

# Briefing on New Feed Regulation, Feed and Feed Additive Assessment System in China



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**Wang Liwen**

**Office of National Feed Assessment Committee**

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# Overview

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1. Framework of New Feed Regulations
2. Introduction to Chinese Feed and Feed Additive Assessment System



# 1. Framework of New Feed Regulations

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**1.1 Feed and Feed Additive Administrative Regulation**, Decree 609 of State Council, published in Nov.3,2011, entered into force on May 1, 2012

- the **basic law** in Chinese feed industry
- firstly published in 1999, revised in 2001



# 1. Framework of New Feed Regulations

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## 1.1 Feed and Feed Additive Administrative Regulation

—main changes compared to the last version:

- a) Responsibilities of the local governments, feed operators (dealers) and feed authorities at central and local levels are clarified;
- b) Feed material catalogue is established, those substances not included in feed material catalogue, feed additive catalogue and medical feed additive catalogue, are not permitted to be used in animal feed production;



# 1. Framework of New Feed Regulations

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## 1.1 Feed and Feed Additive Administrative Regulation

—main changes compared to the last version:

- c) "Quality and safety management practice" (similar to *GMP*) in animal feed mills shall be implemented;
- d) Quality and safety requirement for animal feeding sector are improved;
- e) Supervision measures for the feed authority and penalty measures for behaviors violating the Regulation are fortified.



# 1. Framework of New Feed Regulations

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## 1.2 Complementary measures to the Regulation

- Administrative Measures of Production License for Animal Feed and Feed Additives, MOA decree No. 3;
- Administrative Measures of New Feed and New Feed Additives, MOA decree No.4;
- Administrative Measures of Product Approval Number for Feed Additives and Premixture; MOA decree No.5;
- Administrative Measures of Importation for Feed and Feed Additives;
- Practice of Good Quality and Safety Management.



# 1. Framework of New Feed Regulations

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## 1.2 Complementary measures to the Regulation

- Feed Material Catalogue, MOA notification 1773;
- Feed Additive Catalogue, MOA notification 1226;
- Practice for safety Usage of Feed Additive, MOA 1224;
- Medical Feed Additive Catalogue, MOA noti. 168;
- Prerequisite Requirement for Feed Production License;
- Document Requirement for Feed and Feed Additive Official Authorization;



# 1. Framework of New Feed Regulations

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## 1.2 Complementary measures to the Regulation

- Drug List Prohibited to be Used in Animal Feed and Drinking Water, MOA not. 176;
- Veterinary Drugs and Substances Prohibited to be Used in Food Producing Animals, MOA not.193;
- Substances Prohibited to be Used in Animal Feed and Drinking Water, MOA not. 1519.





# 1. Framework of New Feed Regulations

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## 1.2 Complementary measures to the Regulation

### 2 Mandatory National Standards:

- **Feed Label**, GB 10648-1999;
- **Feed Hygiene Standard**, GB 13087-2001
  
- more than **400** recommended national standards and industry standards.



# 1. Framework of New Feed Regulations

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## 1.3 Feed administration authorities

- Central level: Ministry of Agriculture, NFWO;
- Provincial level: Dept. of animal husbandry and veter., or Dept. of agriculture;
- Prefectural level: Bureau of animal husbandry and veter.;
- County level: Bureau of animal husbandry and veter.



# 1. Framework of New Feed Regulations

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## 1.4 Quality testing agencies

- Central level: National Feed Quality Supervision and Testing Center (Beijing);
- MOA level: 10
- Provincial level: 30
- Prefectural level: majority



# 1. Framework of New Feed Regulations

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## 1.5 MOA feed quality monitoring program

In 2011, 18032 samples were collected nationwide

- For commercial feed: 6686 samples, 95.5% passed;
- For feed add. and materials: 591 samples, 96.6% passed;
- For pet food: 199 samples, 99.5% passed;
- For feed label: 8489 samples, 94% passed;
- For prohibited substances: 6 of the 440 samples detected malachite green; 2 of 2514 samples detected melamine.



## 2. Feed and Feed Additive Assessment

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### 2.1 Legal Basis

- State Council Decree 609: Any new feed and feed additive should pass assessment in efficacy, safety and environment impact and get **New Feed and New Feed Additive Certificate** before it is put into market; The assessment shall be carried out by National Feed Assessment Committee.



## 2. Feed and Feed Additive Assessment

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### 2.1 Legal Basis

- MOA Decree 4:
  - New Feed means new single feed ingredient firstly approved for use in China;
  - New Feed Additive means feed additive not listed in the Feed Additive Catalogue;
  - 5 conditions to be assessed but will not issue New Feed Certi: to enlarge scope of application; to lower the active substance content than the authorized ones; to change processing method remarkably, .....



## 2. Feed and Feed Additive Assessment

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### 2.2 Organizations involved

- National Feed Working Office, MOA
  - In charge of national feed industry administration, incl. New Feed and New Feed Additive Authorization;
  - One of MOA department Sharing staff with Dept. of Animal Husbandry, MOA



## 2. Feed and Feed Additive Assessment

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### 2.2 Organizations involved

- National Feed Assessment Committee
  - scientific assessment for new feed and feed additive, imported feed and feed additive, and re-evaluation of authorized feed and feed additives;
  - comprising 60 experts with background in animal nutrition, physiology, husbandry, chemistry, pharmacology, toxicology, biochemistry, microbiology, veterinary sciences, product quality, etc.





## 2. Feed and Feed Additive Assessment

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### 2.2 Organizations involved

- National Feed Quality Supervision and Testing Center
  - to evaluate and check the specifications and analysis method of the new product;
  - to receive and maintain the product samples.



## 2. Feed and Feed Additive Assessment

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### 2.2 Organizations involved

- efficacy and safety study agencies authorized by MOA
- 20 efficacy study agencies;
- 7 safety study agencies.

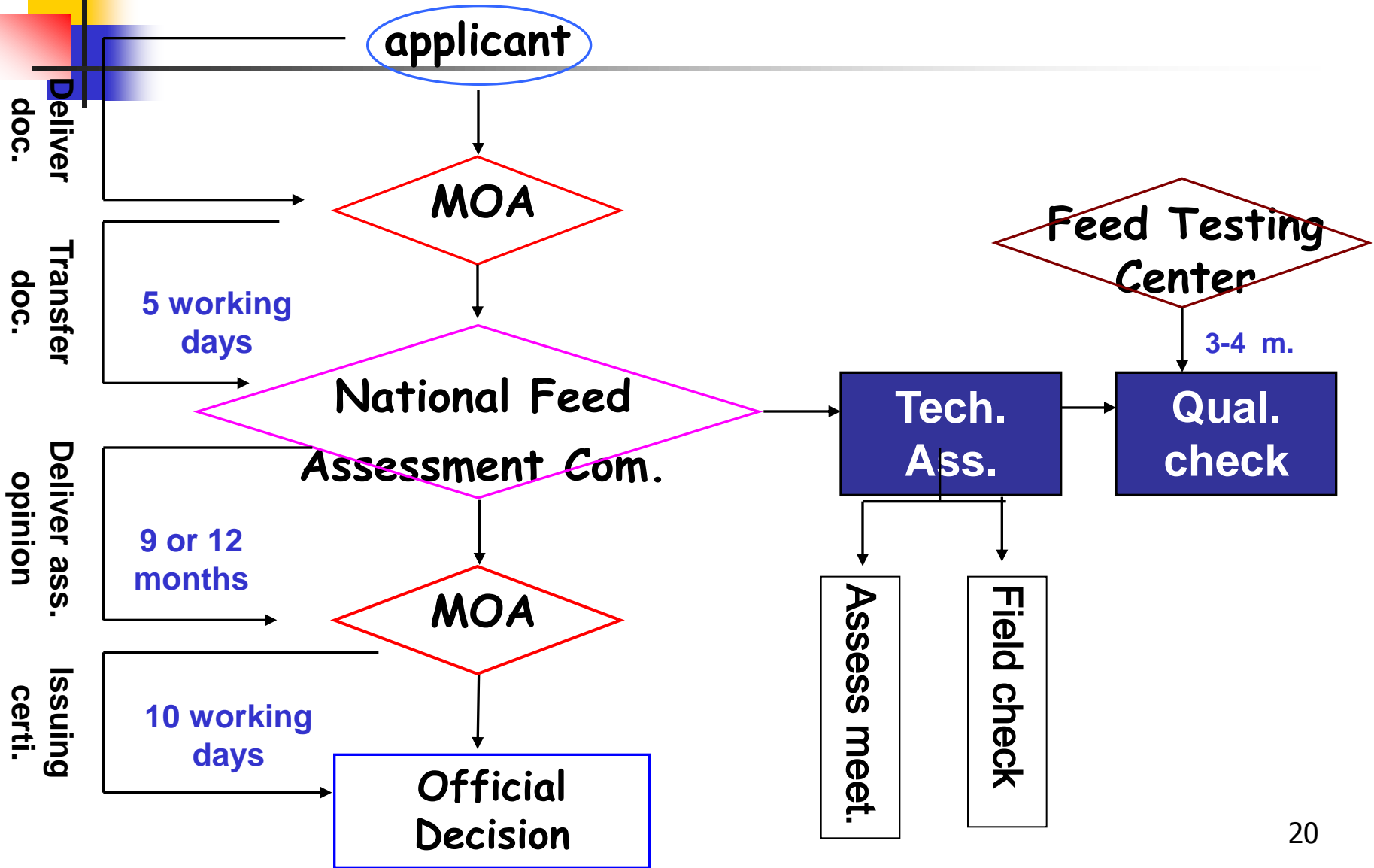


## 2.Feed and Feed Additive Assessment

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### 2.3 Working Process

# Working Process





## 2. Feed and Feed Additive Assessment

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### 2.4 Document requirement for application

- Common name of the product and justification of product development;
- Identification report of Active substance, Certificate of deposition for micro-organisms;
- Scope of application, usage guidelines, recommended level in complete feed, concentrate feed and premixture; maximum limit in complete feed where appropriate;
- Manufacturing process and stability report;



## 2. Feed and Feed Additive Assessment

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### 2.4 Document requirement for application

- Product standard (specification and testing methods) and its rationales; Testing method in complete feed, concentrate and premixture needed where max. limits are set;
- Study report on efficacy and safety by MOA authorized institutions;
- Model of labels, package and storage requirements, shelf life and precautions;
- 3 samples (should come from pilot plant or production line).



## 2. Feed and Feed Additive Assessment

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### 2.5 Technical Guidance for Application

- 2.5.1 Safety study guidance
  - Procedures and methods for toxicological assessment of food, GB/T 15193
  - Tolerance study guidance in target animals for livestock and poultry;
  - Tolerance study guidance in target animals for aquaculture



## 2. Feed and Feed Additive Assessment

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- Tolerance study guidance in target livestock and poultry
  - purpose: to determine short toxicity and safety margin;
  - general principle: to perform experiment in each kind of target animal the application claimed;
  - experiment grouping: control group, use-level group, tolerance group with multi-fold of the use-level;
  - replica: 6
  - numbers of each replica: 1 for swine, cattle and sheep; 10 for poultry;
  - period of experiment: min. 28 days.





## 2. Feed and Feed Additive Assessment

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### 2.5 Technical Guidance for Application

- 2.5.2 Efficacy study guidance
  - Efficacy study guidance in target animals for livestock and poultry;
  - Efficacy study guidance in target animals for aquaculture



## 2. Feed and Feed Additive Assessment

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- Efficacy study guidance in target livestock and poultry
  - purpose: to demonstrate efficacy of the product, normally the lowest recommended level;
  - principle: to perform experiment for each target animal;
  - dose-titration: 4 for cattle and sheep, 5 for the others;
  - replica: 6 for pig and poultry; 15 for cattle, dairy cow and sheep;
  - numbers for each replica: 6 for pig, 15 for poultry; 1 for cattle, dairy cow and sheep;
  - duration: see tables



## 2. Feed and Feed Additive Assessment

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### 2.5 Technical Guidance for Application

- 2.5.3 Guidance for extrapolation of data from major species to minor species
  - data can be extrapolated from major to minor species if they are physiologically similar;
  - extrapolation can only be considered when the product is already authorized for use in major species;
  - major species: pig, laying hens, broiler, cattle, turkey, cattle for fattening, dairy cows, sheep for fattening.



## Office of National Feed Ass. Committee

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Email: pingshenban@sohu.com

Tel: 8610-59194650

Fax: 8610-59194584

For regulation information

MOA website: [www.moa.gov.cn](http://www.moa.gov.cn)



Thank you  
for your attention!

