China Food Safety Law
Implications for Health Foods

CMA & NPNZ Webinar
May 2016

China Food Safety Law (2015)

Stipulations related to health foods

- **Legal status**: "Health food" category retained in Final law
- **Administrative direction**: Notification and registration system
- **Responsibility**: CFDA to issue affiliated regulations

Effective Oct 1, 2015
**Framework**

**Food Safety Law (FSL) 2015 revision**

**FSL Implementation Regulations**

1. Nutrient supplement raw material inventory for Notifications
2. Functional Claims Inventory
3. Detailed Health Food Registration requirements
4. Revision of 6 functional test protocols
5. Detailed rules for health food technical evaluation

**Classification**

NEW Special foods

Health Foods

Food for Special Medical Purposes (FSMP)

Infant formula

“Health Foods” referenced in 13 articles related to Production, License and Surveillance

~ only 1 article in 2009 FSL referencing “food claiming to have a specific health function” ~
Definition

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

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

1. **Application**
2. **Admission**
   - 5 days
   - 3 days
3. **Technical Evaluation**
   - 20 days
   - 5 days
   - 60 days
   - 20 days
4. **Review and double check**
   - 60 days
   - 5 days
   - 10 days
5. **Deliver license or reject the application**

### Health Food Inventories

**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)

   ~ 1st 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

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**NHFPC** = National Health and Family Planning Commission  
**SATCM** = State Administration of Traditional Chinese Medicine
Key Topics Discussed

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

Thank You!

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