

China Food Safety Law Implications for Health Foods

IADSA Annual General Meeting Prague ❖ April 2016





Food Supplement Associations

China Food Safety Law (2015)

Stipulations related to health foods

Legal status "Health food" category retained in Final law

direction system

Administrative Notification and registration

Responsibility CFDA to issue affiliated regulations







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Framework Food Safety Law (FSL) **The National People's Congress of the People's** 2015 revision **Republic of China Food Safety Law** The State Council **Implementation Regulations** CFDA **Administrative Measures / Provisions** Registration **Health Food** & Notification **Functional** Food Food Health **Food** of Health Food Food Claims & Raw **Production Business** Recall Licensing Licensing Labelling **Materials Effective Inventories** July 1, 2015 1. Nutrient supplement raw material inventory for Notifications General General 2. Functional Claims Inventory General inspection rules inspection rules on Food 3. Detailed Health Food Registration requirements on Health Food **Detailed Rules Distribution Production** 4. Revision of 6 functional test protocols Licensing Licensing 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 <u>health function claims</u> or for <u>supplementing nutrients</u>
 (such as vitamins/minerals), for <u>regulating body functions</u>, not intended
 to cure diseases, containing specific functional ingredients, suited for
 specific groups of people, and with <u>fixed amount consumption</u>.

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.





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Product Market Access

Notification (filing) system in addition to Registration

Registration

Using ingredients not in the Heath 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 steps

01 Manufacturer submits

02 Notification number issued

OB Certificate generated

04 Publish on website



Import health food

Notification

Using ingredient in the Heath Food Raw Materials Inventory



apply for food production license



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



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Health Food Inventories

CFDA to publish these inventories together with NHFPC and SATCM

- 1. Raw Materials list
- Basis for notification
- Positive list of ingredients (name, dosage, claim)

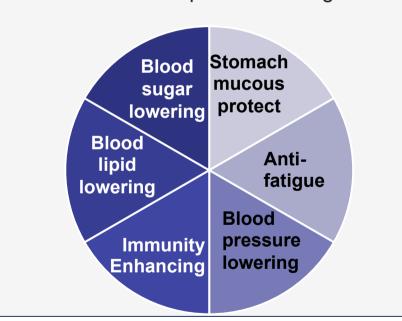
~ 1st list drafted ~



Nutrient Supplement raw material list

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

- 2. Functional claims list
- 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





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





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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