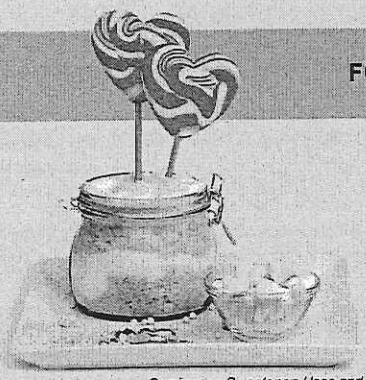
Regulation on Sweeteners in Malaysia

Ms. Norhidayah Othman
Ministry of Health
Malaysia

The Ministry of Health Malaysia through the Food Act 1983 and its regulations sets the legal requirements pertaining to food and related matters, with a primary purpose to protect consumers against health hazards and frauds in the preparation, sale, and use of food. Sweetener is known to be a food additive (other than a mono- or di-saccharide sugar), which imparts a sweet taste to food.

This presentation highlights all related sweeteners including artificial sweetening substances and non-nutritive sweetening substances under Food Regulations 1985. The Food Regulations 1985 defines and prescribes the standard for sweeteners; identity, safety, and quality and labelling requirements. Currently, Malaysia is proposing new amendments to sweeteners provision to be in line with Codex standard. The amendments including scope, transforming food commodities to food additives, specification and maximum level, labelling requirement, and related consequential amendments.

All food industries are responsible in ensuring the products comply with all legal requirements. Harmonisation activities for food additive provision under Food Regulations 1985 with Codex standard is an on-going process and will improve food safety and avoid unnecessary barrier to trade.



NORHIDAYAH BINTI OTHMAN
FOOD SAFETY AND QUALITY DIVISION
MINISTRY OF HEALTH MALAYSIA

REGULATION ON SWEETENERS IN MALAYSIA

OBJECTIVE

- To give update on new proposed amendment for sweeteners as food additives.

INTRODUCTION

- Mandate for Food Safety Regulatory Control
- Food Regulations 1985
- Revision exercise
- Conclusion

Mandate for Food Safety Regulatory Control

Food Regulations 1985

- **Prescribe standards and labelling requirements for all foods e.g. food additives, pesticide residues, heavy metals, residue of veterinary drugs etc.**

nutritional labels for infant formula

FOOD REGULATIONS 1985

PART I	Preliminary
PART II	Warranty
PART III	Procedure for taking samples
PART IV	Labeling
PART V	Food additive and nutrient supplement
PART VI	Packages for food
PART VII	Incidental Constituent
PART VIII	Standards and particular labeling requirements for food
PART XI	Use of water, ice or steam
PART X	Miscellaneous

Sweetening substance

- 118. Sugar
- 118A. Stevia extract
- 118B. Enzymatically modified stevia
- 119. Soft brown sugar
- 120. Coloured sugar or rainbow sugar
- 121. Dextrose anhydrous
- 122. Dextrose monohydrates
- 123. Refiner's syrup
- 124. Glucose
- 125. Glucose syrup
- 125A Trehalose dihydrate
- 126. Gula melaka
- 127. Gula kabung
- 128. Fructose
- 129. High fructose glucose syrup
- 130. Honey
- 131. Icing sugar
- 132. Molasses
- 132A. Artificial sweetening substance
- 133. Non-nutritive sweetening substance
- 134. Aspartame, glycerol and sorbitol
- 134A. Beverage whitener
- 134B. Sweetened creamer
- 134C. Non dairy creamer

Reg 136 Gula Melaka

(1) Gula melaka shall be the sugary product made from the sap of the unopened spathe of the inflorescence of the coconut palm *Cocos nucifera*.

(2) Gula Melaka—

(a) shall not contain more than 10 per cent of water;

(b) shall contain not less than

(i) 1 percent of protein;

(ii) 70 percent of sucrose; and

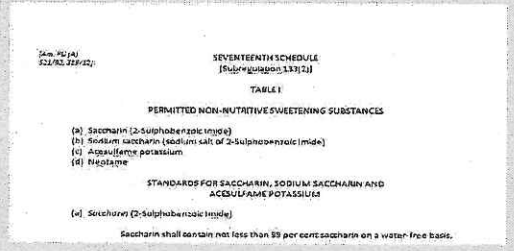
(iii) 1 percent of reducing sugars; and

(c) shall not yield more than 2.5 percent of ash.

Reg. 133 Non-nutritive sweetening substance

(1) In these Regulations, "non-nutritive sweetening substance" means any substance that, when added to food, is capable of imparting a sweet taste to that food but does not have nutritive properties.

(2) The permitted non-nutritive sweetening substance specified in Table I of the Seventeenth Schedule that complies with the standard set out in that Table may be added to low energy food.



[Am. P.U.(A) 521/93, 229/22].

SEVENTEENTH SCHEDULE
[Subregulation 133(2)]

TABLE I

PERMITTED NON-NUTRITIVE SWEETENING SUBSTANCES

(a) Saccharin (2-Sulphobenzoic imide)
(b) Sodium saccharin (sodium salt of 2-Sulphobenzoic imide)
(c) Acesulfame potassium
(d) Neotame

STANDARDS FOR SACCHARIN, SODIUM SACCHARIN AND ACESULFAME POTASSIUM

(a) *Saccharin* (2-Sulphobenzoic imide)

Saccharin shall contain not less than 99 per cent saccharin on a water-free basis.

Reg. 133 Non-nutritive sweetening substance

(12) Where a permitted non-nutritive sweetening substance has been added to any food, there shall be written in the label on a package containing such food, the words "contains (state the appropriate designation of the non-nutritive sweetening substance) as permitted non-nutritive sweetening substance".

(14) The words "UNSUITABLE FOR PHENYLKETONURICS" shall be written in the label on package containing food to which neotame has been added, in not less than 10 point lettering.

HARMONIZATION

- What – Harmonization with Codex standard (General Standard for Food Additive vs Codex Commodity Standard)
- When – 2009 till now (yet to be discussed and gazetted)
- How – matching food commodities under Food Regulation 1985 (Food categories under GSFA vs 1:1 matching with Codex Commodity Standard)
- Where, Who – Secretariat Food Additive

Sweetening substance

- 118. Sugar
- 118A. Stevia extract
- 118B. Enzymatically modified stevia
- 119. Soft brown sugar
- 120. Coloured sugar or rainbow sugar
- 121. Dextrose anhydrous
- 122. Dextrose monohydrates
- 123. Refiner's syrup
- 124. Glucose
- 125. Glucose syrup
- 125A Trehalose dihydrate
- 126. Gula melaka
- 127. Gula kabung
- 128. Fructose
- 129. High fructose glucose syrup
- 130. Honey
- 131. Icing sugar
- 132. Molasses
- 132A. Artificial sweetening substance
- 133. Non-nutritive sweetening substance
- 134. Aspartame, glycerol and sorbitol
- 134A. Beverage whitener
- 134B. Sweetened creamer
- 134C. Non dairy creamer

Revision exercise - scope

Current Regulation	Proposed amendment
Reg. 19. Food additive *"food additive"– includes preservative, colouring substance, flavouring substance, flavour enhancer, antioxidant and food conditioner.*	*Reg. 19. Food additive* *"food additive"– includes acidity regulator, anticaking agent, antifoaming agent, preservative, propellant, raising agent, sequestrant, stabilizer, sweetener, thickener, etc*

Revision exercise – transformation

Current Regulation	Proposed amendment
132A Artificial sweetening substance *133 Non nutritive sweetening substances* *134 Aspartame, glycerol and sorbitol*	*The principal Regulations are amended by deleting Regul ation 132A, 133, 134*
(1) For the purpose of these Regulations, only a non-nutritive sweetening substance specified in regulation 133 and aspartame specified in regulation 134 shall be deemed to be a permitted artificial sweetening substance.	*New Regulation on 20B Sweetener* *'sweetener' refers to a food additive other than a monosaccharide or disaccharide sugar which imparts a sweet taste to a food;* *'sweetener preparation' refers to a product in tablet, granular, powder or liquid form prepared by admixing one or more permitted sweetener in a base with or without other food and includes table- top sweetener.* *'warning statement' – phenylketonurics, laxative effect*

Revision exercise – specification & max level

Current Regulation	Proposed amendment
118A Stevia Extract	The principal Regulations are amended by deleting Regulation 118A.
(1) Stevia extract shall be a substance composed mainly of steviol glycosides obtained by extraction from the leaves of Stevia rebaudiana Bertoni, a plant of chrysanthemum family in the form of a white to light yellow powder, odourless and has a sweet taste. *(2) Stevia extract may be added to food and the maximum permitted proportion in food shall be governed by good manufacturing practice.*	No person shall import, manufacture, advertise for sale or sell or introduce into or on any food, any permit ted food additive which does not comply: - The purity as recommended by the Joint Food and Agriculture Organisation of the United Nations and World Health Organisation (FAO/WHO) Expert Committee on Food Additives (JECFA). - The addition is permitted under the Codex Alimentarius.

Revision exercise – labeling requirement

Current Regulation	Proposed amendment
Where a permitted non-nutritive sweetening substance has been added to any food, there shall be written in the label on a package containing such food, the words *"contains (state the appropriate designation of the non-nutritive sweetening substance) as permitted non-nutritive sweetening substance".*	*Where the food contains food additive, a statement as to the presence in that food of such food additive:* *State the functional class of the relevant food additive, followed by the INS number in brackets;*

Revision exercise – consequential amendment

Exp (1)	Exp (2)
Reg 136 Sugar confection – *Sugar confection may contain permitted colouring substance, permitted flavouring substance, permitted food conditioner and acesulfame potassium not exceeding 3,500 mg/kg as permitted non-nutritive sweetening substance.*	Reg 247 Fruit jelly- *Fruit jelly shall be the gelatinous product prepared by boiling the juice of one or more types of fruits, whether raw, processed or semi-processed, and permitted sweetening substance with or without added pectin. It shall be free from seeds and skin.*

Conclusion

- Food industries are responsible in ensuring their products comply with all legal requirements
- Harmonisation an on-going process and takes into consideration current developments; Codex and ASEAN, technological needs and available data
- Harmonization would improve food safety, facilitate trade and avoid unnecessary barrier

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Global Regulatory Approvals and Safety Assessments of Sweeteners

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Canada

Low calorie sweeteners are widely used worldwide in foods and beverages to provide consumers with products that provide sweetness but are low in calories and are suitable for diabetics. Low calorie sweeteners are categorized as food additives, and therefore must undergo an extensive safety evaluation prior to approval for use in foods and beverages. At the international level, this evaluation is conducted by JECFA (the Joint Food Additives Organization/WHO Expert Committee). Toxicology studies are conducted to assess the absorption, metabolism, distribution, and excretion pathways of the compound when it is consumed in laboratory animals and in humans. Animal studies are also conducted to determine the potential for interaction with genetic material and potential for causing development of cancer or other adverse effects following long term consumption. In addition, potential effects on reproduction and development must be considered. As diabetics are a potential susceptible subgroup of consumers of low calorie sweeteners, lack of effects on blood sugar or insulin levels are critical criteria for approval of these food additives. There is a wide variety of low calorie sugar substitutes available for use globally, including advantame, acesulfame potassium, aspartame, cyclamate, monk fruit extract, neotame, saccharin, stevia extracts, and sucralose. Although there has been considerable controversy raised in recent years, all international regulatory experts agree that current use levels of low calorie sweeteners are safe for all members of the population.

Global Regulatory Approvals and Safety Assessment of Low Calorie Sweeteners

(and Health)

Dr. Berna Magnuson,
PhD, Fellow Academy of Toxicological Science

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Some Low Calorie Sweeteners Available for Use Globally

No natural source:	From Natural Sources:
Advantame	Allulose
Acesulfame K	Monk Fruit Extract
Aspartame	Monatin
Cyclamate	Stevia extract
Neotame	Thaumatin
Saccharin	+ others
Sucralose	

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Low Calorie Sweeteners

Intense Sweeteners

Used to :

- **Reduce caloric content of foods,**
  - Beneficial in weight management
- **Reduce glucose content of foods,**
  - Beneficial for blood glucose control.

controversy

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Approval Process for "Artificial" as compared to "Natural"

All sweeteners that are not found in nature are "food additives" – undergo food additive risk assessment.

Sweeteners that have natural source may be regulated as: food ingredient; natural health product; dietary supplement; or food additive.

Depends on form and purity of sweetener, and regulatory agency.

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Safety Assessment of Food Additive Low Calorie Sweeteners

- **Evaluated for safety by an independent scientific body before being approved for use in the given market;**
- **International safety assessor = JECFA**
  - Joint Food Additives Organization/World Health Organization Expert Committee on Food Additives;
- **Regional or Country:**
  - European = EFSA, the European Food Safety Authority;
  - United States = FDA, U.S. Food & Drug Administration;
- **Role: risk assessors establish the safety, acceptable levels of intake and use for food additives.**

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Toxicology Evaluation

safety evaluation including lifetime exposure

- A extensive number of toxicology tests required
- What happens to the compound when we consume it?
- Toxicity following long-term consumption?
- Any effect on mutations or cancer development?
- Reproductive toxicity?
  - before and during pregnancy
- Teratogenicity – effect on development?
- Also human clinical studies
  - effect on blood sugar or insulin?

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JECFA

- **Established in the 1950's with it's first meeting in 1955;**
- **Set out general principles for evaluation of food additives;**
- **Brought harmonization of the approach of safety assessment of food additives on a worldwide basis;**
- **Toxicological evaluations usually result in allocation of acceptable daily intake (ADI) for food additives;**
- **In 1987, the World Health Organization (WHO) published *Principles for the safety of food additives and contaminants in food.* Updated in 2009.**
  - Provides comprehensive review of the key issues considered by JECFA during their risk assessments of food chemicals

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NOAEL

No Observed Adverse Effect Level

- Wide range of tests to define the potential for harm and adverse effects (at any dose) during the different stages of the life cycle.

- Identification of the most important adverse effect(s) and dose-response to define a level that is **without** effect = **NOAEL**

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Acceptable Daily Intake (ADI)

Is amount "that can be ingested daily over a lifetime without appreciable health risk" (WHO 1987).

Based on No-Observed Effect Level (NOAEL) from long-term studies in 2-3 species, use most sensitive species

- Apply "safety factors" of 100 to account for
  - differences between individuals (10 X)
  - differences between humans and animals (10 X)

NOAEL/safety factor = ADI (mg/kg/day)

- For example: aspartame
  - If NOAEL= 4000 mg/kg/d, ADI = 40 mg/kg/d.
- ADI is very conservative, based on level with no effect when fed to animals for life-time and divided by "safety factor" cushion.

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Sweetness Intensity Means Low Intake

Sweetener	Sweetness Intensity*	To replace 25 g of sugar
Acesulfame K Aspartame	~ 200 x	125 mg
Saccharin	~ 300 x	80 mg
Steviol glycosides	200 - 300 x	80-125 mg
Sucralose	~ 600 x	40 mg

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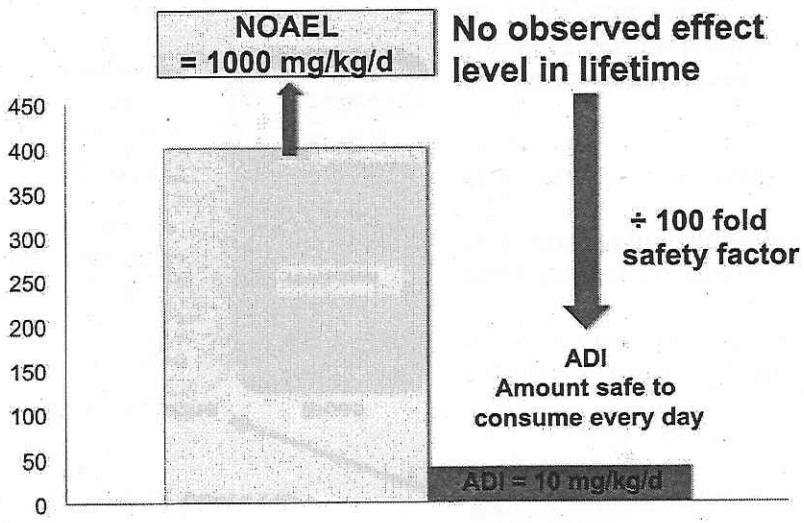
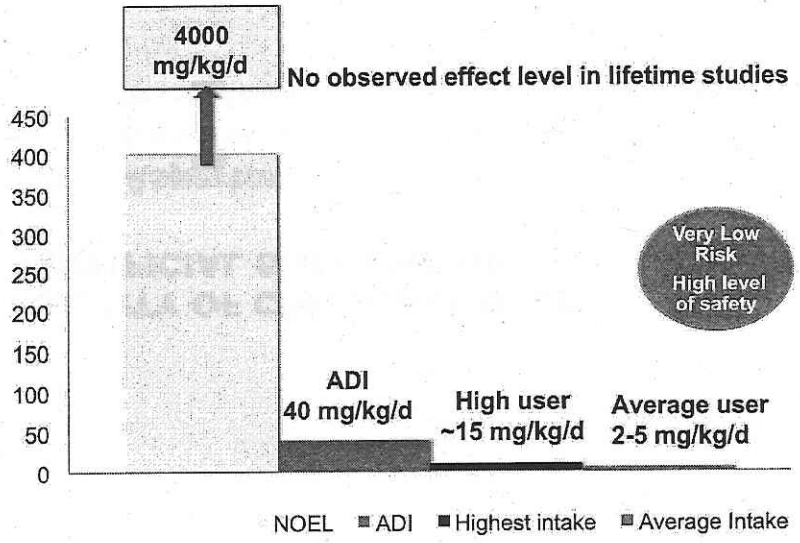
* **compared to sugar**

ADI



NOEL vs ADI vs Consumer Consumption of Aspartame



ADIs established by JECFA for some Low Calorie Sweeteners

Sweetener	JECFA ADI (mg/kg/d)
Advantame	0-5
Acesulfame K	0-15
Aspartame	0-40
Cyclamate	0-11 as cyclamic acid
Saccharin	0-5
Sucralose	0-15
Steviol glycosides	0-4 as steviol equivalents
Thaumatin	Not specified

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SAFETY OF COMMONLY USED ARTIFICIAL SWEETENERS

Aspartame
Saccharin
Sucralose

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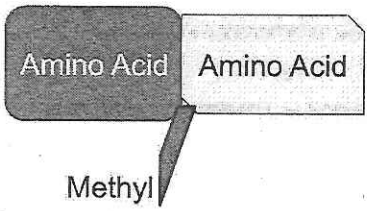
not found in nature

What is Aspartame?



- **About 200X sweet as sugar.**
- **ADI (mg/kg/day)**
  - **JECFA 0-40**
  - **US FDA 0-50**
- **Widely approved food additive**

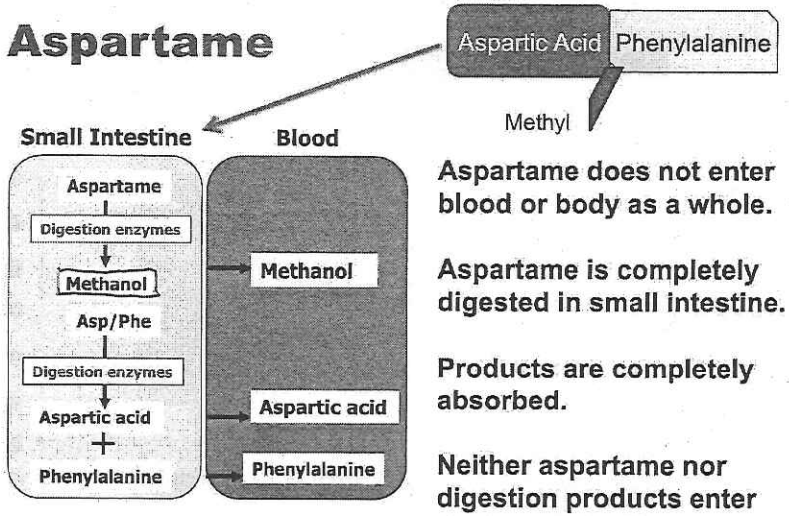
found in proteins found in pectins

Structure: 2 amino acids & methyl group

- Aspartic acid (aspartate)
- Phenylalanine

These are commonly found in foods!

Aspartame



Aspartame does not enter blood or body as a whole.

Aspartame is completely digested in small intestine.

Products are completely absorbed.

Neither aspartame nor digestion products enter the large intestine.

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European Food Safety Authority Review of Aspartame, 2013
http://www.efsa.europa.eu/en/topics/topic/aspartame.htm

Dietary sources of aspartame digestion products

Food	Phenylalanine (mg)	Aspartic acid (mg)	Methanol (mg)
Aspartame-sweetened Soft drink (340 ml) 	90	72	18
Non-fat milk (340 ml) 	606	953	-
Tomato Juice (340 ml) 	58	346	107
Orange juice (340 ml) 	24	180	23

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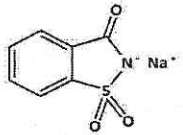
Saccharin



- **Ca, K and Na salts,**
- **Most (95%) absorbed in the small intestine, then excreted unchanged in urine,**
- **Small amount (5%) to colon and excreted in feces.**

Now approved around the world, but safety questioned when studies found very high doses increased incidence of bladder cancer in male rats.

Subsequent studies demonstrated due to specific physiology of rat urinary system and not relevant to humans.

Many clinical and epidemiological studies confirm saccharin is safe for humans.

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Safety of aspartame confirmed Dec 2013

efsa
European Food Safety Authority

In response to many allegations, EFSA conducted an extensive review of all studies and concluded:

- no safety concerns, no evidence of causing cancer and no adverse health effects.

- Safe for pregnant women, children and all members of population.

- Only individuals who need to limit intake of phenylalanine due to genetic disorder should limit intake.

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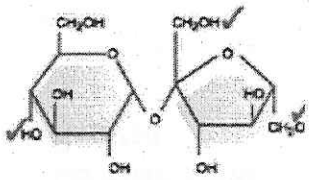
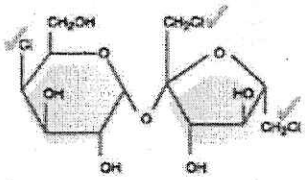
Sucralose



Sucrose ($C_{12}H_{22}O_{11}$)



Sucralose ($C_{12}H_{19}Cl_3O_5$)

- **Structure similar to sugar, but with Cl added.**
- **Cannot be broken down by digestion.**
- **600X sweetening potency so small amounts used.**
- **Heat-stable – can be used in various food applications**

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Sucralose

- Cannot be digested into monosaccharides – no impact on blood glucose.
- Most (85%) is NOT absorbed into the body; and is eliminated in the feces unchanged.
- Only a small amount of sucralose is absorbed and excreted in urine.
- Well established that gut microflora unable to hydrolyse sucralose

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GRICE and GOLDSMITH, 2000

Lo Han Guo (Monkfruit)

Extracted from a Chinese plant: *lo han guo, lo han kuo*, Arhat fruit, Monk Fruit, *Fructus momordicae* and *Momordicae grosvenori* fructus.

Sweet components (named mogrosides) in extract are triterpenoid glycoside structures.

Not many toxicology studies available, most approvals based on history of use in China.

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HIGH INTENSITY SWEETENERS FROM NATURAL SOURCES:

Lo Han Guo
Stevia

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Lo Han Guo (Monkfruit) regulatory approvals.

- Lo han guo fruits and extracts are considered to be foods in China.
- Proposed JECFA evaluation but not yet done.
- Approved for use in foods and beverages as food additive in US through GRAS process.
- Extracts previously only sold as dietary supplement, in Canada. Recently approved for use as table-top sweetener, but cannot be added to commercially prepared foods and beverages

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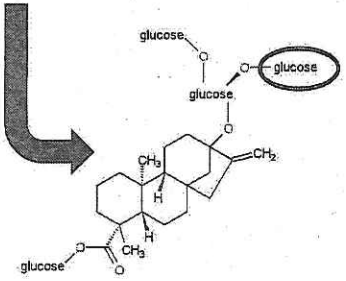
Steviol glycosides

Extraction and purification



Purified extracts from the leaves of the South America shrub - *Stevia rebaudiana;*

Sweetness comes from steviol glycosides, such as rebaudioside A;

Purified glycosides are 30-300x sweet as sugar;

Glycosides contain glucose molecules.

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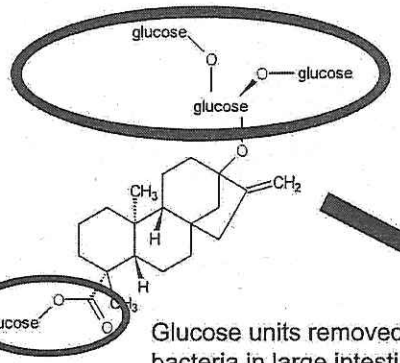
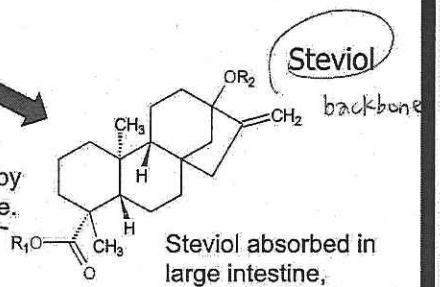
Steviol glycosides



Steviol glycosides are not absorbed.

Glucose units removed by bacteria in large intestine.



Steviol absorbed in large intestine, modified by liver, and excreted.

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http://globalsteviainstitute.com/health-professionals/nutrition-health-hp/metabolism/

Steviol glycosides

Are many different glycosides - different number and position of attachments of glucose.

- Rebaudioside A (Reb A) – sweetest; 4 glucose units
- Stevioside – most abundant; 2 glucose units

All have common steviol backbone,

JECFA ADI = 0-4 mg steviol equivalents/kg/day

- is a group ADI to include all glycosides

- Need to convert from steviol equivalents to glycosides
- *i.e.* ADI for Reb A = 0 - 12 mg rebaudioside A/kg/day

NOTE: ADI is only for extracts purified to contain ≥95% steviol glycosides. Applications for Stevia extract without purification and stevia leaves were not approved.

Regulatory Approval

Many countries–only purified steviol glycosides (meeting JECFA specifications) are approved as food additive for foods and beverages.

Canada, US and others: Unpurified extract allowed as dietary supplement only,

Japan and others – use of unpurified extract allowed in foods

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Global Stevia Institute
http://globalsteviainstitute.com/gsi-map-infographic/

Final Comments

The safety of use of low-calorie sweeteners has been extensively evaluated worldwide.

All sweeteners rapidly move through the body, do not accumulate, and have no adverse effects at levels consumed.

Use of new sweeteners & use of mixtures

- lowers consumption of each sweetener,
- lowers risk of exceeding ADI.

Regulatory agencies worldwide continue to review and confirm safety of use.

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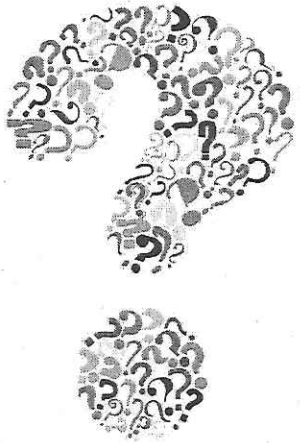
Thank you!



Questions?

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Cyclamate → Some animal cause cancer

rat, high level

但metabolite 兒有rat產生.

人体代謝途徑不同