1.Introduction

The history of China’s fertilizer regulation dates back to 1989, when the Ministry of Agricultural issued the “Interim Provision of Inspection and Registration on Fertilizer, Soil Conditioner and Plant Growth Regulator”. On 12 Jun 2000, the Ministry promulgated Order 32,”Administrative Measures for the Registration of Fertilizers”, which serves the legal basis of the fertilizer registration system. By the end of 2017, China completed a series of amendments and formed a basic regulatory system to manage product specification, labeling, safety and efficacy evaluation, etc. This Pedia page introduces the current scope, administrative procedures, data requirement and relevant technical criteria to help a tactical and effective market access for fertilizer in China.

China Fertilizer Regulations

Measures for the Registration Management on Fertilizer

History

12 Jun 2000 MoA Order 32

Main Supporting Rule in Force

25 May 2001 MoA Announcement 161(Data Requirements on Fertilizer Registration)

11 Feb 2010 MoA Office Letter 12 of 2010

28 Nov 2017 MoA Order 8 of 2017(2 amendments to fertilizer registration )

29 Dec 2017 MoA announcement 2636(guidance on adminstrative procedures of fertilizer registration)

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Scope and Applicant of Fertilizer Registration

Fertilizer usually refers to organic, inorganic and microbial substances and mixture of substances which offer, maintain or improve the nutritional status, output, quality and stress tolerance (abiotic) of crops or the physical, chemical and biological performance of soils or plants, increase the output and quality of agricultural produce or increase stress resistance of plants. Fertilizers cannot be imported, produced, sold, or advertised without prior registration with the competent authorities at a ministerial or provincial level. From a registration prospective, fertilizers can be divided into 3 types:

Exempted from Registration-Fertilizers that have been used for many years domestically and have been established with national or industrial product executive standard are exempted from registration: ammonia sulfate, urea, calcium cyanamide, ammonium phosphate(mono and di), phosphor nitrate, superphosphate, potassium chloride; potassium sulfate, potassium nitrate ,ammonium chloride ,ammonium bicarbonate, calcium magnesium phosphate, potassium dihydrogen phosphate, single microelement fertilizer, high concentration compound fertilizer;

Registered with provincial agricultural department-compound fertilizer; formula fertilizer (no foliar fertilizer); refined organic fertilizer and soil acid regulating agents should be registered with provincial agricultural department and can be only sold within the administration area of the province. If the producer or distributor files a provincially registered fertilizer to the department at another province, the fertilizer can be sold in that province too.

Fertilizers that do not fit above 2 criteria should be registered with the MoA. Fertilizer-pesticide mixtures and the homemade organic fertilizer produced by the farmers are also beyond the scope of fertilizer registration management. Homemade organic fertilizers are usually for self-use purpose and fertilizer-pesticide mixtures are controlled under China’s pesticide registration system.

Imported Fertilizers not exempted from fertilizer registration should be directly registered with the MoA.

Fertilizer registration can only be applied by a domestic producer or local entrusted agency/branch office of overseas producer. The former should be a legal entity registered with the Administration of Industry and Commerce (Business Registration) for corresponding business scope (fertilizer production or distribution) and the latter should be authorized and certified by the overseas producer to import or distribute the fertilizer in China. If the fertilizer is produced overseas but marketed only in China, the data requirement, testing item and approval procedure will be a little different compared with other products.

Classification, Definition and Mandatory Generic Name of Fertilizers in Chinalarge

Fig1.-Categories and Mandatorily Generic Names Fertilizer Registration in China (excluding biofertilizers)

The examination and final approval of the application material, issuance and public announcement of registration certificate are MoA's responsibility. Fertilizers with an established national or industrial mandatory standard are directly reviewed by the Secretariat (permanently established at the MoA) of the National Expert Committee on Fertilizer Registration and directly approved by the MoA. Other products are discussed at each plenary sessions of the Committee and MoA may issue the registration certificate or written decision of disapproval, or require additional data or material based on the technical conclusions. The MoA Office Letter 12 of 2010, the “Agreed Matters Decided at the National Expert Committee on Fertilizer Registration” gathers numerous and specific explanations and requirements targeting products and administrative issues previously proposed by the Committee, which serves as an important addition to the previous ministerial regulations:

Fertilizers should be mandatorily registered as designated generic names in the “Catalogue and Specification on Generic Names for Fertilizer Registration” (Fertilizer Registration Catalogue). The amendment, removal and addition of the Catalogue should be proposed by the Committee and approved by the MoA;

Plenary sessions of the Committee are held in March and September each year. New fertilizers (using new raw material, new production technology and containing new nutrient ingredient) and other fertilizers not yet established with mandatory industrial standard are reviewed during the plenary session on a case by case basis and propose the technical requirement for quality inspection and efficacy evaluation for these fertilizers. Through the assessment on technical and product nature, the Committee may approve the registration.

The latest clarification on direct approval and fertilizer review criteria was offered by the National Expert Committee during the 1st session of the 7th Committee in 2013.

MoA has established mandatory agricultural standards for certain products, defined through raw materials, processing, declarable nutrient content/composition, physical and chemical properties and limits of harmful substance, as well as test methods, etc.). Only fertilizers which meet these criteria can be registered using a corresponding generic name. For example, biostimulants (extracted from organic materials) are well known outside China but mostly registered as organic water soluble fertilizers in China.

Administrative Formality Procedure

Adminstrative Procedures of Fertilizer Registration in Chinalarge

Fig1.-Adminstrative Procedures of Fertilizer Registration in China

On 8 Nov 2017, China MoA issued Order 8 to abolish and revise a series of existing ministerial regulations, of which 2 sections are amendment to fertilizer registration: removal of temporary registration and broadened acceptance scope of field trial report. On 29 Dec 2017, MoA released the Announcement 2636,”Service Guide to the Administrative Approval of MoA (batch 2: fertilizer registration and pesticide registration)”, which standardize the administrative procedure and further clarifies the data requirements including qualification of applicant, timeline, list of required documents/, means of submission and administration fee, etc. Depending on market circulation stage, fertilizer registration registrations can be classified into registration, registration renewal (each 5 years) and registration amendment (only applicable to crop range and administrative information). Domestic products and imported fertilizer are subject to different assessment criteria and approval procedures:

Data Requirements

The application materials consist of applicant form, credential documents, test reports, position paper/ evaluation form, safety data, product executive standard, label sample, enterprise information and product samples. Field trials and one quality inspection test are performed prior to the application and another quality inspection and safety tests will be organized by the Secretariat afterward. Domestic applicants are subject to additional preliminary review and product executive standard filing formality at their provincial department. For imported fertilizers, qualification/identity of overseas producers and business relationship with its domestic agent are particularly reviewed. Technical data and sample requirements may vary depending on product nature, as summarized in the table.

Data Requirements on Fertilizer Registration in Chinalarge

Fig3.-Data Requirements on Fertilizer Registration in China

Renewal of a registration certificate should be applied for 2 months prior to the expiry and 2 new reports are required: annual report on product quality and report on product application situation. Product quality report consists of quality inspection test report issued by qualified labs and relevant information on quality management, certification and inspection. Product application situation report includes the area, acreage, crop and effects of the fertilizer. If the registrant alters the crop range, product trade name or company name, he should update corresponding field trial report, label sample or credential documents in amendment application.

Crop range that included on fertilizer label is determined by the field trial during registration or amendment. If the applicant wants to use the fertilizers on staple crops such as cotton, rice or wheat, etc., he should conduct field trial on each staple crop. During the 5th plenary sessions of the 6th Committee, all fruits, vegetables and ornamentals are classified into 3 group and 17 sub-group. If the applicant completes the trials on 2 crops within the same sub-group, the range can be extrapolated to the whole sub-group:

Vegetables: root vegetables, onions and garlics, leafy vegetables, nightshades, legumes and aquatic vegetables;

Fruits: stone fruits, kernel fruits, berries, citrus, nuts and sub-tropical & tropical fruits;

Ornamentals: ornamental flowers, foliage plants, ornamental fruits and ornamental stems;

Registration Tests and Overlapping Standard System

Compared to the previous regulatory framework, China now offers a broadened acceptance scope of field trial report (either by the applicant or testing facilities). Quality inspection (a repetition of quality test of field trial sample) and safety tests are organized by MoA after submission. MoA also issued the “Announcement on the Selection of Testing Facilities for Fertilizers” in September 2017. CMA labs (CAL, CNAS and CATL qualification preferable) are invited to the selection and MoA finally determined the type, number and distribution of the qualified labs. Meanwhile, the announcement also summarized the recognized methods for quality and safety tests, all of which were previously issued under national or industrial (agricultural) standards. Minimal test scope, expense and criteria on quality and safety of different product category can be concluded as follows:

NO.

STANDARD

SCOPE

Product Quality

1

NY 1107-2010 Water-soluble fertilizers containing nitrogen, phosphorus and potassium

Agricultural standards for specific products(including quality specifications and test method)

2

NY 1429-2010 Water-soluble fertilizers containing amino-acids

3

NY 1106-2010 Water-soluble fertilizers containing humic-acids

4

NY 1428-2010 Water-soluble fertilizers containing micronutrients

5

NY 2266-2012 Water-soluble fertilizers containing calcium and magnesium

6

NY 2268-2012 Modified ammonium nitrate for agriculture

7

NY 2269-2012 Calcium ammonium nitrate for agriculture

8

NY 2670-2015 Urea ammonium nitrate solution

9

NYT886-2016 Agro-forestry absorbent polymer

10

GB 20287-2006 Microbial inoculants in Agriculture

Applicable to microbial fertilizers(biofertilizers)

11

NY/T 798-2015 Compound microbial fertilizer

12

NY 884-2012 Microbial organic fertilizers

13

NY 2321-2013 Code of practice for inspection of microbial fertilizers

14

NY/T 1977-2010 Water-soluble fertilizers-determination of total nitrogen, phosphorus and potassium content

Testing method applicable to water-soluble fertilizers with nutrient claims

15

NY/T 1976-2010 Water-soluble fertilizers-determination of organic matter content

16

NY/T 1975-2010 Water-soluble fertilizers-determination of anomo-acids content

17

NY/T 1974-2010 Water-soluble fertilizers-determination of copper, iron, manganese, zinc, boron, molybdenum content

18

NY/T 1973-2010 Water-soluble fertilizers-determination of water insoluble matter content and pH

19

NY/T 1972-2010 Water-soluble fertilizers-determination of sodium, selenium, silicon content

20

NY/T 1971-2010 Water-soluble fertilizers-determination of humic-acids content

21

NY/T 1117-2010 Water-soluble fertilizers- determination of calcium, magnesium, sulphur and chlorine content

22

NY/T 1116-2014 Fertilizer-determination of nitrate nitrogen, ammonium nitrogen, amid nitrogen contents

Fertilizers/soil conditioners with nitrogen requirements/claim ( form of existence)

23

NY/T 887-2010 Liquid fertilizers-determination of density

Liquid fertilizer

24

NY/T 1978-2010 Fertilizers-determination of mercury, arsenic, cadmium, lead and chromium content

Soil conditioner/soil amendment

25

NY/T 2272-2012 Soil amendment-determination of calcium, magnesium and silicon content

26

NY/T 2273-2012 Soil amendment-determination of phosphrous and potassium content

27

NY/T 2878-2015 Water-soluble fertilizers-determination ofpoly-asparticacid content

Organic water soluble fertilizers containing poly-aspartic acid content

28

NY/T 2877-2015 Fertilizer synergists- determination of dicyandiamide content

Fertilizer synergists containing dicyandiamide

29

NY/T 2876-2015 Fertilizers and soil amendments-grading determination of organic matters

Fertilizers/soil amendments such nutrient claim

30

NY/T 2879-2015 Water-soluble fertilizers-determination of cobalt, titanium content

Fertilizers/soil amendments such nutrient claim

Toxicity

31

GB 15193.3-2014 National food standard- acute oral toxicity test

Toxicity test and criteria for chemical fertilizers and microbial fertilizers

32

NY 1980-2010 Fertilizer registration-determination and evaluation of acute oral toxicity

To be replaced by "NYT 1980-2018 fertilizer and Soil Amendment – Testing of Acute Oral Toxicity and Evaluation Criteria" on 1 Jun 2018

33

NY 1109-2006 General Biosafety Standard for Microbial Fertilizers

Microbial Strain

34

NY/T 1736-2009 Technical standard-specification of strain identification for microbial fertilizers

Strain identification of microbial fertilizers

35

NY/T 2066-2011 Differentiation for strain of microbial fertilizer production by PCR method

ANTI-DETONATION

36

WJ 9050-2006 Test method and criteria of anti-detonation property of farming ammonium nitrate

Applicable to high nitrate nitrogen fertilizers

Degradability

37

GB/T 22047-2008 Plastics—Determination of the ultimate aerobic biodegradability in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide involved

Applicable to certain slow -release fertilizers

38

GB/T 19277.1-2011 Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions-method by analysis of evolved carbon dioxide-Part 1: General Method

39

GB/T 19277.2-2013 (ISO 14855-2-20) Determination of the ultimate aerobic biodegradability of plastic materials under controlled composting conditions—method by analysis of evolved carbon dioxide—part 2:gravimetric measurement of carbon dioxide evolved in a laboratory-scale test

40

GB/T 19276.1-2003(ISO-14851-1999) Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium -- Method by measuring the oxygen demand in a closed respirometer

41

GB/T 19276.2-2003(ISO-14852-1999) Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium -- Method by analysis of evolved carbon dioxide

Apart from these standards for quality and safety tests, MoA has established a series of guidelines on efficacy evaluation, labeling and packaging requirements, technical indicator and criteria for specific category or product. Although they might be different in enforceability (voluntary standard or compulsory standard), they serve as important determinants and judging tools for registration review.

Agricultural Standard

Note

NY 1110-2010 Water-soluble fertilizers-content limits of mercury, arsenic, cadmium, lead and chromium

Applicable to all types of solid or liquid water-soluble fertilizers

NY/T 2274-2012 Slow-release fertilizer-regulations of efficiency experiment and assessment

Trial site selection, area, duration, number and type of control group, treatment, parameters, crop grouping, trial record, evaluation approach, statistical methods and reporting of trial

NY/T 2544-2014General regulations of efficiency experiment and assessment for fertilizers

NY/T 2543-2014 Fertilizer synergist-Regulations of efficiency experiment and assessment

NY/T 2271-2016 Soil amendment-regulations of efficiency experiment and assessment

NY/T 1108-2012 liquid fertilizers-tech-regulations of package

NY/T 2267-2016 General requirements on slow-release fertilizers

Product definition, raw material, classification of product, technical indicators applicable to a group of products

NY/T 3034-2016 General requirements on soil amendments

NY/T 3035-2016 Soil amendment-determination of aluminum and nickel content

Testing method for specific technical parameter.

NY/T 3035-2016 Soil amendment-determination of water content, particle size and fineness

NY/T 3037-2016 Fertilizer synergists- determination of 2-CHLORO-6-(TRICHLOROMETHYL)PYRIDINE content

NY/T 3038-2016 Fertilizer synergists- determination of NBPT and NPPT content

NY/T 3039-2016 Water-soluble fertilizers-determination of polyglutamic acid content

NY/T 3040-2016 Slow-release fertilizer- determination of nutrient release rate

NY 1979 -2010 Fertilizer registration-Tech-regulations of fertilizer labels

The standard will be repplaced by the“NY 1979-2018 Fertilizer and soil amendment-requirements on labeling and declarable nutrient content”on 1 Jun 2018

A series of standards issued are also used for market surveillance purposes. These standards are compiled by other authorities in the form of national standard (GB), chemical industry standard (HG) or other industrial standard. As a result, the same product (quality indicator) may have two different or inconsistent set of criteria. For example, the “NY 1107-2010 Water-soluble fertilizers containing nitrogen, phosphorus and potassium” was issued by MoA. It specifies that the sum of nitrogen, phosphorus pentoxide and potassium oxide shall not be lower than 50 %( 500g/L) and water-insolubles shall not be greater than 5% (50g/L). Higher micronutrient content and lower water-insolubles represents better product quality.

Whereas in the “HGT 4265-2012 Water soluble fertilizers” (issued by MIIT), both limits of micronutrient and water-insolubles were reduced to 30 %( approximately 400g/L) and 0.5% respectively. The most obvious reason for these discrepancies is that during the drafting of the regulation there was input from several authorities with different technical expertise. As the industrial management department, production feasibility and current levels of domestic production are highly valued by MIIT and a lowered criterion for nutrient content was established. Water solubility is closely correlated with drip irrigation practice at agricultural stage and MoA considers there is no need for stringent requirement when drip irrigation area is still limited in China. Lack of coordination among different authorities has led to a situation where producers have to comply with multiple standards. A full collection on these technical criteria becomes much more essential for especially for novel and imported fertilizers.

Critical Advice & Prospects

Usually, only half of the committee-reviewed fertilizers can finally be approved at each plenary session.

The Committee has already internally agreed on typical conditions for registration overruling, which are also important guidelines to use when preparing or improving dossier:

Fertilizers that originate from industrial wastes will be rejected-The committee has increasingly received applications for fertilizers that are based on pulverized cinder or slag fortified with mineral fertilizers (or directly use). The Committee is not supportive of such fertilizers as the safety to farmland and applicability to agricultural is questionable;

Imported organic degradation/extracted fertilizers-The Importation of organic fertilizer is prohibited in China. Imported fertilizers extracted from organic matters which qualify with relevant standards can be registered as water-soluble fertilizers containing amino-acids and water-soluble fertilizers containing humic-acids. For extracted fertilizers extracted from other materials (containing alginic acide, chitin, polyglutamic acid and poly-aspartic acid, etc. ), the Committee will thoroughly evaluate the raw material and processing technology and may approved them as water-soluble organic fertilizers. Product with undefined technical characteristics and low nutrient content will be restricted;

Availability of quality test method-If there is no standardized method or the method submitted by the applicant is determined unavailable or impractical to conduct quality inspection

Others- Fertilizers for secondary processing (by another producers) are also restricted from registration;

Furthermore, comparing a prospective fertilizer to an existing/registered fertilizer on nutrient content/microbial strain, raw material and product processing is a useful method to gauge registration feasibility and conclude the most effective strategy. Unlike the regulatory system of other agricultural inputs such as pesticide and seed, only fertilizer registration is based on a ministerial regulation and the enforceability of the technical criteria are often challenged by standards from other authorities. During the session of the NPC, MoA revealed again that the Ministry will continue to promote development of a national fertilizer regulation.

Resources

News: China Renews 3 Agricultural Standards for Fertilizer Registration

News: CHina Abolishes Fertilizer Temporary Registration

News: China MoA Release 6 Guidance Documents on Adminstative Procedures of Pesticide and Fertilizer Registration

News: China Consults on Mandatory Regulation for Grading and Labeling of Fertilizers

News: 12 New National Fertilizer Standards to be implemented on 1 Jul 2018