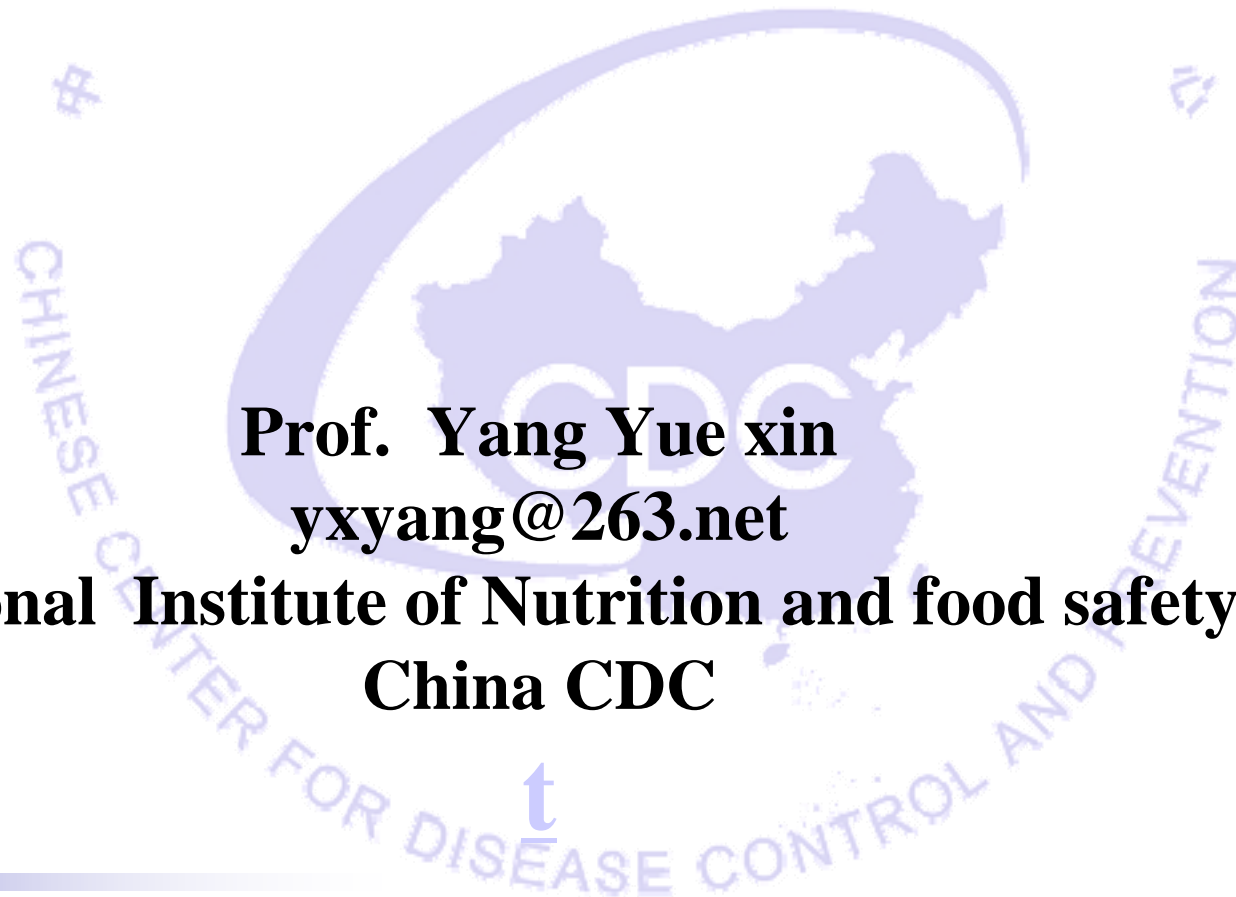




Regulatory System For Food Claims In China

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Outline

Regulatory system on food claims in China

Scientific substantiation for health& nutrition claims on food

New ingredient or Raw materials control ?

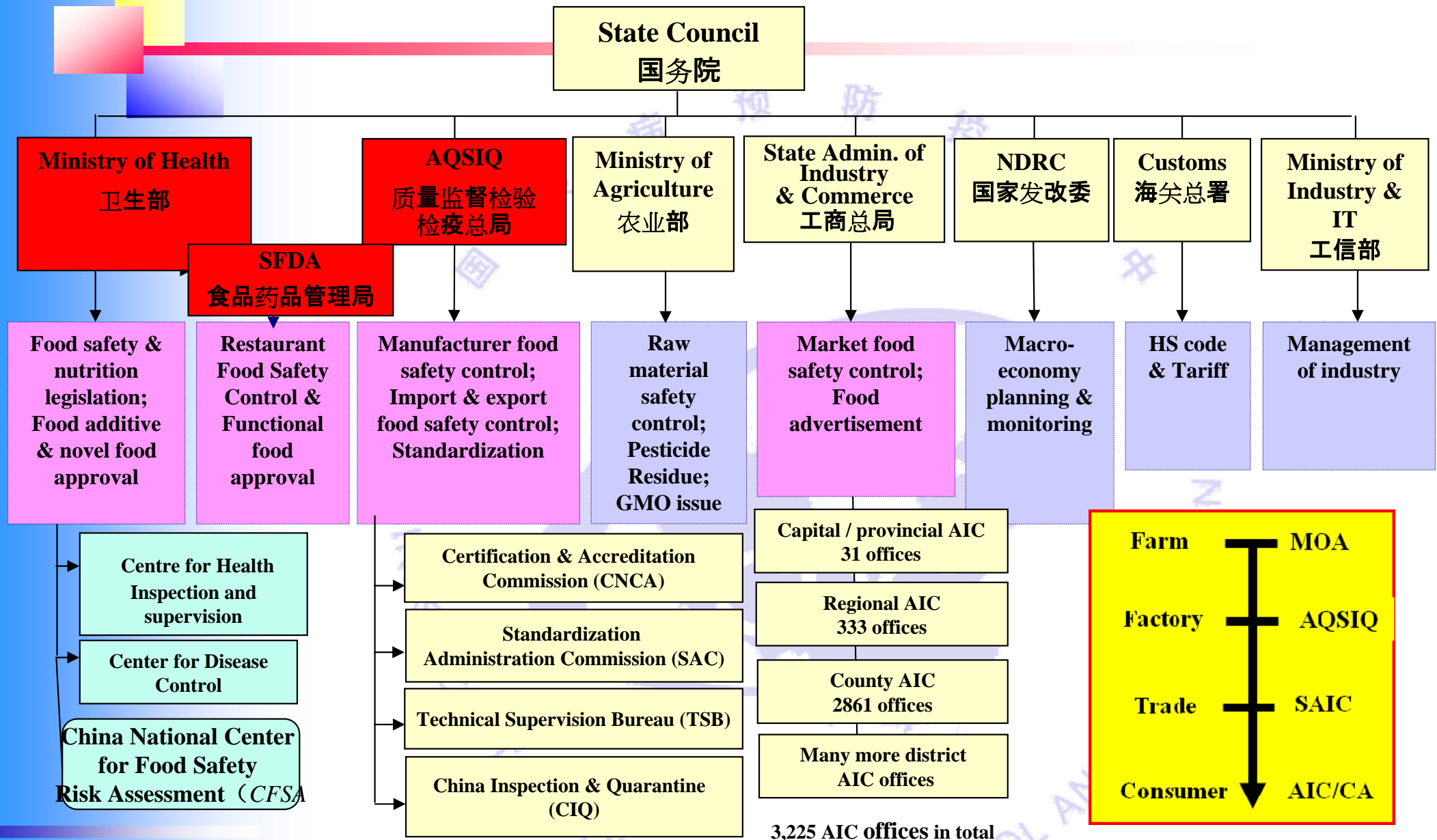
The Challenge for claim in China

FOR DISEASE CONTROL

Regulatory System of Functional Claims in China



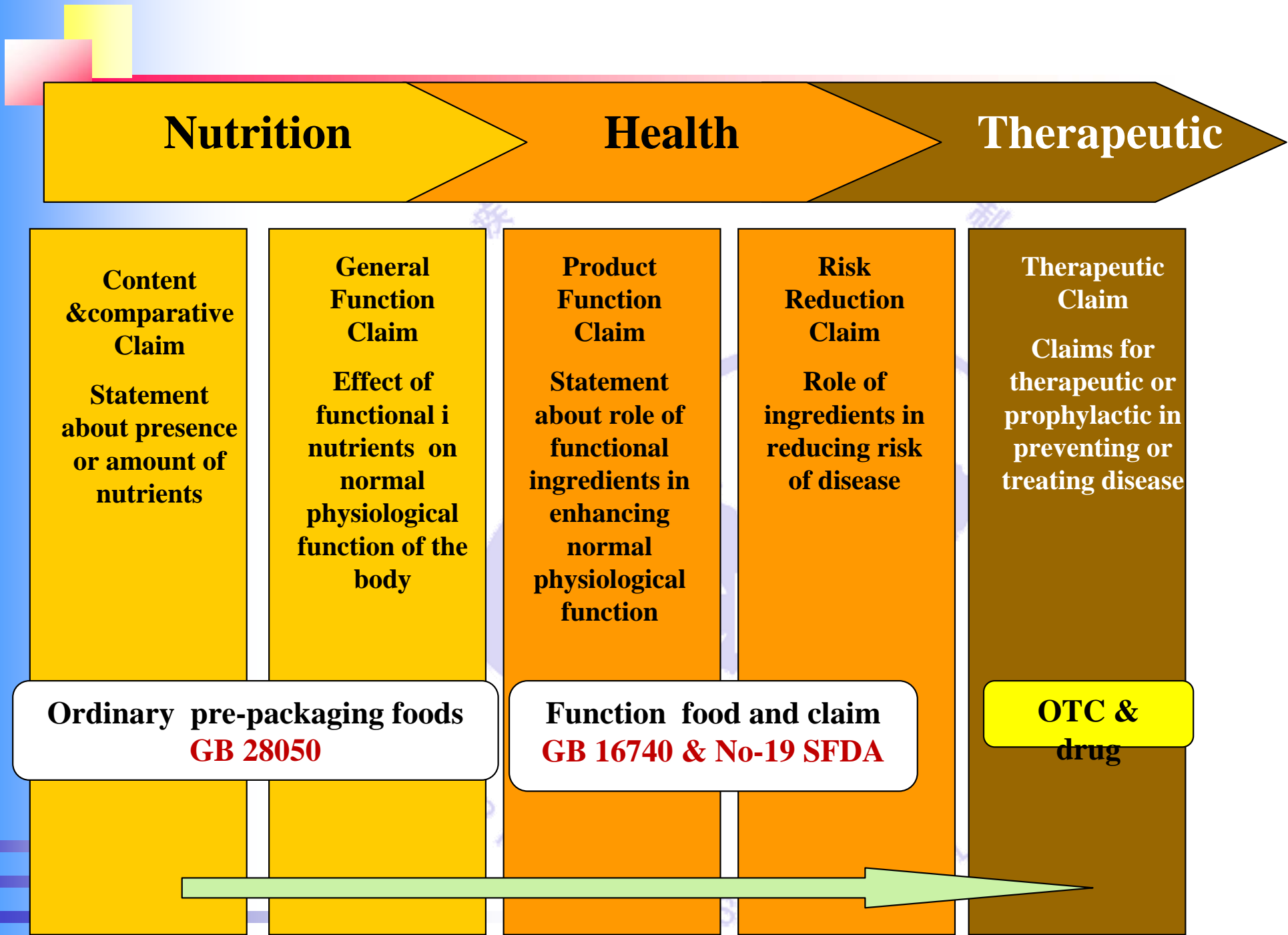
Authorities Related to Food Safety Control



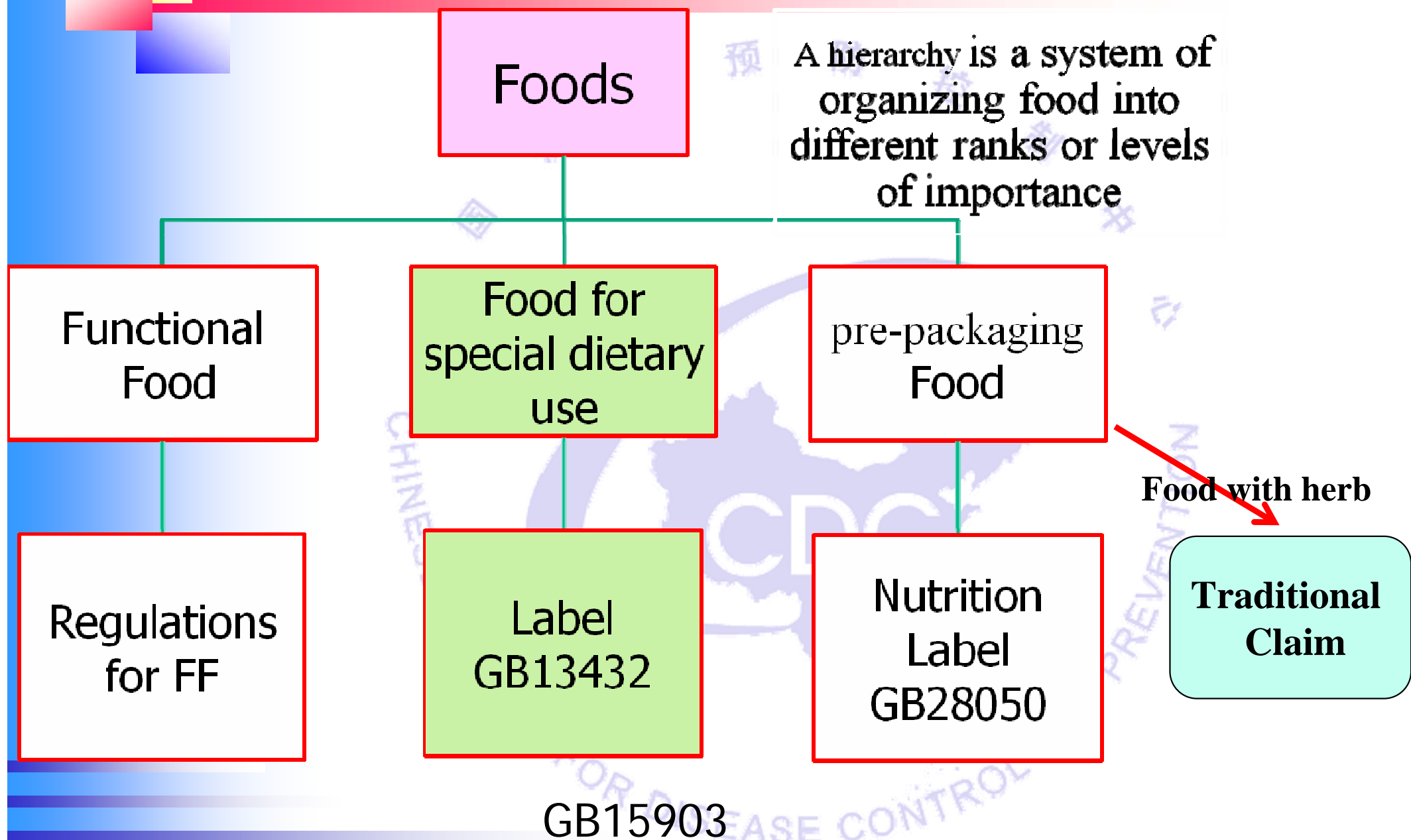
Classification and Definition of Food Claims

- **Nutrient claim** any direct statement about the level (or range) of a nutrient in the food, e.g., “low sodium”
- ***Nutrient Function Claim*** - a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.
- ***Special (Other) function claim*** - These claims concern specific beneficial effects of the food constituents.
- ***Reduction of disease risk claim*** - These claims concern the reduced risk of developing a disease or health-related condition.

Claim Continuum under law



Food claim : regulatory systems



Traditional claims Acquiescence or helpless



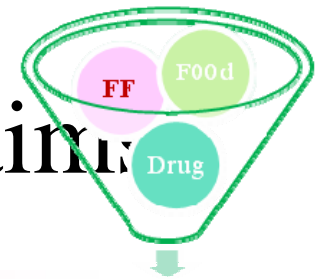


**Scientific substantiation
Functional Claims
& Nutrition Claims**



BY LAW

* Functional claim and nutritional claims



Nutrition claims & nutrients functional claims

- **GB 28050**
- **<General Rule on Nutrition labeling for pre-packaging food>**
- Provide basic nutrition and energy
- for all population groups

Special functional claims and reduction the risk of disease

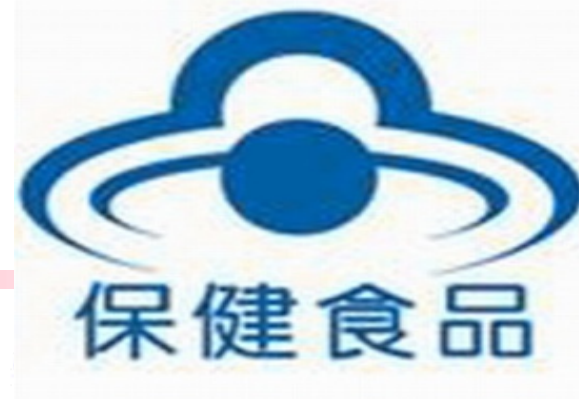
- **GB 16740 & No19 -SFDA**
- **regulation ff**
- Provide primary care or decrease the risk of chronic disease
- for special group



Definition of Health food--

SFDA

- * Health food(function food) is that the food for health care , it is with **special healthy claim** , HFF including nutrients supplement without claim.
- * It is suitable for use by **specific groups** of people to improve their body physiological functions or nutrients intake.
- *but it is not aimed at diseases treatment .
- . and shall not cause any acute, subchronic, or chronic harm to human body.



Functional Food Symbol

once a product is approved should carry the symbol to distinguish it from other non-approved healthy food, the symbol is attractive to consumers as it assures them that food has passed the test.



functional food

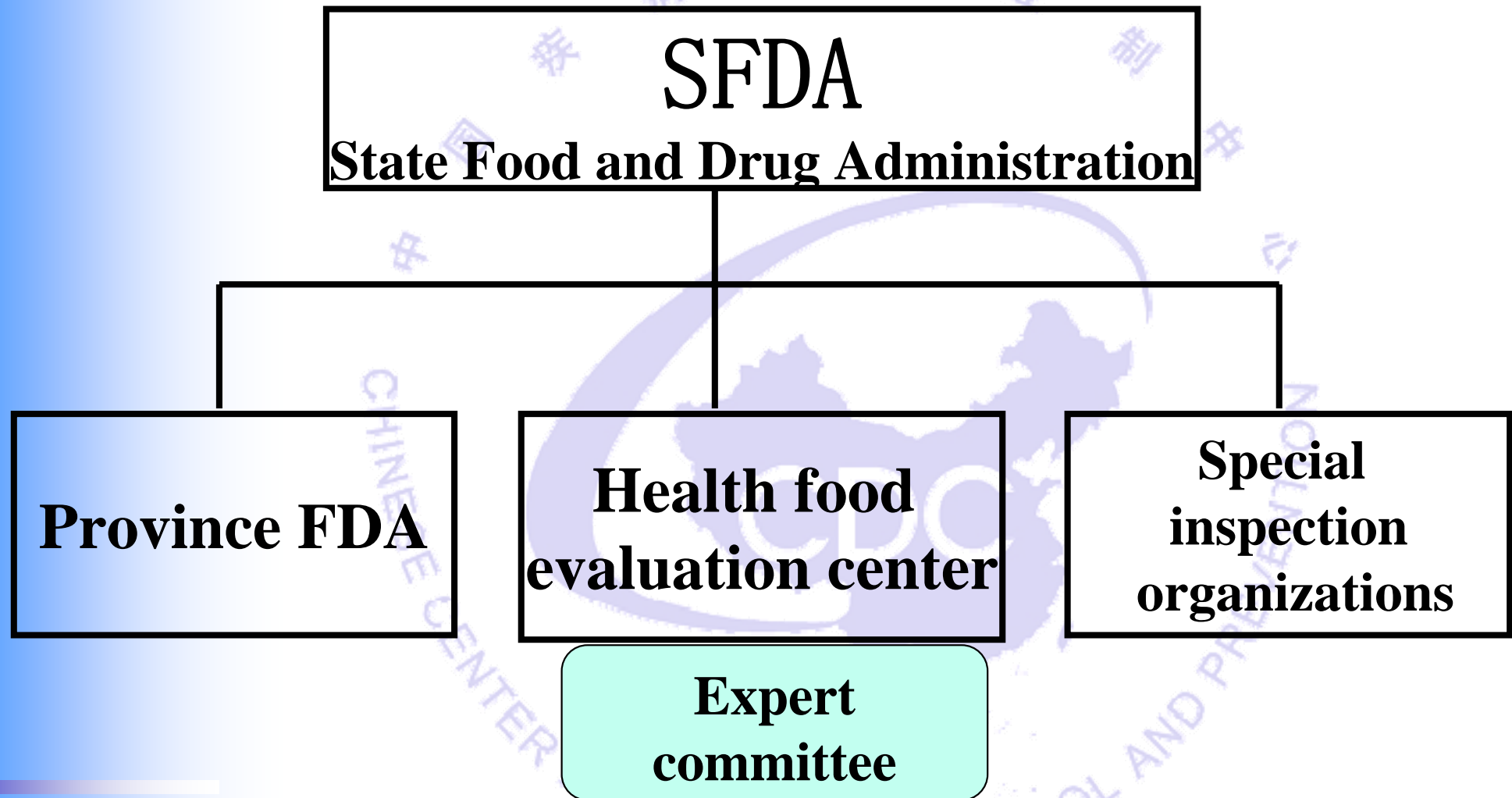
- **Two basic features:**

1 Safety, not cause any acute, subchronic, or chronic harm to human body.

2 functionality, have physiological function regulation effect for a specific population to consume, but not for the purpose of disease treatment. They can not instead of drugs to treat patients and must be strictly distinguished from drugs.

Administration

SFDA is responsible for the regulation of national health food registration and examination and approval of health food.



27 categories of claims are allowed

1. *Enhancing immune systems*
2. *Sleep improvement*
3. *Alleviating physical fatigue*
4. *Enhancing anoxia endurance*
5. *Irradiation hazard protection function*
6. *Increasing bone density*
7. *Assisting liver protection against injury*
8. *Alleviating eye fatigue*
9. *Eliminating acne*
10. *Eliminating skin pigmentation*
11. *Improving skin ability to retain moisture*
12. *Improving skin oil content function*
13. *Assisting blood lipids reduction*
14. *Assisting blood sugar reduction*
15. *Antioxidative function*
16. *Assisting memory improvement*
17. *Alleviating lead excretion*
18. *Improving throat function*
19. *Assisting blood pressure reduction*
20. *Facilitating milk secretion*
21. *Assisting weigh control*
22. *Improving child growth*
23. *Improving nutritional anemia*
24. *Regulating gastrointestinal flora*
25. *Facilitating digestion (regularity)*
26. *Facilitating bowel movement* **constipation**
27. *Protection of gastric mucosa*

Note:

There are 27 standard test procedures for each claim . Normal , animal and human test are required

Main forms :
tablet \liquid \capsule \powder
Only 2.8% food form





Scientific evidence-based for a food health claim

What is the requirement ?



- The management of health food registration should follow the principles of being scientific, open, equal, fair, effective and convenient.
- the SFDA should arrange food, nutrient, medical, pharmaceutical and other technical personnel to carry out technical examination of application materials and administrative examination, and make a decision over the examination.
- SFDA issue the product Approval Certificate.

Objective --regulation and standards

- a) Produce a consensus on principles for the scientific substantiation of health-related claims for food.
- b) Select common criteria for how markers should be identified, validated and used.
- c) To evaluate critically the existing schemes, which assess the scientific substantiation of claims

Prohibited claims

- claims for therapeutic or prophylactic action;
- claims which could be interpreted as advice of a medical nature from any person;
- claims that a food will prevent, alleviate or cure any disease or condition affecting the human body; and
- claims that health or an improved physical condition may be achieved by consuming any food.

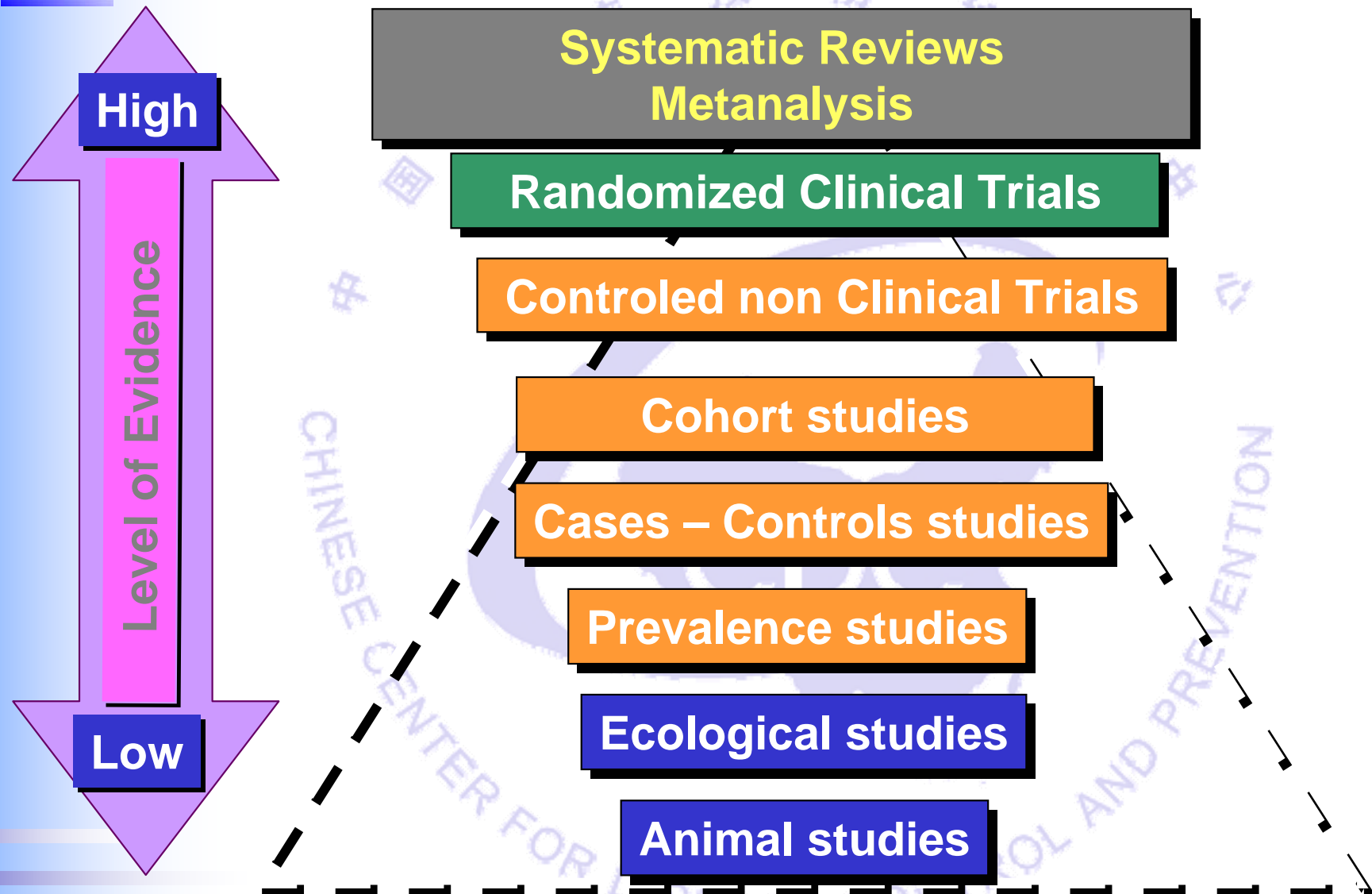
A evidence based approach

- **Key Principles for functional food claims**
 - International standard and domestic regulatory environmental
 - evidence - based review
 - public literature & product test
 - management by classification
 - With and without claim

How to evaluate ?

- 1 *《 The standard Safety assessment Procedure for Functional Food. 》*
- 2 *《 The standard functional assessment procedure for Functional Food. 》*
- 3 *《 The standard analytic methods for Functional Substance 》*

1 Hierarchy in Scientific Evidence



2 Product test

Green Book	Description of Regulation
<i>“The standard functional assessment procedures and methods of health foods”</i>	<i>describes the basic requirement for the test samples, details individual function standard procedures of assessment among 27 functions include animal and human tests, the biomarkers, determinant and judgement indicators in each method are included.</i>
<i>“The standard toxicological assessment procedures and methods of health foods”</i>	<i>describes the basic requirements for the test samples, and details standard procedures of safety assessment such as acute toxicity tests, tests, 30 or 90 days feeding tests etc</i>
<i>“The standard analytic methods for functional components”</i>	<i>describes the basic requirements and components of herb, food or extracts which must be tested if using this substance in your product, and the analytical methods involving hundred plant substances.</i>

Test requirement



1--toxicological detection

acute test, 90-Day Dietary Toxicity Study or others

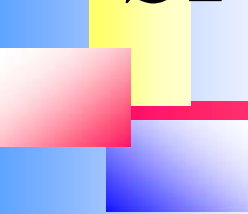
2 --Functional test evaluation

Anima study and human trial

3 --Chemical (& microbe) analysis

- * hygiene(Microorganism & heavy metal)
- * nutrition composition
- * stability of main functional ingredient
- * product specifications

4 --Identify (strain , source, stimulants) and adulteration

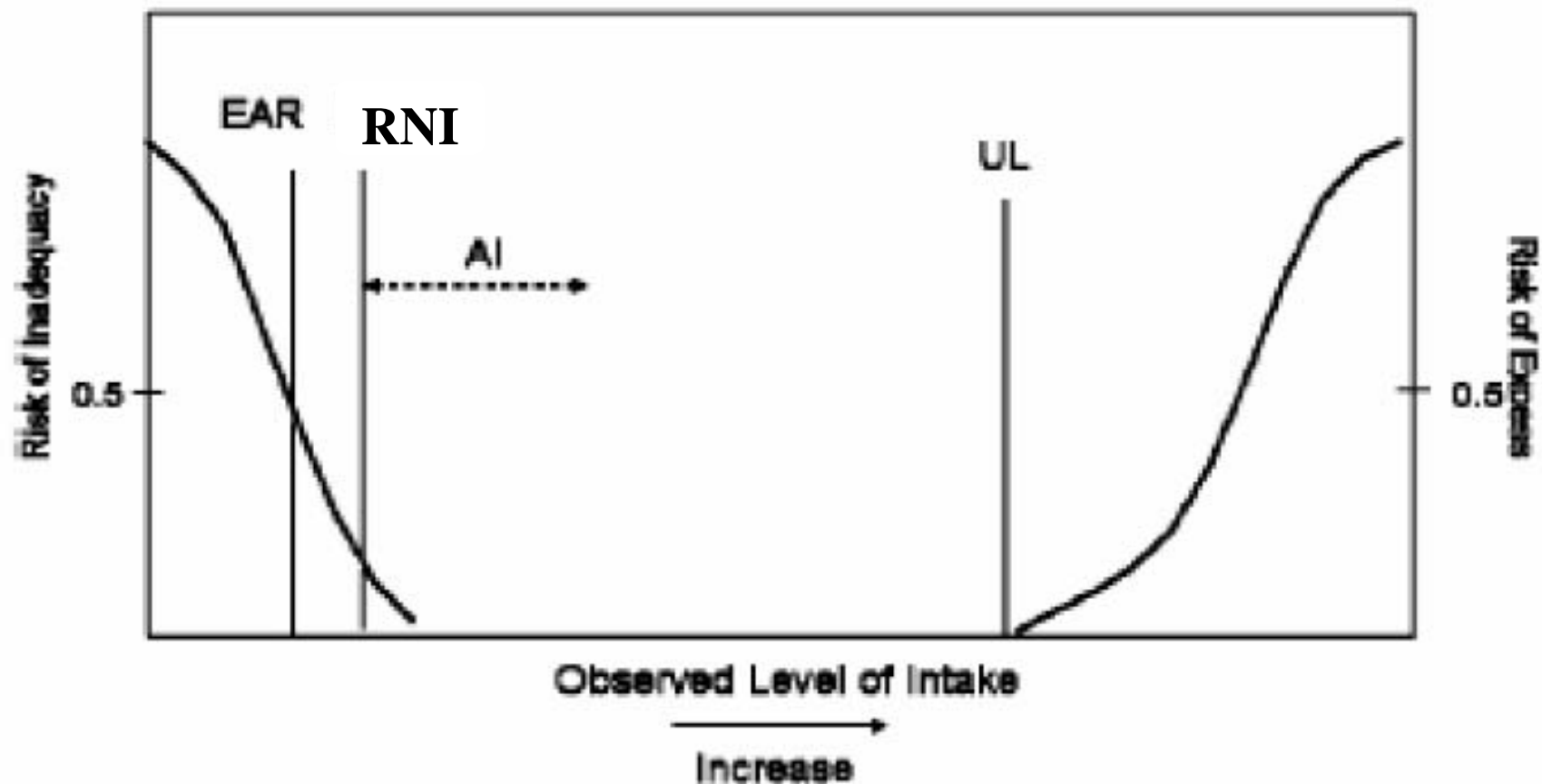


SFDA--“Regulation on nutrient supplements”

- Describes the **definition** of nutrient supplements,
- Describes the **categories of nutrients** and its **compounds** that can be use in nutrient supplements (vitamins and minerals , some fat acids, amino acid)
- The amount (**upper and lower**)of vitamins and minerals that can be used in nutrient supplements.

Framework for DRIs: EAR, RDA, AI & UL

(Figure from Development of DRIs (IOM) at <http://books.nap.edu/topics.php?topic=380>)



DISEASE CONTR

Nutrients Supplement & Dietary supplement

- **Nutrient supplements are products aimed to supply vitamins minerals and not energy, thus to replenish dietary insufficiency, defend nutrition deficiency and reduce the risk of chronic degenerative diseases.**
 - * without energy ,
 - Calcium , or Vit A
 - Multi-vitamins , Multi-minerals
 - Complex -vita +minerals
- **Dietary supplement ?**

Nutrition Labeling

**GB28050
2013.1.1**



营养成分表 Nutrition Information

项目 Items	每份 per Serving	营养素参考值% NRV%
能量 Energy	541千焦 (KJ)	6%
蛋白质 Protein	1.2克 (g)	2%
脂肪 Fat	5.2克 (g)	9%
总碳水化合物 Total Carbohydrate	19.2克 (g)	6%
钠 Sodium	82毫克 (mg)	4%

每份：30克(1枚)

- 麦淇酪(Marshmallow): 不含脂肪
- 蛋白质含量(糕坯/干基计)(%) $\geq 4.5\%$



GB28050--Nutrition Labeling

- **Conventional Food**
all prepackaged foods
 - foods for special dietary uses ,
 - functional food ,
not included

Nutrition Labeling —

- **Nutrient declaration**
- **Nutrition claim**
- **Functional claim**
- **Formats**
-
-
-

GB28050--Nutrition Labeling

- **mandatory enforcement**

- 1+4

**Energy ,
protein ,
fat,
CHO
Sodium**

- **conditional approach or voluntary**

- TFA , if use oil with Tf
- If a nutrient fortified
- If a nutritional claim made
- If a functional claim made

Standardized nutrition and function claims

- Based on GB 28050 .
- Here include the Standardized Claims for 32 nutrients .
- Nutrition claims , function Claims
- These do not need individual review or no-pre-market approval

Nutrition and functional claims

Claim	Nutrient amount allowed
Low Fat	≤ 3 gms
Low Saturated Fat	≤ 1 gm
Reduced Calorie	$\leq 25\%$ of Cal of original
Cholesterol Free	< 2 mg

Zinc : Maintenance of normal skin

CHO : Contribution to normal carbohydrate metabolism

营养成分表Nutrition information

项目	<i>Per 100g (ml)</i> <i>Or per serving</i>	营养素参考值 % (<i>NRV%</i>)
能量 <i>Energy</i>	千焦 (<i>kJ</i>)	%
蛋白质 <i>prot</i>	克 (<i>g</i>)	%
脂肪 <i>fat</i>	克 (<i>g</i>)	%
--饱和脂肪	克 (<i>g</i>)	%
碳水化合物 <i>CHO</i>	克 (<i>g</i>)	%
钠 <i>Na</i>	毫克 (<i>mg</i>)	%

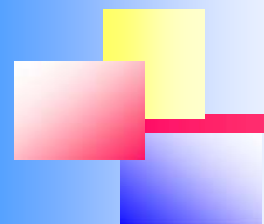
低脂肪 **XX** (*Low fat XX*)

每日膳食中脂肪提供的能量占总能量的比例不宜超过30% (功能声称)

营养声称可以标在营养成分表下端、食品名称或其他任意位置

允许误差 allowable tolerance of declared value

nutrients	allowable tolerance range %	
	Lower limit	Upper limit
Energy, protein, fat and fatty acids, carbohydrate, sugar, dietary fiber and sodium		>120%
Vitamin B ₁ , B ₂ , B ₆ , B ₁₂ , C Other vitamins, minerals	> 80%	
VitA , D	> 80%	< 180%

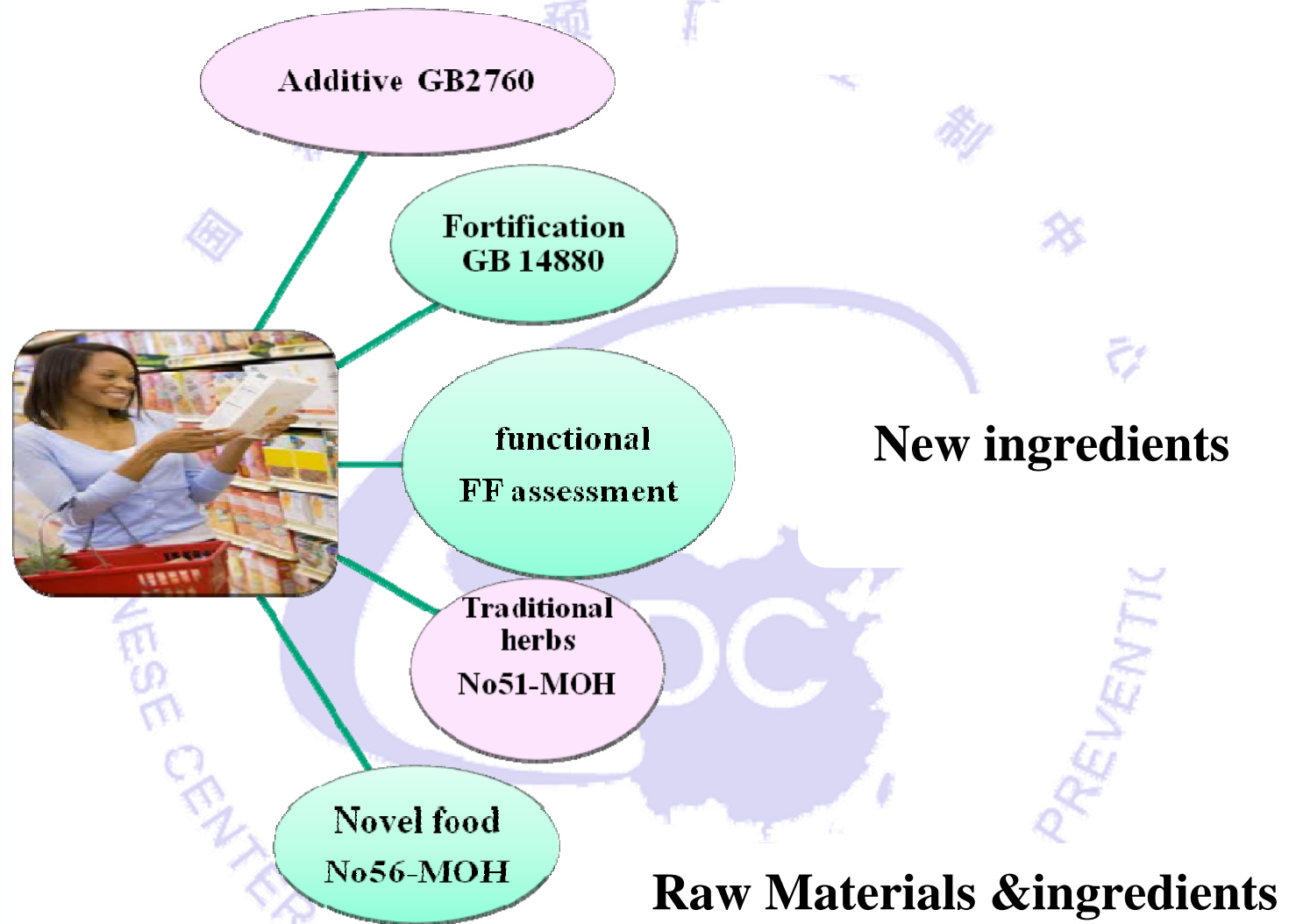


New Ingredients

Approach and management

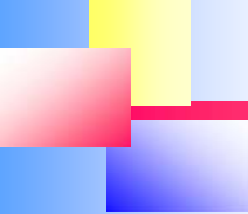
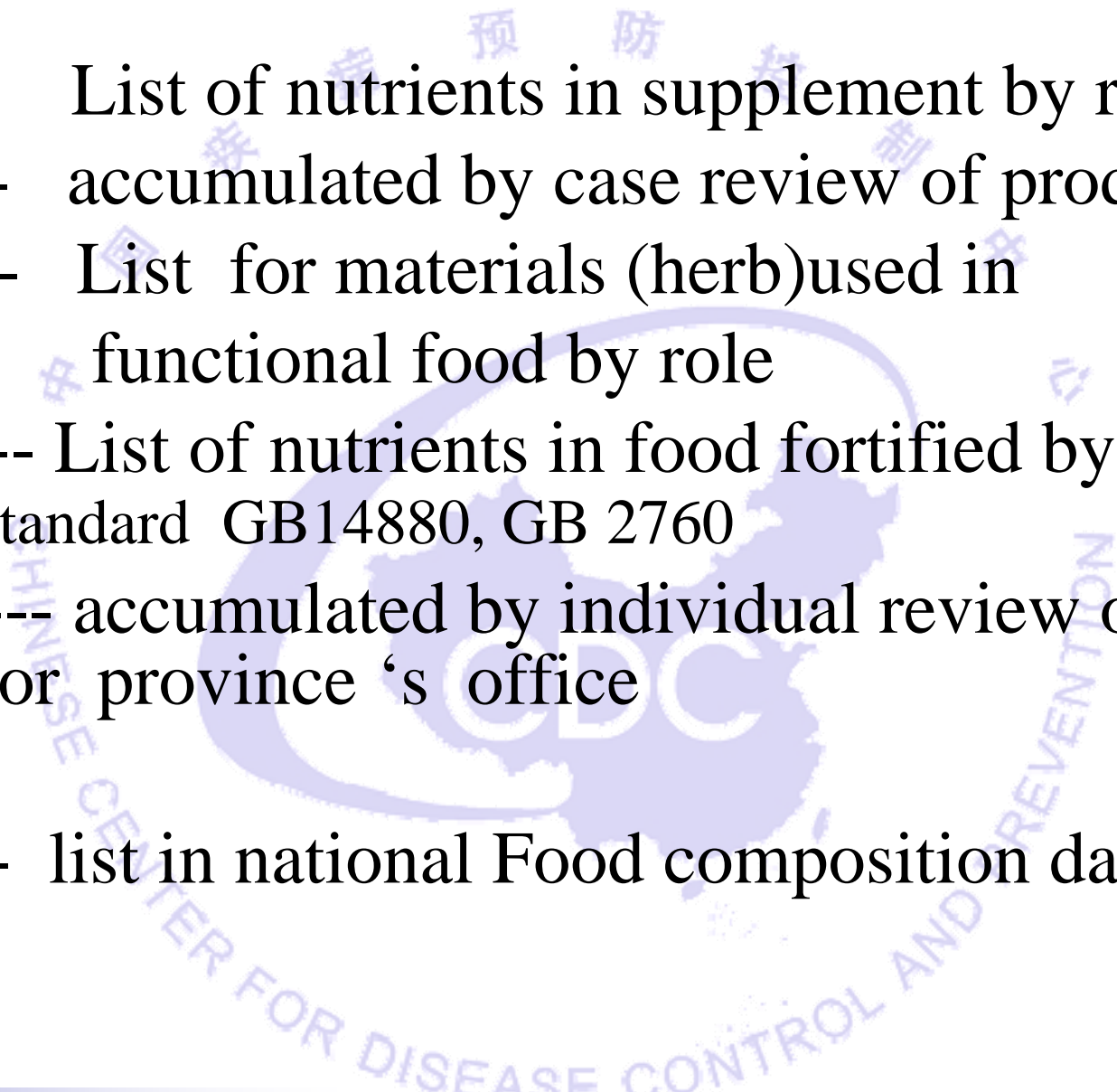


New material and Ingredient classification and management



Positive list

Free used Materials & ingredients

- 
- 1 SFDA -- List of nutrients in supplement by rule
-- accumulated by case review of product
 - 2 MOH --- List for materials (herb)used in
functional food by role
--- List of nutrients in food fortified by
national standard GB14880, GB 2760
--- accumulated by individual review of
industry or province 's office
 - 3 INFS --- list in national Food composition database
- 



MOH

- list for Bacteria and probiotics**
- list for Enzymes**
- list for novel food approved
accumulated by 2007—present**
- list for additive approval**
- Guideline for ingredients combining about
herb and other.**
 - The permitted minimum and maximum dose
on nutrients supplement**

Negative list

- --- list for restrictive herb to used in FF
- ---Substances prohibited from use in food



Example : Novel Foods

- **Definition** : “Novel Foods” are foods and food ingredients that were not yet used on a significant scale for human consumption , there are concerning
 - * novel foods ()
 - * novel food ingredients (),
 - * new subsistent of Structural change ()
 - * new bacterial or other
classified in four categories.
- **Nutritional , safety, Regional, reproducibility, developmental**

Dossier required for novel food

- 1 Traditional (long term edible experience) ;
- 2 edible history and Safety or,
- 3 nutrition composition and functional;
- 4 quality controlled ;
- 5 new Scientific Evidence by literature
- 6 Test reports by product
- 7 The scientific evidence of ingredients and dose
- 8 **Other documents that related to help registration**
--Certificates for the product

Key principal for new ingredient approach

A risk based approach to new ingredient

- Risk Assessment based approach
- Evidence –based review
- Substance Equivalents



Challenge

16 years
experience
and more than
10000 FF



misplay

Experience

Blank

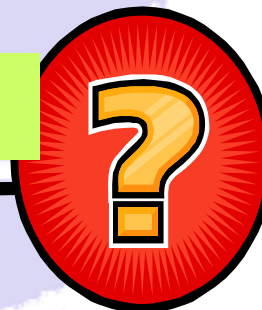
Case by case

How
much



Functional
claim

What



Application by industry

Challenge : the theory on tradition medicine vs nutrition

- 困惑和争论

**Confused &
Debate on
tradition
medicine vs
nutrition**

- Claim for a Single ingredient
- * **multiple ingredients for a claim**
- The requirement for scientific evidence ?
Experience form --?
- Dose ? Methods ?

Challenge : balance with other description in labeling

- 食物标准间的平衡

Diversity of food
and standard

- * Diversity of **claim description** in the labeling
- GB13432 Food for special dietary use
- GB Medical food

News

- **New Chinese DRI**

- DRI **Revised** will be issue by May 2013 .
- Energy , protein and some minerals may have some change
- 21 phyto –chemicals have been reviewed by DRI expert committee

- New definition

- PI

- SGL

Specific guidance level



THANK YOU