



IADSA

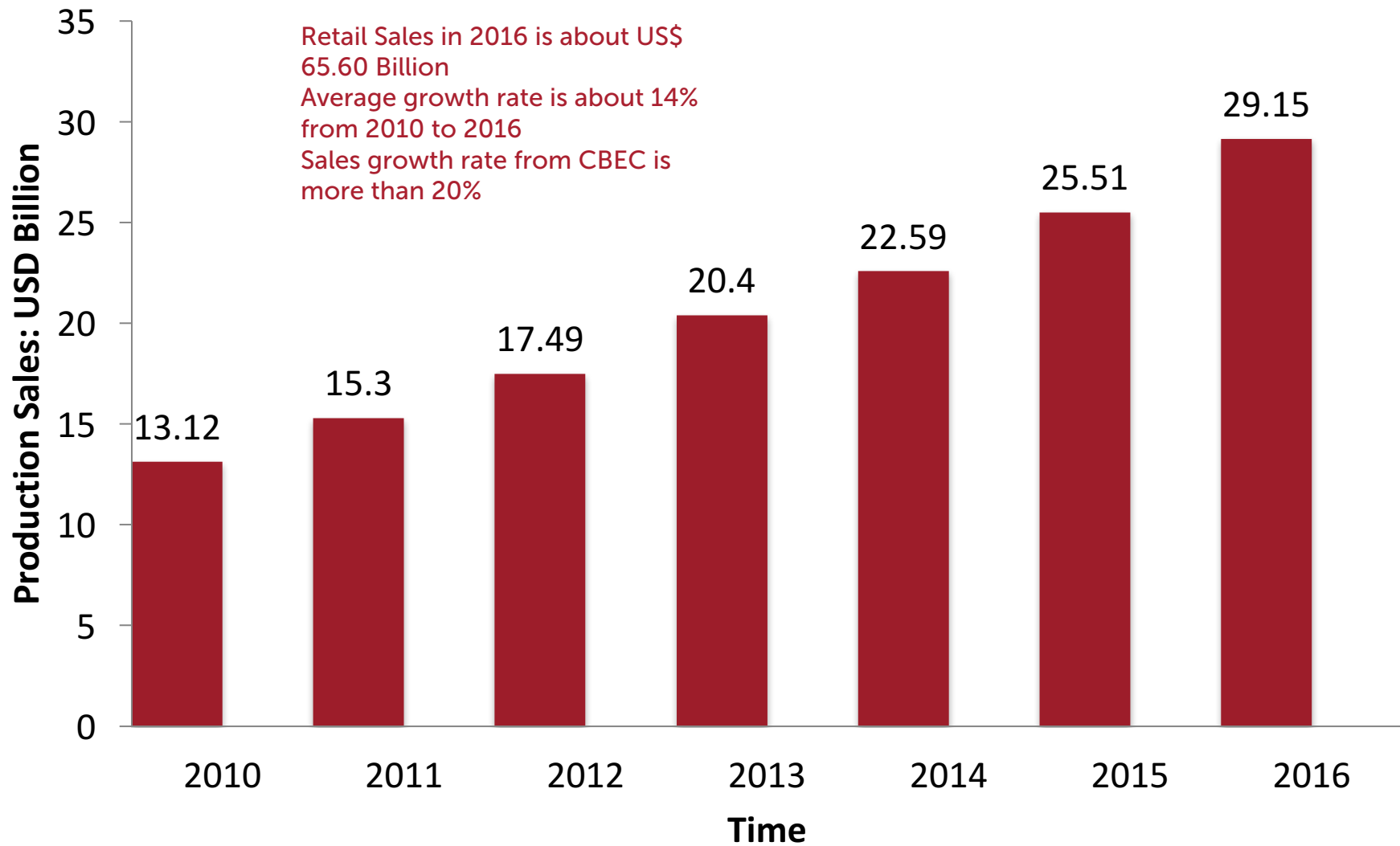
International Alliance of Dietary/
Food Supplement Associations

16 MAY | SEOUL

IADSA | Issue Highlights

China | HongMin Xu

Health Food in China Market



Health Food in New Food Safety Law

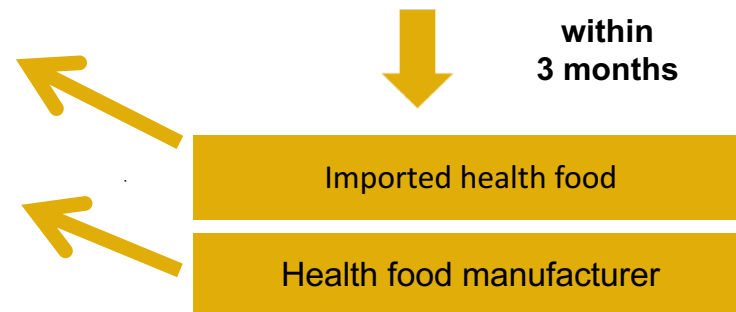


- Health Food was explicitly included in the Law
- New Classification: Special Food, including health food, medical food and infant formula
- Notification system in addition to registration
- Health food functional claims and raw material inventory will be developed by CFDA with NHFPC and SATCM together
- Raw materials registered with product → Raw materials inventory → Notification

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 supplement	
Notification	Using ingredient in the Health Food Raw Materials Inventory	

Notification steps

1. Manufacturer submits notification
2. Notification number issued on spot
3. Notification certificate generated
4. Publish on website



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

Framework



Administrative Measures / Provisions

Food Safety Law (FSL) 2015 revision



The National People's
Congress of the People's
Republic of China

FSL Implementation Regulations

DRAFT

The State Council

Food
Production
Licensing

Food
Business
Licensing

Registration
& Notification
of Health Food

Effective
July 1, 2016

Health
Food
Labelling

DRAFT

Health Food
Functional
Claims & Raw
Materials
Inventories

DRAFT

Food
Recall

General
inspection
rules on
Health Food
Production
Licensing

DRAFT

General
inspection
rules on Food
Distribution
Licensing

General
&
Detailed Rules

1. Nutrient supplement raw material inventory for Notifications **Effective Dec 27 2016**
2. Detailed Health Food Registration requirements (w / technical evaluation) **Effective Nov 14 2016**
3. Auxiliary raw material inventory **Effective Apr 28 2017**
4. Guidance for Notification of Health Food **Effective Apr 28 2017**
5. Health Food Raw Materials Inventory (not for Nutrients)
6. Revision of 6 functional test protocols

DRAFT



Detailed Health Food Registration Requirements

- **General Direction**
 - Registration → inventory of raw materials & claims → notification, **but no implementing rules**
- **Registration testing**
 - Stability and hygiene testing allowed to be performed by applicant in their lab (w/lab inspection)
- **Publication of registration documents**
 - Approved product documents (i.e. active ingredients, mfg process, RM specs) – for market surveillance / consumer info.
- **Nutrient Supplement registration criteria**
 - RNI or AI in 2013 DRI's book published by CNS
 - Applicable national standard for quality control or at least listed in GB14880 for fortified food if a nutrient just in China Pharmacopeia
 - Submitting dossiers which can meet the criteria for adding onto the List for notification
- **New Ingredient registration**
 - Ingredient even used in approved product might still be considered as new
 - New ingredient will be evaluated and approved with product together
 - Safety documents need to be provided by reference of the requirements for evaluation of new food ingredient

NOTE: New Department of Special Food Registration was formed and responsible for all special foods (infant formula, FSMP, health foods)



Detailed Health Food Notification Requirements

- **Nutrient Supplement only**
 - Three relative supporting documents were released, including inventory of raw materials and auxiliary ingredients
- **Applicant for Notification**
 - Applicant for notification of domestic products shall be a manufacturer
 - Applicant for notification of imported products could be either a manufacturer or a seller
- **Notification testing**
 - Stability and hygiene testing allowed to be performed by applicant in their lab (w/lab inspection)
 - Test report covering all items on three batches of samples need to be issued by qualified gov lab as well
- **Product Labeling**
 - Detailed rules were set up strictly in the system
 - Product label, including product name will be automatically generated based upon information provided
- **Registration shift to notification**
 - Need to submit application
 - Shall comply with all requirements for notification
 - **Need to go to registration if anything dose not comply with notification requirements?**
- **Inventory for other ingredients and functional claims**
 - Only a draft with a few raw materials
 - Will be key project for the development in next step

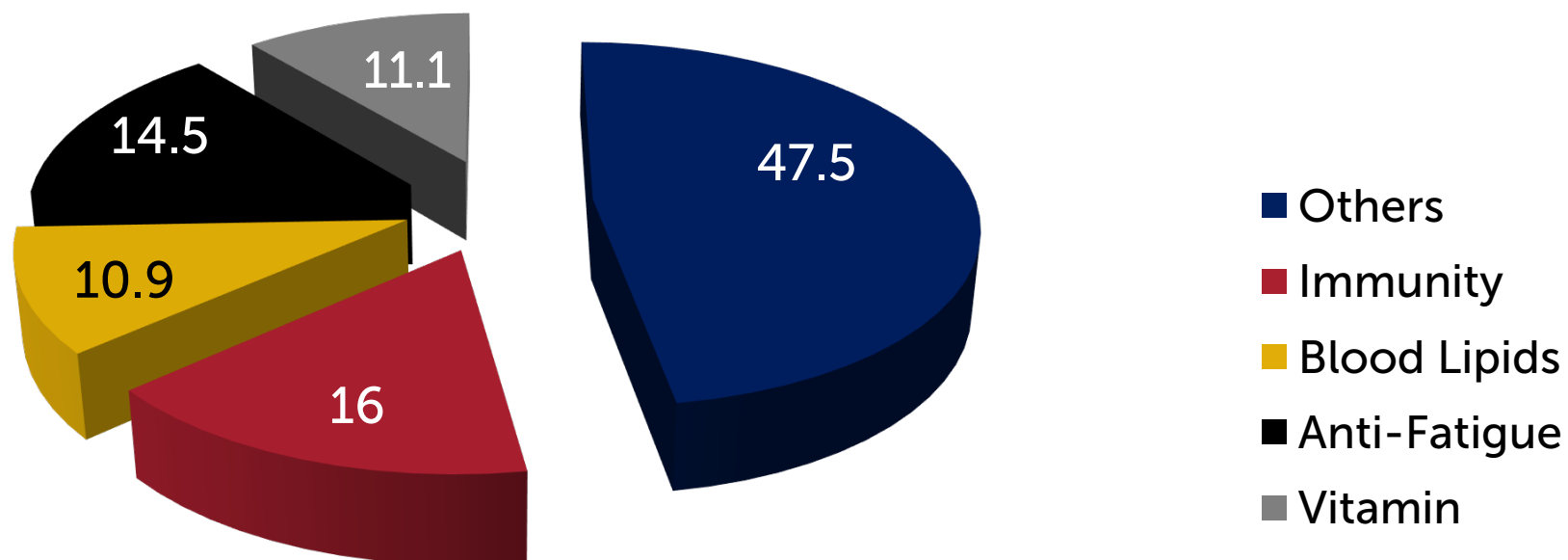
NOTE: notify product via website: <http://bjba.zybh.gov.cn> , and need to submit one set of hard copy to Acceptance Hall in Beijing for notification of imported product



Health Foods Approved

Domestic Products: 15,879

Imported Products: 752



Percentage of Functional Categories



Thank you