

## China Food Safety Law Implications for Health Foods

CMA & NPNZ Webinar  
May 2016



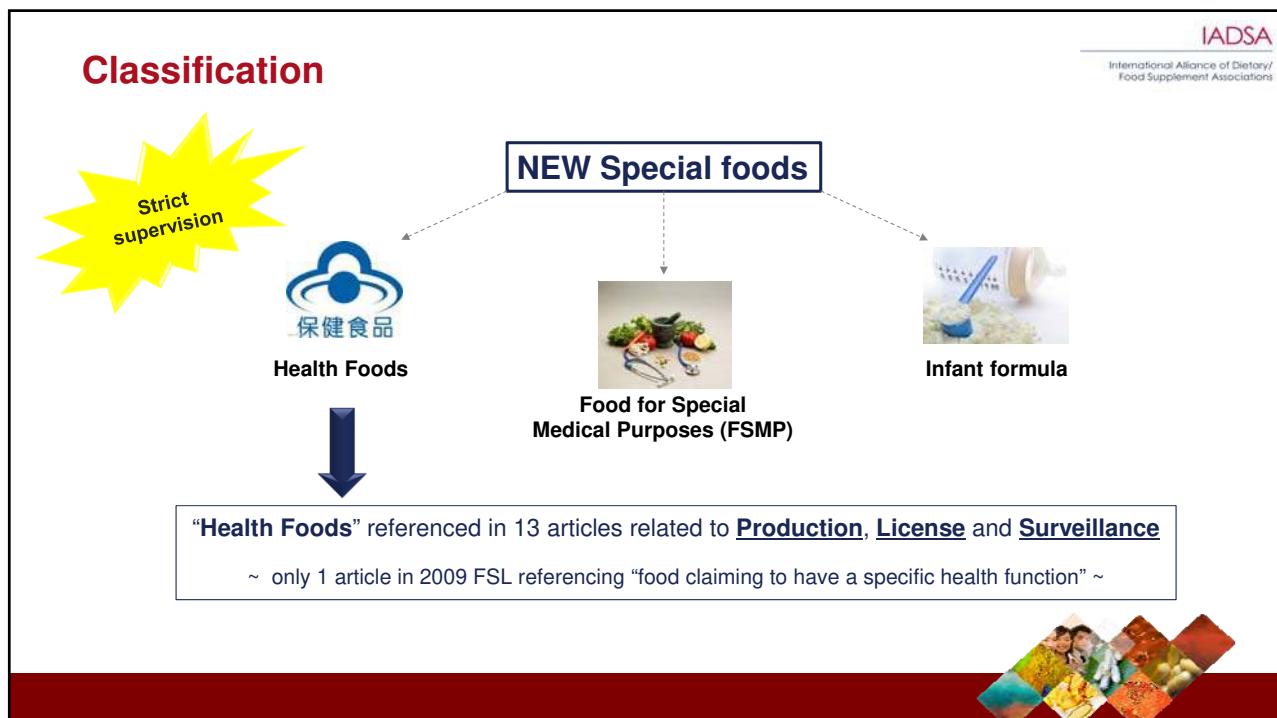
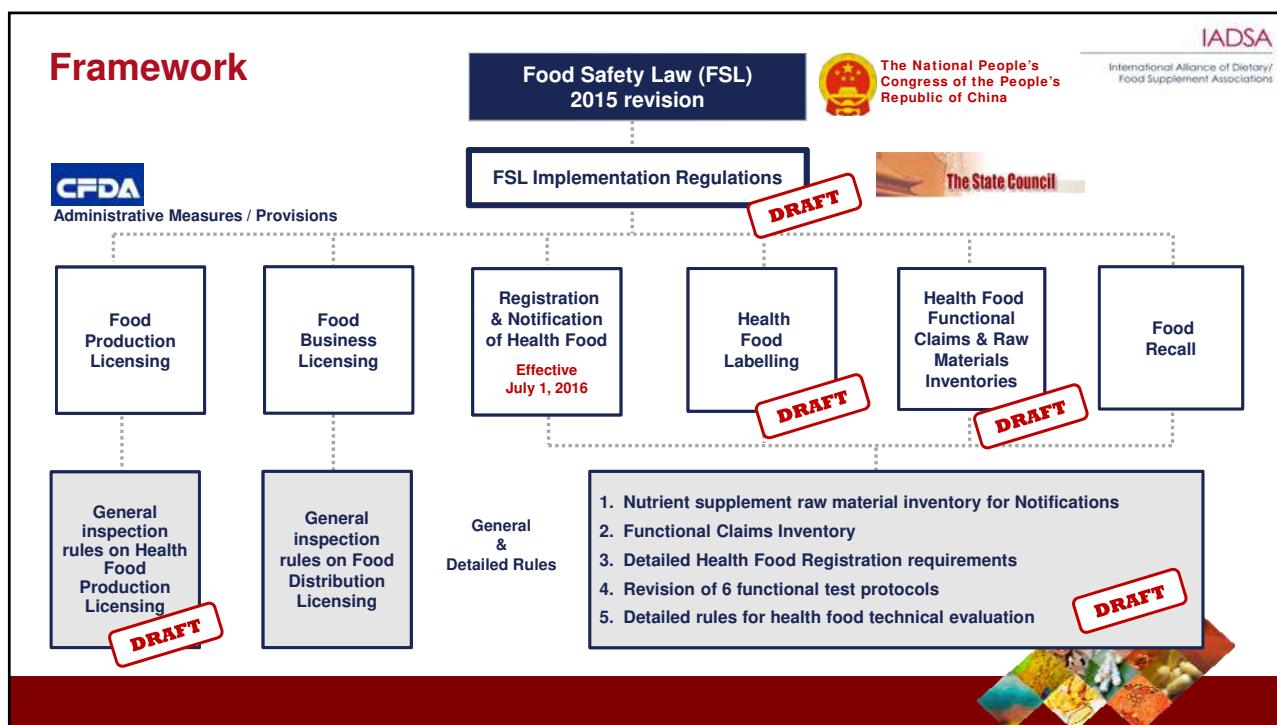
## China Food Safety Law (2015)

### Stipulations related to health foods

|                                 |  |
|---------------------------------|--|
| <b>Legal status</b>             | "Health food" category retained in Final law |
| <b>Administrative direction</b> | Notification and registration system         |
| <b>Responsibility</b>           | CFDA to issue affiliated regulations         |

Effective  
Oct 1, 2015





## Definition

IADSA

International Alliance of Dietary/  
Food Supplement Associations

### FSL Implementing Regulations (DRAFT) - Article 195

- **Health foods:** a food with health function claims or for supplementing nutrients (such as vitamins/minerals), for regulating body functions, not intended to cure diseases, containing specific functional ingredients, suited for specific groups of people, and with fixed amount consumption.
- **Special dosage food products with fixed amount consumption:** foods in special dosage forms, such as capsule, oral agent, tablet, granules, and pills; such foods shall be consumed at fixed amount, or has daily intake volume.



## Product Market Access

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### Notification (filing) system in addition to Registration

|              |  |   |
|--------------|--|---|
| Registration | Using ingredients not in the Health Food Raw Material Inventory    |  |
| Registration | Health food imported for first time* (except nutrient supplements) |  |
| Notification | Health food imported first time* that are nutrient supplements     |  |
| Notification | Using ingredient in the Health Food Raw Materials Inventory        |  |

### Notification steps

- 01 Manufacturer submits notification
- 02 Notification number issued on spot
- 03 Notification certificate generated
- 04 Publish on website

within  
3 months

→ import health food

→ apply for food production license

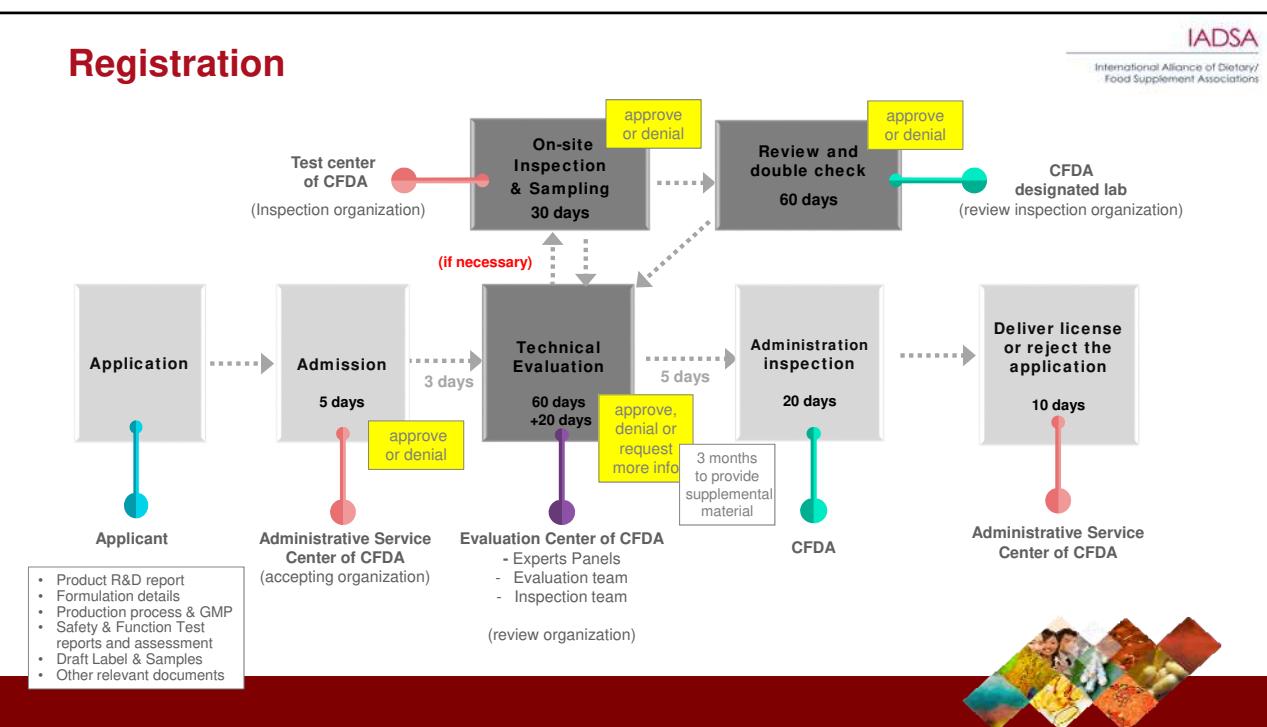
\* Health foods not from the same country, same company, or the same formula (FSL Implementing regulations - Dec 2015 DRAFT)



## Registration

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## Health Food Inventories

IADSA

International Alliance of Dietary/  
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Food Safety Law calls for CFDA to publish these inventories together with NHFPC and SATCM

### 1. Raw Materials list

- Basis for notification
- Positive list of ingredients (name, dosage, claim)

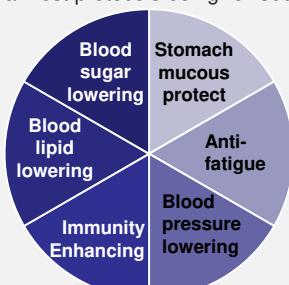
~ 1<sup>st</sup> list drafted ~

Nutrient Supplement raw material list

- 13 vitamins: A, B1, B2, B6, B12, C, D, E, K, niacin, folic acid, biotin, pantothenic acid
- choline
- 8 mineral: Ca, Mg, Zn, Fe, K, Mn, Se, Cu
- sources of nutrients
- minimum and maximum limits

### 2. Functional claims list

- List of categories of functional claims allowed
- Reviewing current 27 Functional claims
- Functional Test protocols being revised



NHFPC = National Health and Family Planning Commission

SATCM = State Administration of Traditional Chinese Medicine



**营养素补充剂新规  
政企协研对话会**

**Workshop on New Regulation of  
Nutrients Supplement**



中国营养学会  
Chinese Nutrition Society



中国营养保健食品协会  
China Nutrition and Health Association



**CNHFA**



**CNS**



**IADSA**



**Peking University**



**CFDA**



**Key Topics Discussed**

- Safety based Vitamin & Mineral limits
- Natural & New Sources of nutrients
- Products outside scope of inventory



**Thank You!**

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