No. 2569 Announcement of the Ministry of Agriculture of the People's Republic of China

This is to announce that we have formulated the *Data Requirements for Pesticide Registration* according to relevant provisions of the *Regulations on Pesticide Management* and the *Measures for the Administration of Pesticide Registration*, and now hereby issue it, which will come into force as of November 1, 2017.

The Ministry of Agriculture

September

Data Requirements for Pesticide Registration

Chapter 1 General Provisions

1.1 These Requirements are formulated in accordance with the *Regulations on Management of Pesticides* and the *Measures on Management of Pesticide Registration*, for the purpose of scientifically evaluating pesticides applied for registration and combing pesticide registration application data.

1.2 The pesticide registration application data include registration test data and evaluation reports, pesticide quality standards and test methods, pesticide labels and manuals, comprehensive reports, registration- supporting documents, the product safety datasheet, the application form, the applicant's certificates and statement and references, etc.

Literature or data as cited in the application materials shall be marked with its name or the name of the work containing them, the name of the journal, and the volume, issue and page where they appear; for unpublished literature, the certificate of permitted use from the owner shall be provided. For literature in a foreign language, the Chinese translation shall be provided upon request.

1.3 The registration test data include test reports and assessment reports, such as the product chemistry, toxicology, efficacy, residue and environmental impact test/assessment reports. For pesticides to be added with any specified adjuvant at the time of application, the test data of such products added with the adjuvant shall be provided out of concern of safety, stability and other reasons.

The data requirements for registration of chemical pesticides, biochemical pesticides, microbial pesticides, botanical pesticides and public health pesticides are defined in Chapter 3 through Chapter 7 of this paper.

1.4 The data requirements for registration of pesticide technical materials (TCs) or technical concentrates (TKs), formulations, public health pesticides, rodenticides, pesticides designed for featured minor crops and for registration alteration are defined in Attachment 1 through Attachment 6.

The selection of efficacy test fields shall meet requirements in Attachment 7. The crop classification for residue tests and the number of test points shall meet requirements in Attachments 8 and 9.

1.5 The applicant shall submit one set of original paper documents. Such documents shall be classified and organized according to the Attachments, contain a table of contents and marked with page numbers, be written in Chinese in Song typeface with a font size of no smaller than 4, or in

English, with a font size no smaller than 11, in A4 paper, individually or separately packaged, and shall submit one set of the electronic version, which shall have the same contents with the paper version.

1.6 In case of application for registration of a new pesticide, the applicant shall provide 2g of the standard active ingredients, 0.5g of the main metabolites and relevant impurities, 100g of the TC (TK) sample, and 250g (mL) of the formulation sample.

1.7 In case of application for registration of a me-too pesticide, the pesticide identification shall be conducted in accordance with specifications in Attachment 10.

1.8 The Chinese common name or simplified common name of a pesticide, rather than its trade name shall be used. In case of application for registration of a new pesticide, the basis for giving the Chinese common name to each of its active ingredient shall be provided. The pesticide naming principle is defined in Attachment 11.

1.9 The contents of active ingredients of a pesticide and its dosage form shall be decided in such a way that will improve the product quality, protect environment, and facilitate quality inspection and effective use. The principle for deciding the contents of active ingredients in a pesticide is defined in Attachment 12; the quality specifications of pesticide formulations in various dosage forms and their physical and chemical properties are defined in Attachment 13. For dosage forms not specified in any national standards, the basis for determining such forms or relevant descriptions shall be provided.

1.10 The toxicity of pesticides is graded based on the toxicity grading standards as defined in Attachment 14.

1.11 In special cases not covered in this paper, additional data from the applicant may be requested in accordance with Article 23 of the *Measures on Management of Pesticide Registration*.

1.12 The pesticide registration data shall be maintained by the institute responsible for pesticide control under the Ministry of Agriculture. Data about new pesticides approved to be registered by the Ministry of Agriculture shall be maintained without time limit; registration data about other products shall be kept for 5 years after they are no longer commercially available, and may be withdrawn by the applicant upon application any time after that day, or they will be destroyed.

Registration data about products disapproved by the Ministry of Agriculture shall be kept for 5 years since the day on which the decision of disapproval is made, and may be withdrawn by the applicant within 1 year upon expiration of the 5-year period, or they will be destroyed. In case of

re-application for registration by an applicant within 5 years, a copy of the registration test report may be used.

The review comments on the pesticide registration application shall be kept for the same period as the application data.

1.13 Format of the pesticide registration certificate: product classification code +year number+ serial number. The product classification code is PD; that for public health pesticides is WP. The year number refers to the year in which the pesticide registration certificate is issued, and is expressed in four Arabic numbers. The serial number is expressed in four Arabic numbers.

Chapter 2 Terms and Definitions

2.1 New pesticides refer to pesticides whose active ingredients have not been approved for registration in China, including new pesticide TCs (TKs) and new pesticide formulations.

2.2 Active ingredients refer to particular biologically active chemical structural components or organisms within pesticides.

2.3 TCs refer to products composed of active ingredients and relevant impurities generated from the production process. They may be added with a small amount of addictive as needed.

2.4 TKs refer to products composed of active ingredients and relevant impurities generated from the production process. They could contain a small amount of necessary additive and applicable diluent.

2.5 Formulations refer to products in a stable state processed with pesticide TCs (TKs) and applicable adjuvants or processed using the biological fermentation and/or the phytoextraction methods, etc.

2.6 Adjuvants refer to single-component or multi- component substances that are added to a pesticide on top of active ingredients, and that do not have any pesticide activity or function of active ingredients themselves, but can or will help improve the physical and chemical properties of the pesticide.

2.7 Impurities and relevant impurities: impurities refer to by-products generated from the pesticide production or storage process; relevant impurities refer to, compared with active ingredients of a pesticide, impurities contained in or generated from the pesticide production or storage process and that are obviously hazardous to humans and the environment, and will poison the crops, cause contamination to or compromise the quality stability of agricultural products or give rise to other adverse effects.

2.8 Me-too TCs refer to TCs applied for registration that have the contents of active ingredients and other main quality specifications no lower than the registered TCs, and the adverse effect of impurities which contain is basically on the same level or lower than the registered ones.

2.9 Me-too formulations refer to formulations applied for registration that have the same content of active ingredients, the same type and content of other restrictive components, the same dosage form, and the same TC as the registered ones, and that do not contain any other adjuvant that will result in significant increase of the product toxicity or environmental risks, and have main quality specifications no lower than those of registered products.

2.10 Similar formulations refer to formulations applied for registration that have a content of active ingredients and a dosage form same as, and other components different from, the registered ones.

2.11 Formulations in new dosage forms refer to formulations containing the same active ingredients as the registered formulations but whose dosage form has not been registered.

2.12 Formulations with new content refer to formulations containing the same active ingredients as the registered formulations but the content of such ingredients (the volume ratio between all ingredients of the pesticide ready-mixture remains unchanged) has not been registered.

2.13 New pesticide ready-mixtures refer to formulations that have the same active ingredients and dosage forms as the registered mixtures, but contain the active ingredients of more than two types of pesticides for the first time, or have a volume ratio between active ingredients different from the registered ones which have the same active ingredients.

2.14 Products of new application scope refer to products containing the same active ingredients as the registered products, but whose application scope has not been registered.

2.15 Products of new application method refer to products containing the same active ingredients as the registered products, but whose application method has not been registered.

2.16 Chemical pesticides refer to pesticides artificially synthesized with chemical substances.

2.17 Biochemical pesticides refer to pesticides that meet the following two conditions simultaneously: 1. They pose no toxicity to the control object, and just play the particular role of adjusting the growth, disturbing mating or alluring the object or the like; 2. They are native compounds, and if artificially synthesized, they have the same structure as native compounds (difference in isomer ratio is allowable). They are mainly categorized into the following:

2.17.1 Semiochemicals, which are chemical substances produced by plants and animals and can change the behavior of the same or different kinds of receptors.

2.17.2 Natural plant growth regulators, which are chemical substances produced by plants or microorganisms and can help inhibit or stimulate the growth and development of the same or different kinds of plants (including their germination, growth, flowering, fertilization, fruit setting,

ripening and fall off processes), or adjust their resistance to adversity (cold, heat, dryness, damp, wind, pest and disease damage)

2.17.3 Natural insect growth regulators, which are chemical substances produced by insects, and can help inhibit or stimulate their growth process.

2.17.4 Plant defense activators, which are natural substances capable of inducing plants to defend against infection of pests and enhancing their resistance.

2.17.5 Other biochemical pesticides refer to substances that satisfy the definition of "biochemical pesticide", in addition to the above.

2.18 Microbial pesticides refer to pesticides using bacteria, fungi, viruses, protozoans or genetically modified microorganisms or other living organisms as active ingredients.

2.19 Botanical pesticides refer to pesticides with their active ingredients directly coming from plants.

2.20 Public health pesticides refer to pesticides used to prevent and control mosquitoes, flies, cockroaches, ants and other harmful organisms in the living environment of humans and in that of animals in the process of animal breeding in the agriculture and forestry industry. They may be classified into household insecticides and environmental health insecticides based on their application place and methods. Household insecticides refer to public health pesticides that may be used directly in households without being further treated like dilution. Environmental health insecticides refer to public health pesticides that may be used indoor and outdoor after being further treated like dilution.

2.21 Rodenticides refer to pesticides designed to prevent and control rats and other harmful rodents.

2.22 Main pesticide metabolites refer to metabolites whose mole fraction or radioactive intensity in crops, animals or environment (soil, water and sediments) is greater than 10% following the application of the pesticide.

Chapter 3 Chemical Pesticides

3.1 Chemical Pesticide TCs (TKs)

3.1.1 Product chemistry

3.1.1.1 Identification of active ingredients, stabilizers, synergists and other restrictive components

3.1.1.2 Production process

3.1.1.2.1 Raw material description

3.1.1.2.2 Chemical reaction equation

3.1.1.2.3 Production process description

3.1.1.2.4 Production process flow chart

3.1.1.2.5 Production unit process flow chart and description

3.1.1.2.6 In-process quality control description

3.1.1.3 Physicochemical properties

3.1.1.3.1 Physicochemical properties of active ingredients

3.1.1.3.2 Physicochemical properties of TCs (TKs)

3.1.1.4 Full component analysis

3.1.1.4.1 Full components analysis report

3.1.1.4.2 Impurity formation analysis

3.1.1.4.3 Content of active ingredients and impurity limit

3.1.1.5 Product quality specifications

3.1.1.5.1 Appearance

3.1.1.5.2 Content of active ingredients

3.1.1.5.3 Content of relevant impurities

3.1.1.5.4 Content of other restrictive components

3.1.1.5.5 Acidity, alkalinity or pH range

3.1.1.5.6 Insoluble matter

3.1.1.5.7 Water or heating loss

3.1.1.6 Detection methods for product quality control and method validation

3.1.1.6.1 Methods for identification of active ingredients in products

3.1.1.6.2 Methods for detection of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and method validation

3.1.1.6.3 Methods for detection of other technical indexes

3.1.1.7 Product quality specification description

3.1.1.8 Product quality test report and test method validation report

3.1.1.9 Package (material, shape, size, net content), storage and transportation, and safety warning, etc.

3.1.2 Toxicology

3.1.2.1 Acute toxicity test

3.1.2.1.1 Acute oral toxicity test data

3.1.2.1.2 Acute percutaneous toxicity test data

3.1.2.1.3 Acute inhalation toxicity test data

3.1.2.1.4 Eye irritation test data

3.1.2.1.5 Skin irritation test data

3.1.2.1.6 Skin sensitization test data

3.1.2.2 Acute neurotoxicity test data

3.1.2.3 Delayed neurotoxicity test data

3.1.2.4 Sub-chronic (acute) toxicity test data

3.1.2.4.1 Sub-chronic oral toxicity test data

3.1.2.4.2 Sub-chronic (acute) percutaneous toxicity test data

3.1.2.4.3 Sub-chronic (acute) inhalation toxicity test data

3.1.2.5 Mutagenicity test data

3.1.2.6 Reproductive toxicity test data

3.1.2.7 Teratogenicity test data

3.1.2.8 Chronic toxicity and carcinogenicity test data

3.1.2.9 Metabolism and toxicokinetics test data

3.1.2.10 Endocrine disrupting effect test data

3.1.2.11 Human exposure investigation data

3.1.2.12 Relevant impurities and main metabolite/degradation product toxicity

3.1.2.13 Acceptable daily intake (ADI) and acute reference dosage (ARFD)

3.1.2.14 Toxic symptoms, first aid and treatment measures

3.1.3 Environmental impact

3.1.3.1 Lab degradation test data

3.1.3.1.1 Hydrolysis test data

3.1.3.1.2 In-water photolysis test data

3.1.3.1.3 Soil surface photolysis test data

3.1.3.2 Lab metabolism test data

3.1.3.2.1 Soil aerobic metabolism test data

3.1.3.2.2 Soil anaerobic metabolism test data

3.1.3.2.3 Water-sediment system aerobic metabolism test data

3.1.3.3 Soil adsorption (leaching) test data

3.1.3.4 Environment analysis test

3.1.3.4.1 In-water pesticide analysis method and validation

3.1.3.4.2 In-soil pesticide analysis method and validation

3.1.3.5 Bird toxicity test data

3.1.3.5.1 Bird acute oral toxicity test data

3.1.3.5.2 Bird short-term feeding toxicity test data

3.1.3.5.3 Bird reproduction test data

3.1.3.6 Aquatic toxicity test data

3.1.3.6.1 Fish acute toxicity test data

3.1.3.6.2 Fish early stage toxicity test data

3.1.3.6.3 Fish life cycle test data

3.1.3.6.4 Daphnia magna acute activity inhibition test data

3.1.3.6.5 Daphnia magna reproduction test data

3.1.3.6.6 Green algae growth inhibition test data

3.1.3.6.7 Aquatic plant toxicity test data

3.1.3.6.8 Fish bio-concentration test data

3.1.3.6.9 Aquatic ecology simulation system (Mesocosm) test data

3.1.3.7 Terrestrial non-target arthropod toxicity test data

3.1.3.7.1 Bee acute oral toxicity test data

3.1.3.7.2 Bee acute exposure toxicity test data

3.1.3.7.3 Bee larvae developmental toxicity test data

3.1.3.7.4 Bee semi-field test data

3.1.3.7.5 Silkworm acute toxicity test data

3.1.3.7.6 Silkworm chronic toxicity test data

3.1.3.7.7 Parasitic natural enemy acute toxicity test data

3.1.3.7.8 Predatory natural enemy acute toxicity test data

3.1.3.8 Soil biotoxicity test data

3.1.3.8.1 Earthworm acute toxicity test data

3.1.3.8.2 Earthworm reproductive toxicity test data

3.1.3.8.3 Soil microbial effect (nitrogen conversion method) test data

3.1.3.9 Carnivore secondary intoxication data

3.1.3.10 Endocrine disrupting effect test data

3.1.3.11 Other advanced-stage test data required for environmental risk assessment

3.2 Chemical pesticide formulation

3.2.1 Product chemistry

3.2.1.1 Identification of active ingredients, stabilizers, synergists and other restrictive components

3.2.1.2 Basic information about TC (TK)

3.2.1.3 Product component

3.2.1.4 Processing method description

3.2.1.4.1 Process flow chart

3.2.1.4.2 Component addition amount and sequence

3.2.1.4.3 Main equipment and operating conditions

3.2.1.4.4 In-process quality control description

3.2.1.5 Physicochemical properties

3.2.1.6 Product quality specifications

3.2.1.6.1 Appearance

3.2.1.6.2 Content of active ingredients

3.2.1.6.3 Content of relevant impurities

3.2.1.6.4 Content of other restrictive components

3.2.1.6.5 Other dosage-form related control items and indexes

3.2.1.7 Detection methods for product quality control and method validation

3.2.1.7.1 Methods for identification of active ingredients in products

3.2.1.7.2 Methods for detection of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and method validation

3.2.1.7.3 Methods for detection of other technical indexes

3.2.1.8 Product quality specification description

3.2.1.9 Ambient temperature storage stability test data

3.2.1.10 Product quality test report and test method validation report

3.2.1.11 Package (material, shape, size, net content), storage and transportation, safety warning and shelf life, etc.

3.2.2 Toxicology

3.2.2.1 Acute oral toxicity test data

3.2.2.2 Acute percutaneous toxicity test data

3.2.2.3 Acute inhalation toxicity test data

3.2.2.4 Eye irritation test data

3.2.2.5 Skin irritation test data

3.2.2.6 Skin sensitization test data

3.2.2.7 Other advanced-stage test data required for health risk assessment

3.2.2.8 Health risk assessment report

3.2.3 Efficacy

3.2.3.1 Benefit analysis

3.2.3.1.1 Profile of the crop involved in registration application and the target organism.

3.2.3.1.2 Registered product substitutability analysis and benefit analysis report

3.2.3.2 Efficacy test data

3.2.3.2.1 Indoor biological activity test data

3.2.3.2.2 Indoor crop safety test data

3.2.3.2.3 Field plot efficacy test data

3.2.3.2.4 Large plot efficacy test data

3.2.3.3 Resistance risk assessment data

3.2.3.3.1 Indoor resistance risk test data

3.2.3.3.2 Field resistance risk monitoring method

3.2.3.4 Other data

3.2.3.4.1 Effect on main field predatory and parasitic natural enemies

3.2.3.4.2 Effect on neighboring crops

3.2.3.4.3 Product features and application attentions

3.2.3.4.4 Registered application of the product to the crop or the control object overseas

3.2.3.4.5 Other data related to the pesticide and its application range

3.2.3.5 Comprehensive assessment report

3.2.4 Residue

3.2.4.1 In-plant metabolism test data

3.2.4.2 In-animal metabolism test data

3.2.4.3 In-environment metabolism test data

3.2.4.4 Pesticide residue storage stability test data

3.2.4.5 Residue analytical method

3.2.4.6 Crop pesticide residue test data

3.2.4.7 Processed agricultural product pesticide residue test data

3.2.4.8 Data about crops registered in other countries and residue limit

3.2.4.9 Dietary risk assessment report

3.2.5 Environmental impact

3.2.5.1 TC (TK) environmental test summary

3.2.5.2 Bird acute oral toxicity test data

3.2.5.3 Aquatic toxicity test data

3.2.5.3.1 Fish acute toxicity test data

3.2.5.3.2 Daphnia magna acute activity inhibition test data

3.2.5.3.3 Green algae growth inhibition test data

3.2.5.4 Terrestrial non-target arthropod toxicity test data

3.2.5.4.1 Bee acute oral toxicity test data

3.2.5.4.2 Bee acute exposure toxicity test data

3.2.5.4.3 Silkworm acute toxicity test data

3.2.5.4.4 Silkworm chronic toxicity test data

3.2.5.4.5 Parasitic natural enemy acute toxicity test data

3.2.5.4.6 Predatory natural enemy acute toxicity test data

3.2.5.5 Mulberry leaf final residue test data

3.2.5.6 Earthworm acute toxicity test data

3.2.5.7 Other advanced-stage test data required for environmental risk assessment

3.2.5.8 Environmental risk assessment report

Chapter 4 Biochemical Pesticides

4.1 Biochemical pesticide TC (TK)

4.1.1 Product chemistry

4.1.1.1 Identification of active ingredients, stabilizers, synergists and other restrictive components

4.1.1.2 Production process

4.1.1.2.1 Raw material description

4.1.1.2.2 Chemical reaction equation or biological reaction description

4.1.1.2.3 Production process description

4.1.1.2.4 Production process flow chart

4.1.1.2.5 Production unit process flow chart and description

4.1.1.2.6 In-process quality control description

4.1.1.3 Physicochemical properties

4.1.1.3.1 Physicochemical properties of active ingredients

4.1.1.3.2 Physicochemical properties of TCs (TKs)

4.1.1.4 Full component analysis

4.1.1.4.1 Full components analysis report

4.1.1.4.2 Impurity formation analysis

4.1.1.4.3 Content of active ingredients and impurity limit

4.1.1.5 Product quality specifications

4.1.1.5.1 Appearance

4.1.1.5.2 Content of active ingredients

4.1.1.5.3 Content of relevant impurities

4.1.1.5.4 Content of other restrictive components

4.1.1.5.5 Acidity, alkalinity or pH range

4.1.1.5.6 Insoluble matter

4.1.1.5.7 Water or heating loss

4.1.1.6 Detection methods for product quality control and method validation

4.1.1.6.1 Methods for identification of active ingredients in products

4.1.1.6.2 Methods for detection of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and method validation

4.1.1.6.3 Methods for detection of other technical indexes

4.1.1.7 Product quality specification description

4.1.1.8 Product quality test report and test method validation report

4.1.1.9 Package (material, shape, size, net content), storage and transportation, and safety warning, etc.

4.1.2 Toxicology

4.1.2.1 Basic toxicology data

4.1.2.1.1 Acute oral toxicity test data

4.1.2.1.2 Acute percutaneous toxicity test data

4.1.2.1.3 Acute inhalation toxicity test data

4.1.2.1.4 Eye irritation test data

4.1.2.1.5 Skin irritation test data

4.1.2.1.6 Skin sensitization test data

4.1.2.1.7 Sub-chronic oral toxicity test data

4.1.2.1.8 Mutagenicity test data

4.1.2.2 Supplementary toxicology test data

4.1.2.3 Human exposure investigation data

4.1.2.4 Relevant impurities and main metabolite/degradation product toxicity

4.1.2.5 Acceptable daily intake (ADI) and acute reference dosage (ARFD)

4.1.2.6 Toxic symptoms, first aid and treatment measures

4.1.3 Environmental impact

4.1.3.1 Bird acute oral toxicity test data

4.1.3.2 Bee acute oral toxicity test data

4.1.3.3 Fish acute toxicity test data

4.1.3.4 Daphnia magna acute activity inhibition test data

4.2 Biochemical pesticide formulation

4.2.1 Product chemistry

4.2.1.1 Identification of active ingredients, stabilizers, synergists and other restrictive components

4.2.1.2 Basic information about TC (TK)

4.2.1.3 Product component

4.2.1.4 Processing method description

4.2.1.4.1 Process flow chart

4.2.1.4.2 Component addition amount and sequence

4.2.1.4.3 Main equipment and operating conditions

4.2.1.4.4 In-process quality control description

4.2.1.5 Physicochemical properties

4.2.1.6 Product quality specifications

4.2.1.6.1 Appearance

4.2.1.6.2 Content of active ingredients

4.2.1.6.3 Content of relevant impurities

4.2.1.6.4 Content of other restrictive components

4.2.1.6.5 Other dosage-form related control items and indexes

4.2.1.7 Detection methods for product quality control and method validation

4.2.1.7.1 Methods for identification of active ingredients in products

4.2.1.7.2 Methods for detection of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and method validation

4.2.1.7.3 Methods for detection of other technical indexes

4.2.1.8 Product quality specification description

4.2.1.9 Ambient temperature storage stability test data

4.2.1.10 Product quality test report and test method validation report

4.2.1.11 Package (material, shape, size, net content), storage and transportation, safety warning and shelf life, etc.

4.2.2 Toxicology

4.2.2.1 Acute oral toxicity test data

4.2.2.2 Acute percutaneous toxicity test data

4.2.2.3 Acute inhalation toxicity test data

4.2.2.4 Eye irritation test data

4.2.2.5 Skin irritation test data

4.2.2.6 Skin sensitization test data

4.2.2.7 Other advanced-stage test data required for health risk assessment

4.2.2.8 Health risk assessment report

4.2.3 Efficacy

4.2.3.1 Benefit analysis

4.2.3.1.1 Profile of the crop involved in registration application and the target organism.

4.2.3.1.2 Registered product substitutability analysis and benefit analysis report

4.2.3.2 Efficacy test data

4.2.3.2.1 Indoor biological activity test data

4.2.3.2.2 Indoor crop safety test data

4.2.3.2.3 Field plot efficacy test data

4.2.3.2.4 Large plot efficacy test data

4.2.3.3 Other data

4.2.3.3.1 Effect on main field predatory and parasitic natural enemies

4.2.3.3.2 Product features and application attentions

4.2.3.4 Comprehensive assessment report

4.2.4 Residue

4.2.4.1 In-plant metabolism test data

4.2.4.2 In-animal metabolism test data

4.2.4.3 In-environment metabolism test data

4.2.4.4 Pesticide residue storage stability test data

4.2.4.5 Residue analytical method

4.2.4.6 Crop pesticide residue test data

4.2.4.7 Processed agricultural product pesticide residue test data

4.2.4.8 Data about crops registered in other countries and residue limit

4.2.4.9 Dietary risk assessment report

4.2.5 Environmental impact

4.2.5.1 Bird acute oral toxicity test data

4.2.5.2 Bee acute oral toxicity test data

4.2.5.3 Fish acute toxicity test data

4.2.5.4 Daphnia magna acute activity inhibition test data

Chapter 5 Microbial Pesticides

5.1 Microbial pesticide TK

5.1.1 Product chemical and biological characteristics

5.1.1.1 Identification of active ingredients, biological characteristics, stabilizers, synergists and other restrictive components

5.1.1.2 Strain description

5.1.1.2.1 Strain source

5.1.1.2.2 Host range

5.1.1.2.3 Spread ability

5.1.1.2.4 History and application

5.1.1.2.5 Strain preservation

5.1.1.3 Production process

5.1.1.3.1 Raw material description

5.1.1.3.2 Production process description

5.1.1.3.3 Production process flow chart

5.1.1.3.4 Production unit process flow chart and description

5.1.1.3.5 In-process quality control description

5.1.1.4 Physicochemical properties

5.1.1.5 Product component analysis report

5.1.1.6 Product quality specifications

5.1.1.6.1 Appearance

5.1.1.6.2 Content of active ingredients

5.1.1.6.3 Content of microbiological contaminants and detrimental impurities

5.1.1.6.4 Content of other restrictive components

5.1.1.6.5 Acidity, alkalinity or pH range

5.1.1.6.6 Insoluble matter

5.1.1.6.7 Water or heating loss

5.1.1.7 Detection methods for product quality control and method validation

5.1.1.7.1 Methods for identification of active ingredients in products

5.1.1.7.2 Methods for detection of active ingredients, microbiological contaminants and detrimental impurities, safeners, stabilizers, synergists and other restrictive components and method validation

5.1.1.7.3 Methods for detection of other technical indexes

5.1.1.8 Product quality specification description

5.1.1.9 Product quality test report and test method validation report

5.1.1.10 Package (material, shape, size, net content), storage and transportation, and safety warning, etc.

5.1.2 Toxicology

5.1.2.1 Proof that any active ingredient is not any known pathogene found in human or any other mammals.

5.1.2.2 Basic toxicology data

5.1.2.2.1 Acute oral toxicity test data

5.1.2.2.2 Acute percutaneous toxicity test data

5.1.2.2.3 Acute inhalation toxicity test data

5.1.2.2.4 Eye irritation test data/infection test data

5.1.2.2.5 Sensitization test, investigation data about sensitization of exposed personnel, and reports on sensitization cases at home and abroad

5.1.2.2.6 Acute oral pathogenicity test data

5.1.2.2.7 Acute respiratory tract pathogenicity test data

5.1.2.2.8 Acute injection pathogenicity test data

5.1.2.2.9 Cell culture test data

5.1.2.3 Supplementary toxicology data

5.1.2.4 Human exposure investigation data

5.1.2.5 Toxic symptoms, first aid and treatment measures

5.1.3 Environmental impact

5.1.3.1 Bird toxicity test data

5.1.3.2 Bee toxicity test data

5.1.3.3 Silkworm toxicity test data

5.1.3.4 Fish toxicity test data

5.1.3.5 Daphnia magna test data

5.1.3.6 Microbial proliferation test data

5.2 Microbial pesticide formulation

5.2.1 Product chemical and biological characteristics

5.2.1.1 Identification of active ingredients, biological characteristics, stabilizers, synergists and other restrictive components

5.2.1.2 Basic information about TK

5.2.1.3 Product component

5.2.1.4 Processing method description

5.2.1.4.1 Process flow chart

5.2.1.4.2 Component addition amount and sequence

5.2.1.4.3 Main equipment and operating conditions

5.2.1.4.4 In-process quality control description

5.2.1.5 Physicochemical properties

5.2.1.6 Product quality specifications

5.2.1.6.1 Appearance

5.2.1.6.2 Content of active ingredients

5.2.1.6.3 Content of microbiological contaminants and detrimental impurities

5.2.1.6.4 Content of other restrictive components

5.2.1.6.5 Other dosage-form related control items and indexes

5.2.1.7 Detection methods for product quality control and method validation

5.2.1.7.1 Methods for identification of active ingredients in products

5.2.1.7.2 Methods for detection of active ingredients, microbiological contaminants and detrimental impurities, safeners, stabilizers, synergists and other restrictive components and method validation

5.2.1.7.3 Methods for detection of other technical indexes

5.2.1.8 Product quality specification description

5.2.1.9 Storage stability

5.2.1.10 Product quality test report and test method validation report

5.2.1.11 Package (material, shape, size, net content), storage and transportation, safety warning and shelf life, etc.

5.2.2 Toxicology

5.2.2.1 Acute oral toxicity test data

5.2.2.2 Acute percutaneous toxicity test data

5.2.2.3 Acute inhalation toxicity test data

5.2.2.4 Eye irritation test data

5.2.2.5 Skin irritation test data

5.2.2.6 Skin sensitization test data

5.2.2.7 Other advanced-stage test data required for health risk assessment

5.2.2.8 Health risk assessment report

5.2.3 Efficacy

5.2.3.1 Benefit analysis

5.2.3.1.1 Profile of the crop involved in registration application and the target organism.

5.2.3.1.2 Registered product substitutability analysis and benefit analysis report

5.2.3.2 Efficacy test data

5.2.3.2.1 Indoor biological activity test data

5.2.3.2.2 Field plot efficacy test data

5.2.3.2.3 Large plot efficacy test data

5.2.3.3 Other data

5.2.3.3.1 Effect on main field predatory and parasitic natural enemies

5.2.3.3.2 Product features and application attentions

5.2.3.4 Comprehensive assessment report

5.2.4 Residue

Submit data about residue of such substances in agricultural products that are proved to be

toxicologically significant by the toxicology test upon request by the pesticide registration review committee

5.2.5 Environmental impact

5.2.5.1 Bird toxicity test data

5.2.5.2 Bee toxicity test data

5.2.5.3 Silkworm toxicity test data

5.2.5.4 Fish toxicity test data

5.2.5.5 Daphnia magna test data

Chapter 6 Botanical Pesticides

6.1 Botanical pesticide TC (TK)

6.1.1 Product chemistry

6.1.1.1 Product identification

6.1.1.1.1 Product name

6.1.1.1.2 Identification of active ingredients or symbolic active ingredients, stabilizers, synergists and other restrictive components

6.1.1.2 Production process

6.1.1.2.1 Raw material description

6.1.1.2.2 Production process description

6.1.1.2.3 Production process flow chart

6.1.1.2.4 Production unit process flow chart and description

6.1.1.2.5 In-process quality control description

6.1.1.3 Physicochemical properties

6.1.1.3.1 Physicochemical properties of active ingredients or symbolic active ingredients

6.1.1.3.2 Physicochemical properties of TKs

6.1.1.4 Component analysis

6.1.1.4.1 Component analysis report

6.1.1.4.2 Content of active ingredients or symbolic active ingredients and limit of relevant impurities

6.1.1.5 Product quality specifications

6.1.1.5.1 Appearance

6.1.1.5.2 Content of active ingredients or symbolic active ingredients

6.1.1.5.3 Content of relevant impurities

6.1.1.5.4 Content of other restrictive components

6.1.1.5.5 Acidity, alkalinity or pH range

6.1.1.5.6 Insoluble matter

6.1.1.6 Detection methods for product quality control and method validation

6.1.1.6.1 Product identification method

6.1.1.6.2 Methods for detection of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and method validation

6.1.1.6.3 Methods for detection of other technical indexes

6.1.1.7 Product quality specification description

6.1.1.8 Product quality test report and test method validation report

6.1.1.9 Package (material, shape, size, net content), storage and transportation, and safety warning, etc.

6.1.2 Toxicology

Same as general new pesticides Test data about reproductive toxicity, teratogenicity, chronic toxicity and carcinogenicity, metabolism and toxicokinetics, and the endocrine disrupting effect may not be provided if the pesticide concerned has been approved by the competent department of state to be registered and used as a food additive, a health-care food or a pharmaceutical ingredient, and the review based on proof and test literature provided by relevant department has confirmed that the pesticide meets relevant safety requirements.

6.1.2.1 Acute toxicity test data

6.1.2.1.1 Acute oral toxicity test data

6.1.2.1.2 Acute percutaneous toxicity test data

6.1.2.1.3 Acute inhalation toxicity test data

6.1.2.1.4 Eye irritation test data

6.1.2.1.5 Skin irritation test data

6.1.2.1.6 Skin sensitization test data

6.1.2.2 Acute neurotoxicity test data

6.1.2.3 Delayed neurotoxicity test data

6.1.2.4 Sub-chronic (acute) toxicity test data

6.1.2.4.1 Sub-chronic oral toxicity test data

6.1.2.4.2 Sub-chronic (acute) percutaneous toxicity test data

6.1.2.4.3 Sub-chronic (acute) inhalation toxicity test data

6.1.2.5 Mutagenicity test data

6.1.2.6 Reproductive toxicity test data

6.1.2.7 Teratogenicity test data

6.1.2.8 Chronic toxicity and carcinogenicity test data

6.1.2.9 Metabolism and toxicokinetics test data

6.1.2.10 Endocrine disrupting effect test data

6.1.2.11 Human exposure investigation data

6.1.2.12 Relevant impurities and main metabolite/degradation product toxicity

6.1.2.13 Acceptable daily intake (ADI) and acute reference dosage (ARFD)

6.1.2.14 Toxic symptoms, first aid and treatment measures

6.1.3 Environmental impact

6.1.3.1 Hydrolysis test data

6.1.3.2 In-water photolysis test data

6.1.3.3 Soil aerobic degradation test data

6.1.3.4 Soil adsorption (leaching) test data

6.1.3.5 Bird acute oral toxicity test data

6.1.3.6 Fish acute toxicity test data

6.1.3.7 Daphnia magna acute activity inhibition test data

6.1.3.8 Terrestrial non-target arthropod toxicity test data

6.1.3.8.1 Bee acute oral toxicity test data

6.1.3.8.2 Bee acute exposure toxicity test data

6.1.3.8.3 Silkworm acute toxicity test data

6.1.3.8.4 Parasitic natural enemy acute toxicity test data

6.1.3.8.5 Predatory natural enemy acute toxicity test data

6.1.3.9 Other advanced-stage test data required for environmental risk assessment

6.2 Botanical pesticide formulation

6.2.1 Product chemistry

6.2.1.1 Product identification

6.2.1.1.1 Product name

6.2.1.1.2 Identification of active ingredients or symbolic active ingredients, stabilizers, synergists and other restrictive components

6.2.1.2 Basic information about TC (TK)

6.2.1.3 Product component

6.2.1.4 Processing method description

6.2.1.4.1 Process flow chart

6.2.1.4.2 Component addition amount and sequence

6.2.1.4.3 Main equipment and operating conditions

6.2.1.4.4 In-process quality control description

6.2.1.5 Physicochemical properties

6.2.1.6 Product quality specifications

6.2.1.6.1 Appearance

6.2.1.6.2 Content of active ingredients or symbolic active ingredients

6.2.1.6.3 Content of relevant impurities

6.2.1.6.4 Content of other restrictive components

6.2.1.6.5 Other dosage-form related control items and indexes

6.2.1.7 Detection methods for product quality control and method validation

6.2.1.7.1 Identification method for active ingredients or symbolic active ingredients in products

6.2.1.7.2 Detection methods for active ingredients or symbolic active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and method validation

6.2.1.7.3 Methods for detection of other technical indexes

6.2.1.8 Product quality specification description

6.2.1.9 Ambient temperature storage stability test data

6.2.1.10 Product quality test report and test method validation report

6.2.1.11 Package (material, shape, size, net content), storage and transportation, safety warning and shelf life, etc.

6.2.2 Toxicology

6.2.2.1 Acute oral toxicity test data

6.2.2.2 Acute percutaneous toxicity test data

6.2.2.3 Acute inhalation toxicity test data

6.2.2.4 Eye irritation test data

6.2.2.5 Skin irritation test data

6.2.2.6 Skin sensitization test data

6.2.2.7 Other advanced-stage test data required for health risk assessment

6.2.2.8 Health risk assessment report

6.2.3 Efficacy

6.2.3.1 Benefit analysis

6.2.3.1.1 Profile of the crop involved in registration application and the target organism.

6.2.3.1.2 Registered product substitutability analysis and benefit analysis report

6.2.3.2 Efficacy test data

6.2.3.2.1 Indoor biological activity test data

6.2.3.2.2 Indoor crop safety test data

6.2.3.2.3 Field plot efficacy test data

6.2.3.2.4 Large plot efficacy test data

6.2.3.3 Other data

6.2.3.3.1 Effect on main field predatory and parasitic natural enemies

6.2.3.3.2 Product features and application attentions

6.2.3.4 Comprehensive assessment report

6.2.4 Residue

Submit data about residue of such substances in agricultural products that are proved to be toxicologically significant by the toxicology test upon request by the pesticide registration review committee

6.2.5 Environmental impact

6.2.5.1 TK (TC) environmental test summary

6.2.5.2 Bird acute oral toxicity test data

6.2.5.3 Fish acute toxicity test data

6.2.5.4 Daphnia magna acute activity inhibition test data

6.2.5.5 Bee acute oral toxicity test data

6.2.5.6 Bee acute exposure toxicity test data

6.2.5.7 Silkworm acute toxicity test data

6.2.5.8 Parasitic natural enemy acute toxicity test data

6.2.5.9 Predatory natural enemy acute toxicity test data

Chapter 7 Public Health Pesticide Formulations

7.1 Public health chemical pesticide formulation

7.1.1 Product chemistry

7.1.1.1 Identification of active ingredients, stabilizers, synergists and other restrictive components

7.1.1.2 Basic information about TC (TK)

7.1.1.3 Product component

7.1.1.4 Processing method description

7.1.1.4.1 Process flow chart

7.1.1.4.2 Component addition amount and sequence

7.1.1.4.3 Main equipment and operating conditions

7.1.1.4.4 In-process quality control description

7.1.1.5 Physicochemical properties

7.1.1.6 Product quality specifications

7.1.1.6.1 Appearance

7.1.1.6.2 Content of active ingredients

7.1.1.6.3 Content of relevant impurities

7.1.1.6.4Content of other restrictive components

7.1.1.6.5 Other dosage-form related control items and indexes

7.1.1.7 Detection methods for product quality control and method validation

7.1.1.7.1 Methods for identification of active ingredients in products

7.1.1.7.2 Methods for detection of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and method validation

7.1.1.7.3 Methods for detection of other technical indexes

7.1.1.8 Product quality specification description

7.1.1.9 Ambient temperature storage stability test data

7.1.1.10 Product quality test report and test method validation report

7.1.1.11 Package (material, shape, size, net content), storage and transportation, safety warning and shelf life, etc.

7.1.2 Toxicology

7.1.2.1 Acute oral toxicity test data

7.1.2.2 Acute percutaneous toxicity test data

7.1.2.3 Acute inhalation toxicity test data

7.1.2.4 Eye irritation test data

7.1.2.5 Skin irritation test data

7.1.2.6 Skin sensitization test data

7.1.2.7 Other advanced-stage test data required for health risk assessment

7.1.2.8 Health risk assessment report

7.1.3 Efficacy

7.1.3.1 Benefit analysis

7.1.3.1.1 Information about the target organism involved in registration application

7.1.3.1.2 Registered product substitutability analysis and benefit analysis report

7.1.3.2 Efficacy test data

7.1.3.2.1 Indoor activity test data

7.1.3.2.2 Indoor efficacy test data

7.1.3.2.3 Simulated field efficacy test data

7.1.3.2.4 Field efficacy test data

7.1.3.3 Resistance risk assessment data

7.1.3.3.1 Indoor resistance risk test report

7.1.3.3.2 Field resistance risk monitoring method

7.1.3.4 Product features and application attentions

7.1.3.5 Comprehensive assessment report

7.1.4 Environmental impact

7.1.4.1 TC (TK) environmental test summary

7.1.4.2 Bird acute oral toxicity test data

7.1.4.3 Aquatic toxicity test data

7.1.4.3.1 Fish acute toxicity test data

7.1.4.3.2 Daphnia magna acute activity inhibition test data

7.1.4.3.3 Green algae growth inhibition test data

7.1.4.4 Terrestrial non-target arthropod toxicity test data

7.1.4.4.1 Bee acute oral toxicity test data

7.1.4.4.2 Bee acute exposure toxicity test data

7.1.4.4.3 Silkworm acute toxicity test data

7.1.4.5 Other advanced-stage test data required for environmental risk assessment

7.1.4.6 Environmental risk assessment report

7.2 Public health biochemical pesticide formulation

7.2.1 Product chemistry

7.2.1.1 Identification of active ingredients, stabilizers, synergists and other restrictive components

7.2.1.2 Basic information about TC (TK)

7.2.1.3 Product component

7.2.1.4 Processing method description

7.2.1.4.1 Process flow chart

7.2.1.4.2 Component addition amount and sequence

7.2.1.4.3 Main equipment and operating conditions

7.2.1.4.4 In-process quality control description

7.2.1.5 Physicochemical properties

7.2.1.6 Product quality specifications

7.2.1.6.1 Appearance

7.2.1.6.2 Content of active ingredients

7.2.1.6.3 Content of relevant impurities

7.2.1.6.4Content of other restrictive components

7.2.1.6.5 Other dosage-form related control items and indexes

7.2.1.7 Detection methods for product quality control and method validation

7.2.1.7.1 Methods for identification of active ingredients in products

7.2.1.7.2 Methods for detection of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and method validation

7.2.1.7.3 Methods for detection of other technical indexes

7.2.1.8 Product quality specification description

7.2.1.9 Ambient temperature storage stability test data

7.2.1.10 Product quality test report and test method validation report

7.2.1.11 Package (material, shape, size, net content), storage and transportation, safety warning and shelf life, etc.

7.2.2 Toxicology

7.2.2.1 Acute oral toxicity test data

7.2.2.2 Acute percutaneous toxicity test data

7.2.2.3 Acute inhalation toxicity test data

7.2.2.4 Eye irritation test data

7.2.2.5 Skin irritation test data

7.2.2.6 Skin sensitization test data

7.2.2.7 Other advanced-stage test data required for health risk assessment

7.2.2.8 Health risk assessment report

7.2.3 Efficacy

7.2.3.1 Benefit analysis

7.2.3.1.1 Information about the target organism involved in registration application

7.2.3.1.2 Registered product substitutability analysis and benefit analysis report

7.2.3.2 Efficacy test data

7.2.3.2.1 Indoor activity test data

7.2.3.2.2 Indoor efficacy test data

7.2.3.2.3 Simulated field efficacy test data

7.2.3.2.4 Field efficacy test data

7.2.3.3 Product features and application attentions

7.2.3.4 Comprehensive assessment report

7.2.4 Environmental impact

7.2.4.1 Bird acute oral toxicity test data

7.2.4.2 Bee acute oral toxicity test data

7.2.4.3 Fish acute toxicity test data

7.2.4.4 Daphnia magna acute activity inhibition test data

7.3 Public health microbial pesticide formulation

7.3.1 Product chemical and biological characteristics

7.3.1.1 Identification of active ingredients, biological characteristics, stabilizers, synergists and other restrictive components

7.3.1.2 Basic information about TK

7.3.1.3 Product component

7.3.1.4 Processing method description

7.3.1.4.1 Process flow chart

7.3.1.4.2 Component addition amount and sequence

7.3.1.4.3 Main equipment and operating conditions

7.3.1.4.4 In-process quality control description

7.3.1.5 Physicochemical properties

7.3.1.6 Product quality specifications

7.3.1.6.1 Appearance

7.3.1.6.2 Content of active ingredients

7.3.1.6.3 Content of microbiological contaminants and detrimental impurities

7.3.1.6.4Content of other restrictive components

7.3.1.6.5 Other dosage-form related control items and indexes

7.3.1.7 Detection methods for product quality control and method validation

7.3.1.7.1 Methods for identification of active ingredients in products

7.3.1.7.2 Methods for detection of active ingredients, microbiological contaminants and detrimental impurities, safeners, stabilizers, synergists and other restrictive components and method validation

7.3.1.7.3 Methods for detection of other technical indexes

7.3.1.8 Product quality specification description

7.3.1.9 Storage stability

7.3.1.10 Product quality test report and test method validation report

7.3.1.11 Package (material, shape, size, net content), storage and transportation, safety warning and shelf life, etc.

7.3.2 Toxicology

7.3.2.1 Acute oral toxicity test data

7.3.2.2 Acute percutaneous toxicity test data

7.3.2.3 Acute inhalation toxicity test data

7.3.2.4 Eye irritation test data

7.3.2.5 Skin irritation test data

7.3.2.6 Skin sensitization test data

7.3.2.7 Other advanced-stage test data required for health risk assessment

7.3.2.8 Health risk assessment report

7.3.3 Efficacy

7.3.3.1 Benefit analysis

7.3.3.1.1 Information about the target organism involved in registration application

7.3.3.1.2 Registered product substitutability analysis and benefit analysis report

7.3.3.2 Efficacy test data

7.3.3.2.1 Indoor activity test data

7.3.3.2.2 Indoor efficacy test data

7.3.3.2.3 Simulated field efficacy test data

7.3.3.2.4 Field efficacy test data

7.3.3.3 Product features and application attentions

7.3.3.4 Comprehensive assessment report

7.3.4 Environmental impact

7.3.4.1 Bird toxicity test data

7.3.4.2 Bee toxicity test data

7.3.4.3 Silkworm toxicity test data

7.3.4.4 Fish toxicity test data

7.3.4.5 Daphnia magna test data

7.4 Public health botanical pesticide formulation

7.4.1 Product chemistry

7.4.1.1 Product identification

7.4.1.1.1 Product name

7.4.1.1.2 Identification of active ingredients or symbolic active ingredients, stabilizers, synergists and other restrictive components

7.4.1.2 Basic information about TC (TK)

7.4.1.3 Product component

7.4.1.4 Processing method description

7.4.1.4.1 Process flow chart

7.4.1.4.2 Component addition amount and sequence

7.4.1.4.3 Main equipment and operating conditions

7.4.1.4.4 In-process quality control description

7.4.1.5 Physicochemical properties

7.4.1.6 Product quality specifications

7.4.1.6.1 Appearance

7.4.1.6.2 Content of active ingredients or symbolic active ingredients

7.4.1.6.3 Content of relevant impurities

7.4.1.6.4Content of other restrictive components

7.4.1.6.5 Other dosage-form related control items and indexes

7.4.1.7 Detection methods for product quality control and method validation

7.4.1.7.1 Identification method for active ingredients or symbolic active ingredients in products

7.4.1.7.2 Methods for detection of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and method validation

7.4.1.7.3 Methods for detection of other technical indexes

7.4.1.8 Product quality specification description

7.4.1.9 Ambient temperature storage stability test data

7.4.1.10 Product quality test report and test method validation report

7.4.1.11 Package (material, shape, size, net content), storage and transportation, safety warning and shelf life, etc.

7.4.2 Toxicology

7.4.2.1 Acute oral toxicity test data

7.4.2.2 Acute percutaneous toxicity test data

7.4.2.3 Acute inhalation toxicity test data

7.4.2.4 Eye irritation test data

7.4.2.5 Skin irritation test data

7.4.2.6 Skin sensitization test data

7.4.2.7 Other advanced-stage test data required for health risk assessment

7.4.2.8 Health risk assessment report

7.4.3 Efficacy

7.4.3.1 Benefit analysis

7.4.3.1.1 Information about the target organism involved in registration application

7.4.3.1.2 Registered product substitutability analysis and benefit analysis report

7.4.3.2 Efficacy test data

7.4.3.2.1 Indoor activity test data

7.4.3.2.2 Indoor efficacy test data

7.4.3.2.3 Simulated field efficacy test data

7.4.3.2.4 Field efficacy test data

7.4.3.3 Product features and application attentions

7.4.3.4 Comprehensive assessment report

7.4.4 Environmental impact

7.4.4.1 TK (TC) environmental test summary

7.4.4.2 Bird acute oral toxicity test data

7.4.4.3 Fish acute toxicity test data

7.4.4.4 Daphnia magna acute activity inhibition test data

7.4.4.5 Bee acute oral toxicity test data

7.4.4.6 Bee acute exposure toxicity test data

7.4.4.7 Silkworm acute toxicity test data

Chapter 8 Registration Alteration

8.1 Expansion of the application scope

8.1.1 Copies of the registration certificate

8.1.2 Label and specification

8.1.3 Toxicology

8.1.3.1 Other advanced-stage test data required for health risk assessment

8.1.3.2 Health risk assessment report

8.1.4 Efficacy

8.1.4.1 Efficacy test data

8.1.4.1.1 Indoor biological activity test data

8.1.4.1.2 Indoor crop safety test data

8.1.4.1.3 Field plot efficacy test data

8.1.4.2 Resistance risk assessment data

8.1.4.3 Other data

8.1.4.3.1 Effect on main field predatory and parasitic natural enemies

8.1.4.3.2 Effect on neighboring crops

8.1.4.3.3 Product features and application attentions

8.1.4.3.4 Registered application of the product to the crop or the control object overseas

8.1.4.3.5 Other data related to the pesticide and its application range

8.1.4.4 Comprehensive assessment report

8.1.5 Residue

8.1.5.1 Pesticide residue storage stability data

8.1.5.2 Residue analytical method data

8.1.5.3 Crop pesticide residue test data

8.1.5.4 Processed agricultural product pesticide residue test data

8.1.5.5 Dietary risk assessment report

8.1.6 Environmental impact

8.1.6.1 Supplementary environmental impact data

8.1.6.2 Environmental risk assessment report

8.2 Application method alteration

8.2.1 Copies of the registration certificate

8.2.2 Label and specification

8.2.3 Toxicology

8.2.3.1 Other advanced-stage test data required for health risk assessment

8.2.3.2 Health risk assessment report

8.2.4 Efficacy

8.2.4.1Field plot efficacy test data

8.2.4.2Other data

8.2.4.2.1 Effect on main field predatory and parasitic natural enemies

8.2.4.2.2 Effect on neighboring crops

8.2.4.2.3 Product features and application attentions

8.2.4.3 Comprehensive assessment report

8.2.5 Residue

8.2.5.1 Residue analytical method data

8.2.5.2 Crop pesticide residue test data

8.2.5.3 Dietary risk assessment report

8.2.6 Environmental impact

8.2.6.1 Supplementary environmental impact data

8.2.6.2 Environmental risk assessment report

8.3 Increase of the application dosage

8.3.1 Copies of the registration certificate

8.3.2 Label and specification

8.3.3 Toxicology

8.3.3.1 Other advanced-stage test data required for health risk assessment

8.3.3.2 Health risk assessment report

8.3.4 Efficacy

8.3.4.1 Field plot efficacy test data

8.3.4.2 Comprehensive assessment report

8.3.5 Residue

8.3.5.1 Residue analytical method data

8.3.5.2 Crop pesticide residue test data

8.3.5.3 Dietary risk assessment report

8.3.6 Environmental impact

Environmental risk assessment report

8.4 Decrease of the application dosage

8.4.1 Copies of the registration certificate

8.4.2 Label and specification

8.4.3 Efficacy

8.4.3.1 Field plot efficacy test data

8.4.3.2 Comprehensive assessment report

8.5 TC (TK) quality specification or component alteration

8.5.1 Copies of the registration certificate

8.5.2 Label and specification

8.5.3 Product chemical data

8.5.3.1 Physicochemical properties of TCs (TKs)

8.5.3.2 Full component analysis

8.5.3.3 Product quality test report

8.5.3.4 Product quality specifications

8.5.4 Other test data and descriptions

Submit relevant test data or descriptions according to the contents applied for change.

8.6 Formulation quality specification or component alteration

8.6.1 Copies of the registration certificate

8.6.2 Label and specification

8.6.3 Product chemistry

8.6.3.1 Product component

8.6.3.2 Physicochemical properties

8.6.3.3 Product quality specifications

8.6.3.4 Storage stability test data

8.6.3.5 Product quality test report

8.6.4 Other test data and descriptions

Submit relevant test data or descriptions according to the contents applied for change.

8.7 Toxicity grade alteration

8.7.1 Copies of the registration certificate

8.7.2 Label and specification

8.7.3 Alteration descriptions

8.7.4 Other test data and descriptions

Submit relevant toxicology test reports or descriptions according to the contents applied for change.

Chapter 9 Registration Extension

9.1 Pesticide registration extension application form

9.2 Copies of the registration certificate stamped with the common seal of the applicant

9.3 Most recently filed product quality standards

9.4 Copies of the registration certificate stamped with the common seal of the applicant provided by the pesticide producer

9.5 Comprehensive report

9.5.1 Product annual output, sales volume (at home and abroad), sales value (at home and abroad) and sale territories

9.5.2 Resistance and hazard triggered by the application of the product, effect on natural enemies (or environmental organisms), human and animals, and product residue, etc.

9.5.3 Safety concerns in product production, sale and transportation

9.5.4 The product's latest research result, test reports and other supplementary information

9.5.5 Rectification of the product following the spot inspection

9.5.6 For formulations, the maximum residual limit (MRL) of active ingredients, their application method, dosage and application times shall be provided.

9.6 For pesticides in need of periodical assessment, supplementary test reports or relevant materials shall be provided according to assessment requirements.

9.7 Other data required by the Ministry of Agriculture

Chapter 10 Supplementary Provisions

10.1 These Requirements shall be interpreted by the Ministry of Agriculture.

10.2 These Requirements shall come into force as of November 1, 2017.

Attachments:

1. Data Requirements for Pesticide TC (TK) Registration and the Detailed List
2. Data Requirements for Pesticide Formulation Registration and the Detailed List
3. Data Requirements for Public Health Pesticide Formulation Registration and the Detailed List
4. Data Requirements for Rodenticide Formulation Registration and the Detailed List
5. Data Requirements for Registration Alteration and the Detailed List
6. Data Requirements for Registration of Pesticides Used for Featured Minor Crops
7. Guideline on Field Efficacy Test Plots Required for Pesticide Registration
8. Classification of Crops Used in Residue Test for Pesticide Registration
9. Residue Test Point Requirements for Pesticide Registration
10. Me-to Pesticide Identification Specifications
11. Pesticide Naming Principle
12. Principle for Deciding Contents of Active Ingredients in Pesticide Products
13. Quality Specifications of Pesticide Formulations in Various Dosage Forms and Their Physical and Chemical Properties
14. Pesticide Toxicity Grading Standards

Attachment 1.

Interpretation and Specification of the Data Requirements for Pesticide TC (TK) Registration

1 Chemical Pesticide TCs (TKs)

Pesticide Classes	1. Class A: New pesticide TCs (TKs), including pesticides that have been registered but are not in a valid state, and pesticides that have not been authorized within the 6-year registration protection period; 2. Class B: Me-too TCs (TKs), including TCs that have been authorized within the 6-year protection period. 3. Class C: Non-me-too TCs (TKs) Note: "●"means Yes，"✖"means No，"◐"means No for rodenticides.

Data classification	Items	Interpretation and description	A	B	C
General data	1. Application form	Complete the application form issued by the Ministry of Agriculture		●	
	2. The applicant's certificates	(1) Copies of the production permit, the business license and the unified social credit code stamped with the common seal of the pesticide producer; (2) Descriptions about the pesticide registration application by the new pesticide developer; (3) ID paper of the overseas producer, descriptions about the registration and application of the product in relevant regions and jurisdictions, descriptions about is offices or agencies in China and the business license.		●	
	3. The applicant's statement	A statement that the application data are true and legal.		●	
	4. Product overview	Information about the place of origin, product chemistry, toxicology, environmental impact, summary of risk assessment and overseas registration information.		●	

	5. Labels and manuals	Specimen of labels and manuals prepared in accordance with the *Measures on Management of Pesticide Labels and Manuals*	●
	6. Other registration-supporting documents	(1) Product chemistry, toxicology, or environmental impact data or comprehensive reports currently available in other countries or jurisdictions; (2) Basis for naming active ingredients of a new pesticide	●
	7. Product safety datasheet		●
	8. References	Please give their source	●
Product chemistry①	1. Identification of active ingredients, stabilizers, synergists and other restrictive components	(1) Common names of active ingredients, safeners, stabilizers, synergists and other restrictive components, names approved by the international organization for standardization (ISO), common names adopted by other international organizations and nations, chemical names, Chemical Abstracts Service (CAS) registry number, Collaborative International Pesticides Analytic Council (CIPAC) digital code, development code, molecular formula, structural formula, isomer composition, relative molecular mass or molecular mass range (please provide the release time of the international relative atomic mass table used for calculation); (2) When an active ingredient exists in the form of any salt, identification data about relevant derivatives shall also be provided.	●
	2. Production process		
	2.1 Raw material description	Chemical names of compounds and main solvents involved in reactions, CAS registry number, technical specifications and sources, etc.	●
	2.2 Chemical reaction equation		●
	2.3 Production process description	Describe the actual production units in sequence	●
	2.4 Production flow chart		●
	2.5 Production unit process flow chart and description		●

	2.6 In-process quality control description		●	
	3. Physicochemical properties			
	3.1 Physicochemical properties of active ingredients	(1) Including: Appearance (color, physical state, odor), melting point/melting range, boiling point, solubility in water and in organic solvents (polar, nonpolar and aromatic solvents), density, n-octanol/water partition coefficient (applicable to nonpolar organic compounds), saturated vapor pressure (inapplicable to salt compounds), ionization constant in water (applicable to weak acid and weak alkali compounds), photolysis, in-water hydrolysis, ultraviolet/visible light absorption and specific rotation, etc.; (2) Provide physicochemical property test report or relevant literature consulted based on characteristics of the compound and in accordance with the *Guideline on Pesticide Physiochemical Property Test*. The content of active ingredients in samples used for such tests shall not be lower than 98%.	●	✖
	3.2 Physicochemical properties of TCs (TKs)	(1) Including: Appearance (color, physical state, odor), melting point/melting range, boiling point, stability (heat, metal and metal ions), explosiveness, combustibility, oxidation/reducibility, corrosion to packaging materials and specific rotation, etc; (2) Provide physicochemical property test report based on characteristics of the compound and in accordance with the *Guideline on Pesticide Physiochemical Property Test*. If the TC content is not lower than 98%, data about physicochemical properties of active ingredients may be used.	●	
	4. Full component analysis			

	4.1 Full components analysis report	Prepare the report in accordance with the *Guideline on Full Component Analysis for Technical Materials in Pesticide Registration*. Determine based on the production process whether the TC (TK) contains the following impurities, including but without limited to: aniline and substituted aniline, dimethyl sulfate, dichloro diphenyl trichloroethane (DDT), ethylene thiourea (ETU) and propylene thioureaallyl (PTU), polychlorinateddibenzo-p-dioxin (PCDD), polychlorinateddibenzofuran (PCDF), hydrazine and substituted hydrazine, nitrosamine, phosphine oxide, tetraethyl, 4-ethylthio diphosphate (sulfotep), sulfoxide and fipronil sulfone derived from organophosphorus ester and carbamic acid ester, chlorinated azobenzene, methyl isoeyanate ,polychlorinated biphenyls (PCBs), hexachlorobenzene (HCB) and phenol. The full component analysis process shall involve the qualitative and quantitative analysis of these possible impurities.	●
	4.2 Impurity formation analysis	Analyze reasons behind the formation of detected and possible impurities from perspectives of chemical theory, raw materials and the production process.	●
	4.3 Content of active ingredients and impurity limit	Define the minimum content of TC, the marked content of TK and the maximum content of impurities. Describe the statistics based on which the limits are established.	●
	5. Product quality specifications		
	5.1 Appearance	Accurately describe the color, physical state and odor of the product.	●

	5.2 Content of active ingredients	(1) Define the minimum content of active ingredients (not graded) in TCs (expressed in mass fraction), which shall not be less than 90% of the total volume typically and shall be determined based on the mean value and the standard deviation of five batches of representative samples detected, and provide the statistical method used; (2) The content of TK typically consists of the marked content and the allowable fluctuation range; the marked content is the mean value of five batches of representative samples detected, and the allowable function range is determined according to the preparation requirements; (3) When an active ingredient contains any isomer, if the isomer is defined by the common name, there is no need to repetitively define the isomer proportion in control items; if the mixture applied for registration is not defined by the common name, the isomer proportion shall be defined; (4) If an active ingredient exists in the form of any salt (such as glyphosate sodium and copper agent), the product name and mass fraction shall be expressed in its actual existence form, and marked with the content of the active ingredient and of paired countra-ions.	●
	5.3 Content of relevant impurities	For products containing relevant impurities, define the maximum content of such impurities, which is expressed in mass fraction.	●
	5.4 Content of other restrictive components	For products containing safeners, stabilizers, synergists or any other restrictive components, their content shall consist of the marked content and the allowable fluctuation range. The latter shall be determined according to the chemical pesticide preparation requirements.	●
	5.5 Acidity, alkalinity or pH range	Express the acidity or alkalinity in the mass fraction of sulfuric acid or sodium hydroxide, regardless of its actual existence form.	●
	5.6 Insoluble matter	Define the maximum allowable content, which is expressed in mass fraction (%).	●
	5.7 Water or heating loss	Define the maximum allowable content, which is expressed in mass fraction (%).	●

	6. Detection methods corresponding to product quality control items and method validation		
	6.1 Methods for identification of active ingredients in products②	Adopt at least one test method to identify the active ingredients in products When a chemical method is adopted, at least two identification methods shall be provided. When an active ingredient exists in the form of any salt, the identification method shall be able to identify the type of the salt.	●
	6.2 Methods for detection of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and method validation	(1) Detection method: Provide a complete set of detection method, which typically includes the method summary, principle, sample information, standard information, instruments, reagent, solution preparation, operation conditions, detection procedures, result calculation, statistical method and allowable tolerance; (2) Method validation Comply with the *Guideline on Validation of Pesticide Product Quality Analysis Method*.	●
	6.3 Methods for detection of other technical indexes	Comply with the *Guideline on Validation of Pesticide Product Quality Analysis Method*.	●
	7. Product quality specification description	Give necessary descriptions about the basis for setting the technical indexes and its reasonability.	●
	8. Product quality test report and test method validation report③	(1) The product quality test report shall include all items specified in the product quality specifications; (2) Methods for detection of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components shall be validated by the registration testing institute responsible for issuing the product quality test report, which will issue a test method validation report after completion of validation; the detection method designed for other control items may be not validated; (3) The test method validation report shall include: Testing conditions provided by the entrusting party, actual testing conditions adopted by the registration testing institute (such as the chromatographic conditions and	●

		sample preparation), descriptions about any alteration, results of parallel measurements, standard deviation, typical spectrograms (including standards and samples), and method feasibility evaluation.			
	9. Package (material, shape, size, net content), storage and transportation, and safety warning, etc.				
	9.1 Package, storage and transportation	The applicant shall choose proper packaging materials, and proper package size and transportation tools by taking into account the hazard classification of products, and compile the transportation and storage attentions in accordance with relevant safe production and transportation laws, regulations and standards of the state.	●		
	9.2 Safety warning	Evaluate, classify and label the hazard degree of products based on their physicochemical properties and in accordance with the *Chemical Hazard Classification Standards*, and make it known to the public in the form of Material Safety Data Sheet (MSDS).	●		
Toxicology	1. Acute toxicity test				
	1.1 Acute oral toxicity test data		●	×	●
	1.2 Acute percutaneous toxicity test data		●	×	●
	1.3 Acute inhalation toxicity test data		●	×	●
	1.4 Eye irritation test data		●	×	●
	1.5 Skin irritation test data		●	×	●

	1.6 Skin sensitization test data		●	×	●
	2. Acute neurotoxicity test data		●	×	●
	3. Delayed neurotoxicity test data	Applicable to organophosphorus pesticides, or pesticides having a chemical structure similar to that of the positive matter resulting in delayed neurotoxicity	●	×	●
	4. Sub-chronic (acute) toxicity test data				
	4.1 Sub-chronic oral toxicity test data	90-day oral toxicity test	●	×	●
	4.2 Sub-chronic (acute) percutaneous toxicity test data	28-day or 90-day percutaneous toxicity test	●	×	●
	4.3 Sub-chronic (acute) inhalation toxicity test data	28-day or 90-day inhalation toxicity test	●	×	●
	5. Mutagenicity test data	(1) Mutagenicity composite tests include: a Salmonella typhimurium/reverse mutation test b In vitro mammalian cell gene mutation test c In vitro mammalian cell chromosomal aberration test d In vivo mammalian marrow cell micronucleus test (2) If either test in clauses a through c produces a positive result, and the test in clause d produces a negative result, add another in vivo test (such as mammalian cell UDS test); if each test in clauses a through c produces a negative result, and the test in clause produces a positive result, add in vivo mammalian germ cell chromosome aberration test or dominant lethal test.	●	×	●
	6. Reproductive toxicity test data		●	×	●
	7. Teratogenicity test data	Submit data about teratogenicity test of two types of mammals, preferably rats and rabbits	●	×	●
	8. Chronic toxicity and carcinogenicity test data④	Submit data about carcinogenicity test of two types of rodents, preferably rats and mice	●	×	●

	9. Metabolic and toxicokinetics test data		◐	✖	◐
	10. Endocrine disrupting effect test data	If the chronic toxicity or reproductive toxicity test shows that the product is toxic to the endocrine system, provide the test report on endocrine disrupting effect.	◐	✖	◐
	11. Human exposure investigation data		◐	✖	◐
	12. Relevant impurities and main metabolite/degradation product toxicity		◐	✖	◐
	13. Acceptable daily intake (ADI) and acute reference dosage (ARFD)		◐	✖	◐
	14. Toxic symptoms, first aid and treatment measures		●	✖	●
Environmental impact⑤	1. Hydrolysis test data	Hydrolysis test data about the radioactive marker of active ingredients or TC in buffer solutions at 25°C, with ph values of 4, 7 and 9 respectively	●	✖	✖
	2. In-water photolysis test data	Photolysis test data about the radioactive marker of active ingredients or TC in pure water or buffer solution	●	✖	✖
	3. Soil surface photolysis test data	Photolysis test data about the radioactive marker of active ingredients or TC on surface of at least one type of soil	●	✖	✖
	4. Soil aerobic metabolism test data	Aerobic metabolism data about the radioactive marker of active ingredients in at least four types of representative soil For main metabolites, obtain their degradation rate in at least three types of representative soil; if the main metabolites are test substances, conduct the degradation rate test only. If the test results or relevant data show that the metabolic pathway or metabolic rate of the pesticide in soil is dependent on the pH value of soil, the four types of representative test oil shall	●	✖	✖

		include one red oil and one soil with a higher pH value (such as black soil, moisture soil or brown soil) or the like.			
	5. Soil anaerobic metabolism test data	Anaerobic metabolism test data about the radioactive marker of active ingredients in at least one type of soil. If the anaerobic test results show the metabolic pathway or metabolic rate of the pesticide in test soil is different from that obtained from the aerobic test, conduct tests with at least four types of representative soil (except DT_{50}>180 days under anaerobic conditions).	●	✖	✖
	6. Water-sediment system aerobic metabolism test data	Aerobic metabolism test data about the radioactive marker of active ingredients in at least two types of representative water-sediment systems	●	✖	✖
	7. Soil adsorption (leaching) test data	Provide soil adsorption (batch equilibrium method) test data about the TC and main metabolites or the radioactive marker of active ingredients and main metabolites; when the pesticide parent or its main metabolites cannot be used for soil adsorption test using the batch equilibrium method, conduct the soil column leaching test. The batch equilibrium method or column leaching method shall produce the soil adsorption coefficient of active ingredients in at least four types of representative soil (including at least one soil containing organic matter＜1%), and that of main metabolites in at least three types of representative soil (including at least one soil containing organic matter＜1%); If the active ingredients or the main metabolites are unstable in soil-calcium chloride solution or insoluble in water, provide soil adsorption (high performance liquid chromatography) test data. If the test results or relevant data show that the adsorption of the pesticide in soil is dependent on the pH value of soil, the	●	✖	✖

		four types of representative test oil shall include one red oil and one soil with a higher pH value (such as black soil, moisture soil or brown soil) or the like.			
	8. In-water pesticide analysis method and validation	Provide methods for analyzing active ingredients and main metabolites in water and the method validation report. The analysis method quantification limit shall not exceed 0.1μg/L, or 1% of the acute LC_{50} (EC_{50}) of the test substance to fish, or daphnia or 10% of the EC_{50} of the test substance to algae (whichever is lower).	●	×	●
	9. In-soil pesticide analysis method and validation	Provide methods for analyzing active ingredients and main metabolites in soil and the method validation report. The analysis method quantification limit shall not exceed 5μg/Kg, or EC_{10}, NOEC or LC_{50} of the test substance to soil organisms and benthos (whichever is lower).	●	×	●
	10. Bird acute oral toxicity test data	The high or extremely high toxicity to one type of bird (LD50≤50mg a.i./kg body weight) needs to be confirmed by the test of another type of bird	●	×	●
	11. Bird short-term feeding toxicity test data	The high or extremely high toxicity to one type of bird (LC50≤50mg a.i./kg feed or LD50≤50mg a.i./kg body weight) needs to be confirmed by the test of another type of bird. Provide the daily intake of birds and test results, which shall be expressed in LC50and LD50.	●	×	●
	12. Bird reproduction test data	Birds used for the test shall be of the type that is sensitive in the acute oral toxicity test or the short-term feeding toxicity test.	●	×	●

	13. Fish acute toxicity test data	Fish acute toxicity test data about TC and main metabolites. The TC test shall be conducted with at least one type of cold water fish (such as rainbow trout) and at least one type of warm water fish (such as zebra fish and medaka); The main metabolites test shall be conducted with one type of fish that is sensitive in the TC test.	●	✖	●
	14. Fish early stage toxicity test data		●	✖	●
	15. Fish life cycle test data	Provide fish life cycle test data when the following two conditions are met: (1) The predicted environmental concentration (PECtwa) >0.1×no-effect concentration (NOEC) in the fish early stage toxicity test; (2) The bio-concentration factor (BCF) >1000, or the substance is stable in water or sediments (in water-sediment systems, $DegT_{90}$>100 days).	●	✖	●
	16. Daphnia magna acute activity inhibition test data	Daphnia magna acute activity inhibition test data about TC and main metabolites	●	✖	●
	17. Daphnia magna reproduction test data		◐	✖	◐
	18. Green algae growth inhibition test data	Green algae growth inhibition test data about TC and main metabolites	◐	✖	◐
	19. Aquatic plant toxicity test data	Applicable to herbicides only. Conduct myriophyllum spicatum toxicity test for herbicides that work on dicotyledons, and lemna sp. growth inhibition test for herbicides that work on monocotyledons	◐	✖	◐
	20. Fish bio-concentration test data	The bio-concentration test data about the radioactive marker of active ingredients or TC obtained from one type of fish may not be provided under any of the following circumstances: (1) N-caprylic alcohol/water distribution coefficient of the pesticide and its main metabolites <1000 (or log Pow<3); (2) Hydrolysis DT_{50} in 25°C buffer solutions with pH values of 4, 7, 9 <5 days.	◐	✖	◐

	21. Aquatic ecology simulation system (Mesocosm) test data	If the risk assessment shows that the risk posed by the pesticide to the aquatic ecology system is unacceptable, provide the aquatic ecology simulation system (Mesocosm) test data about a representative formulation.	◐	✖	◐
	22. Bee acute oral toxicity test data		◐	✖	◐
	23. Bee acute exposure toxicity test data		◐	✖	◐
	24. Bee larvae developmental toxicity test data	Applicable to insect growth modifiers only	◐	✖	◐
	25. Bee semi-field test data③	If the primary risk assessment shows that the risk posed by the pesticide to bees is unacceptable, provide the bee semi-field test data about a representative formulation.	◐	✖	◐
	26. Silkworm acute toxicity test data③		◐	✖	◐
	27. Silkworm chronic toxicity test data③	Applicable to insect growth modifiers only	◐	✖	◐
	28. Parasitic natural enemy acute toxicity test data	Provide the acute toxicity test data about at least one type of parasitic natural enemy	◐	✖	◐
	29. Predatory natural enemy acute toxicity test data	Provide the acute toxicity test data about at least one type of predatory natural enemy	◐	✖	◐
	30. Earthworm acute toxicity test data		◐	✖	◐
	31. Earthworm reproductive toxicity test data	Provide earthworm reproductive toxicity test data about TC or a representative formulation under any of the following circumstances: (1) The predicated environmental concentration (PEC) >0.1× earthworm acute LC_{50}; (2) Other data show that there is a potential chronic toxicity risk to earthworms.	◐	✖	◐

	32. Soil microbial effect (nitrogen conversion method) test data	Soil microbial effect (nitrogen conversion method) test data about TC or a representative formulation in at least one type of soil	◐	✖	◐
	33. Carnivore secondary intoxication data	For rodenticides that might cause secondary intoxication of carnivores, provide data about the secondary intoxication of TC or of a representative formulation.	●	✖	●
	34. Endocrine disrupting effect test data	If the chronic toxicity test shows that the product is toxic to the endocrine system of environmental organisms, provide data about the endocrine disrupting effect on relevant environmental organisms.	◐	✖	◐
	35. Other advanced-stage test data required for environmental risk assessment	If the primary risk assessment shows that the risk posed by the pesticide to a particular protection object is unacceptable, provide data about corresponding advanced-stage tests	●	✖	●

Note:

①If a TK is processed with any registered TC of the producer, submit product chemical data according to requirements on formulations, data about ambient temperature storage stability test being exempted, and describe reasons behind production of the TK and its appropriate dosage forms. In case of application for registration of any other TK, submit product chemical data according to requirements on TCs, and:

-describe reasons behind the TK production, and its appropriate dosage forms;

-set the top and bottom limits for the content of active ingredients according to requirements on that of formulations;

-provide data about the heat storage stability test and the low-temperature stability test.

②If any public health pesticide TK with the content lower than 1% involves isomer separation, and if descriptions about the test of identification of active ingredients in the product (including identification of isomers) have been given, the applicant may not provide the isomer separation method and the method validation report, but shall provide data containing the following:

-When the active ingredient in the product is a particular isomer, the content of the active ingredient shall be the total content multiplied by the proportionality coefficient of the active isomer in the TC used;

-When the active ingredient in the product is composed of more than one isomer in different proportions, the total content and proportions of different isomers shall be defined;

-If the identification test is conducted, describe the proportional range of the isomer in TC, and the isomer separation method and chromatograms.

③ The test shall be completed within the territory of China in accordance with Article 16 of the *Measures on management of Pesticide Registration*.

④ For rodenticides, submit data about the 6-month chronic toxicity test.

⑤ If adequate data prove that the pesticide is less likely to be exposed to certain environmental organisms (for example, the pesticide is only applied to ponds, rivers, lakes or other water bodies or to protection areas or to land crops, grasslands or forests), relevant data may be exempted upon application, but relevant supporting documents shall be submitted; For pesticide TCs produced exclusively for public health purpose, only environmental impact data under items 1, 2, 4, 6, 7, 8, 9,10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 22, 23 and 26 in the table need to be provided (for processed public health pesticide TCs that are produced exclusively for indoor use, only data under items 10 and 11 need to be provided); for pesticides produced exclusively for indoor use (such as pesticides used to inhibit the sprouting of harvested potatoes), only data under items 8 and 9 need to be provided.

2 Biochemical pesticide TCs (TKs)

Pesticide Classes	1. Class A: New pesticide TCs (TKs), including pesticides that have been registered but are not in a valid state, and pesticides that have not been authorized within the 6-year registration protection period; 2. Class B: Me-too TCs (TKs), including TCs that have been authorized within the 6-year protection period. 3. Class C: Non-me-too TCs (TKs) Note: "●"means Yes，"✖"means No，"◐"means No for rodenticides.

Data classification	Items	Interpretation and description	A	B	C
General data	1. Application form	Complete the application form issued by the Ministry of Agriculture		●	
	2. The applicant's certificates	(1) Copies of the production permit, the business license and the unified social credit code stamped with the common seal of the pesticide producer; (2) Descriptions about the pesticide registration application by the new pesticide developer; (3) ID paper of the overseas producer, descriptions about the registration and application of the product in relevant regions and jurisdictions, descriptions about is offices or agencies in China and the business license.		●	
	3. The applicant's statement	A statement that the application data are true and legal.		●	
	4. Product overview	(1) Copies of the production permit, the business license and the unified social credit code stamped with the common seal of the pesticide producer; (2) Descriptions about the pesticide registration application by the new pesticide developer; (3) ID paper of the overseas producer, descriptions about the registration and application of the product in relevant regions and jurisdictions, descriptions about is offices or		●	

		agencies in China and the business license.	
	5. Labels and manuals	Specimen of labels and manuals prepared in accordance with the *Measures on Management of Pesticide Labels and Manuals*	●
	6. Other registration-supporting documents	(1) Product chemistry, toxicology, or environmental impact data or comprehensive reports currently available in other countries or jurisdictions; (2) Basis for naming active ingredients of a new pesticide	●
	7. Product safety datasheet		●
	8. References	Please give their source	●
Product chemistry ①	1. Identification of active ingredients, stabilizers, synergists and other restrictive components	(1) Common names of active ingredients, safeners, stabilizers, synergists and other restrictive components, names approved by the international organization for standardization (ISO), common names adopted by other international organizations and nations, chemical names, Chemical Abstracts Service (CAS) registry number, Collaborative International Pesticides Analytic Council (CIPAC) digital code, development code, molecular formula, structural formula, isomer composition, relative molecular mass or molecular mass range (please provide the release time of the international relative atomic mass table used for calculation); (2) When an active ingredient exists in the form of any salt, data about the identification of relevant derivatives	●

		shall be provided.		
	2. Production process			
	2.1 Raw material description	Chemical names of compounds and main solvents involved in reactions, CAS registry number, technical specifications and sources, etc. If the product is extracted from any organism, describe in detail the organism and raw materials involved in the extraction process.	●	
	2.2 Chemical reaction equation or biological reaction description		●	
	2.3 Production process description	Describe the actual production units in sequence	●	
	2.4 Production flow chart		●	
	2.5 Production unit process flow chart and description		●	
	2.6 In-process quality control description		●	
	3. Physicochemical properties			
	3.1 Physicochemical properties of active ingredients	(1) The physicochemical properties of active ingredients include: Appearance (color, physical state, odor), melting point/melting range, boiling point, solubility in water and in organic solvents (polar, nonpolar and aromatic solvents), density, n-octanol/water partition coefficient (applicable to nonpolar organic compounds), saturated vapor pressure (inapplicable to salt compounds), ionization constant in water (applicable to weak acid and	●	✖

		weak alkali compounds), photolysis, in-water hydrolysis, ultraviolet/visible light absorption and specific rotation, etc; (2) Provide physicochemical property test report or relevant literature consulted based on characteristics of the compound and in accordance with the *Guideline on Pesticide Physiochemical Property Test*. The content of active ingredients in samples used for such tests shall not be lower than 98%.		
	3.2 Physicochemical properties of TCs (TKs)	(1) The physicochemical properties of TCs or TKs include: Appearance (color, physical state, odor), melting point/melting range, boiling point, stability (heat, metal and metal ions), explosiveness, combustibility, oxidation/reducibility, corrosion to packaging materials and specific rotation, etc; (2) Provide physicochemical property test report based on characteristics of the compound and in accordance with the *Guideline on Pesticide Physiochemical Property Test*. If the TC content is not be lower than 98%, data about physicochemical properties of active ingredients may be used.		●
	4. Full component analysis			

	4.1 Full components analysis report	Prepare the report in accordance with the *Guideline on Full Component Analysis for Technical Materials in Pesticide Registration*. Determine based on the production process whether the TC (TK) contains the following impurities, including but without limited to: aniline and substituted aniline, dimethyl sulfate, dichloro diphenyl trichloroethane (DDT), ethylene thiourea (ETU) and propylene thioureaallyl (PTU), polychlorinateddibenzo-p-dioxin (PCDD), polychlorinateddibenzofuran (PCDF), hydrazine and substituted hydrazine, nitrosamine, phosphine oxide, tetraethyl, 4-ethylthio diphosphate (sulfotep), sulfoxide and fipronil sulfone derived from organophosphorus ester and carbamic acid ester, chlorinated azobenzene, methyl isoeyanate ,polychlorinated biphenyls (PCBs), hexachlorobenzene (HCB) and phenol. The full component analysis process shall involve the qualitative and quantitative analysis of these possible impurities.	●
	4.2 Impurity formation analysis	Analyze reasons behind the formation of detected and possible impurities from perspectives of chemical theory, raw materials and the production process.	●
	4.3 Content of active ingredients and impurity limit	Define the minimum content of TC, the marked content of TK and the maximum content of impurities. Describe the statistics based on which the limits are established.	●
	5. Product quality specifications		
	5.1 Appearance	Describe the color, physical state and odor of the product.	●

	5.2 Content of active ingredients	(1) Define the minimum content of active ingredients (not graded) in TCs (expressed in mass fraction), which shall not be less than 90% of the total volume typically and shall be determined based on the mean value and the standard deviation of five batches of representative samples detected, and provide the statistical method used; (2) The content of TK typically consists of the marked content and the allowable fluctuation range; the marked content is the mean value of five batches of representative samples detected, and the allowable function range is determined according to the preparation requirements; (3) When an active ingredient contains any isomer, if the isomer is defined by the common name, there is no need to repetitively define the isomer proportion in control items; if the mixture applied for registration is not defined by the common name, the isomer proportion shall be defined; (4) If an active ingredient exists in the form of any salt, the product name and mass fraction shall be expressed in its actual existence form, and marked with the content of the active ingredient and of paired countra-ions.	●
	5.3 Content of relevant impurities	For products containing relevant impurities, define the maximum content of such impurities, which is expressed in mass fraction.	●

	5.4 Content of other restrictive components	For products containing safeners, stabilizers, synergists or any other restrictive components, their content shall consist of the marked content and the allowable fluctuation range. The latter shall be determined according to the chemical pesticide preparation requirements.	●
	5.5 Acidity, alkalinity or pH range	Express the acidity or alkalinity in the mass fraction of sulfuric acid or sodium hydroxide, regardless of its actual existence form.	●
	5.6 Insoluble matter	Define the maximum allowable content, which is expressed in mass fraction (%).	●
	5.7 Water or heating loss	Define the maximum allowable content, which is expressed in mass fraction (%).	●
	6. Detection methods corresponding to product quality control items and method validation		
	6.1 Methods for identification of active ingredients in products②	Adopt at least one test method to identify the active ingredients in products When a chemical method is adopted, at least two identification methods shall be provided. When an active ingredient exists in the form of any salt, the identification method shall be able to identify the type of the salt.	●
	6.2 Methods for detection of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and method validation	(1) Detection method: Provide a complete set of detection method, which typically includes the method summary, principle, sample information, standard information, instruments, reagent, solution preparation, operation conditions, detection procedures, result calculation, statistical method and allowable tolerance; (2) Method validation Comply with the *Guideline on*	●

		Validation of Pesticide Product Quality Analysis Method.	
	6.3 Methods for detection of other technical indexes	Comply with the *Guideline on Validation of Pesticide Product Quality Analysis Method*.	●
	7. Product quality specification description	Give necessary descriptions about the basis for setting the technical indexes and its reasonability.	●
	8. Product quality test report and test method validation report③	(1) The product quality test report shall include all items specified in the product quality specifications; (2) Methods for detection of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components shall be validated by the registration testing institute responsible for issuing the product quality test report, which will issue a test method validation report after completion of validation; the detection method designed for other control items may be not validated; (3) The test method validation report shall include: Testing conditions provided by the entrusting party, actual testing conditions adopted by the registration testing institute (such as the chromatographic conditions and sample preparation), descriptions about any alteration, results of parallel measurements, standard deviation, typical spectrograms (including standards and samples), and method feasibility evaluation.	●
	9. Package (material, shape, size, net content), storage and transportation, and safety warning, etc.		

	9.1 Package, storage and transportation	The applicant shall choose proper packaging materials, and proper package size and transportation tools by taking into account the hazard classification of products, and compile the transportation and storage attentions in accordance with relevant safe production and transportation laws, regulations and standards of the state.	●		
	9.2 Safety warning	Evaluate, classify and label the hazard degree of products based on their physicochemical properties and in accordance with the *Chemical Hazard Classification Standards*, and make it known to the public in the form of Material Safety Data Sheet (MSDS).	●		
Toxicology	1. Basic toxicology test data				
	1.1 Acute oral toxicity test data		●	×	●
	1.2 Acute percutaneous toxicity test data		●	×	●
	1.3 Acute inhalation toxicity test data		●	×	●
	1.4 Eye irritation test data		●	×	●
	1.5 Skin irritation test data		●	×	●
	1.6 Skin sensitization test data		●	×	●
	1.7 Sub-chronic oral toxicity test data	90-day oral toxicity test	●	×	●

	1.8 Mutagenicity test data	(1) Mutagenicity composite tests include: a Salmonella typhimurium/reverse mutation test b In vitro mammalian cell gene mutation test c In vitro mammalian cell chromosomal aberration test d In vivo mammalian marrow cell micronucleus test (2) If either test in clauses a through c produces a positive result, and the test in clause d produces a negative result, add another in vivo test (such as mammalian cell UDS test); if each test in clauses a through c produces a negative result, and the test in clause produces a positive result, add in vivo mammalian germ cell chromosome aberration test or dominant lethal test.	●	✖	●
	2. Supplementary toxicology test data	If the basic toxicology test finds it has any toxicological significance, provide data about acute neurotoxicity, 28-day percutaneous toxicity, 28-day inhalation toxicity, reproductive toxicity, teratogenicity, chronic toxicity and carcinogenicity, metabolism, toxicokinetics and endocrine disrupting effect tests.	●	✖	●
	3. Human exposure investigation data		◐	✖	◐
	4. Relevant impurities and main metabolite/degradation product toxicity		◐	✖	◐
	5. Acceptable daily intake (ADI) and acute reference dosage (ARFD)		◐	✖	◐
	6. Toxic symptoms, first aid and treatment measures		●	✖	●
Environmental impact④	1. Bird acute oral toxicity test data		●	✖	●
	2. Bee acute oral toxicity test data⑤		◐	✖	◐

	3. Fish acute toxicity test data		●	×	●
	4. Daphnia magna acute activity inhibition test data		●	×	●

Note:

①If a TK applied for is processed with the registered TC of the producer, submit product chemical data according to requirements on formulations, data about ambient temperature storage stability test being exempted, and describe reasons behind production of the TK and its appropriate dosage forms. In case of application for registration of any other TK, submit product chemical data according to requirements on TCs, and:

-describe reasons behind the TK production, and its appropriate dosage forms;

-set the top and bottom limits for the content of active ingredients according to requirements on that of formulations;

-provide data about the heat storage stability test and the low-temperature stability test.

②If any public health pesticide TK with the content lower than 1% involves isomer separation, and if descriptions about the test of identification of active ingredients in the product (including identification of isomers) have been given, the applicant may not provide the isomer separation method and the method validation report, but shall provide data containing the following:

-When the active ingredient in the product is a particular isomer, the content of the active ingredient shall be the total content multiplied by the proportionality coefficient of the active isomer in the TC used;

-When the active ingredient in the product is composed of more than one isomer in different proportions, the total content and proportions of different isomers shall be defined;

-If the identification test is conducted, describe the proportional range of the isomer in TC, and the isomer separation method and chromatograms.

③ The test shall be completed within the territory of China in accordance with Article 16 of the *Measures on management of Pesticide Registration*.

④ If any test result shows that the ecotoxicity of the TC is above the medium level (including the medium level), the test report or materials shall be provided according to the data requirements for chemical pesticide TCs. For processed public heath pesticide formulations produced exclusively for indoor use, such data may not be provided; if adequate data prove that the pesticide is less likely to be exposed to certain environmental organisms, relevant data may be exempted upon application, but relevant supporting documents shall be submitted; For pesticides produced exclusively for use in protection areas or indoors (such as pesticides used to inhibit the sprouting of harvested potatoes), the environmental data may not be provided.

⑤ For pesticides produced exclusively for direct use in ponds, rivers, lakes or other water bodies (such as pesticides produced for lotus roots), such data may not be provided.

3 Microbial pesticide TKs

Pesticide Classes	1. Class A: New pesticide TKs, including pesticides that have been registered but are not in a valid state, and pesticides that have not been authorized within the 6-year registration protection period; 2. Class C: Non-me-too TKs Note: "●" means Yes，"✖"means No，"◐"means No for rodenticides.			
Data classification	Items	Interpretation and description	A	C
General data	1. Application form	Complete the application form issued by the Ministry of Agriculture	●	
	2. The applicant's certificates	(1) Copies of the production permit, the business license and the unified social credit code stamped with the common seal of the pesticide producer; (2) Descriptions about the pesticide registration application by the new pesticide developer; (3) ID paper of the overseas producer, descriptions about the registration and application of the product in relevant regions and jurisdictions, descriptions about is offices or agencies in China and the business license.	●	
	3. The applicant's statement	A statement that the application data are true and legal.	●	

	4. Product overview	(1) Copies of the production permit, the business license and the unified social credit code stamped with the common seal of the pesticide producer; (2) Descriptions about the pesticide registration application by the new pesticide developer; (3) ID paper of the overseas producer, descriptions about the registration and application of the product in relevant regions and jurisdictions, descriptions about is offices or agencies in China and the business license.	●
	5. Labels and manuals	Specimen of labels and manuals prepared in accordance with the *Measures on Management of Pesticide Labels and Manuals*	●
	6. Other registration-supporting documents	(1) Product chemistry, toxicology, or environmental impact data or comprehensive reports currently available in other countries or jurisdictions; (2) Basis for naming active ingredients of a new pesticide	●
	7. Product safety datasheet		●
	8. References	Please give their source	●

Product chemical and biological characteristics	1. Identification of active ingredients, biological characteristics, stabilizers, synergists and other restrictive components	(1) Common names of effective ingredients, international common names (usually Latin names), classification (such as the family, genus, species and subspecies, strain, serotype, pathovar and other microorganism-related names, etc.) (2) Strain identification report issued by the authoritative microorganism research institute of the state; (3) Strain code (code compiled by the Microbiological Culture Collection Center); (4) Common names of safeners, stabilizers, synergists and other restrictive components, names approved by the international organization for standardization (ISO), common names adopted by other international organizations and nations, chemical names, Chemical Abstracts Service (CAS) registry number, Collaborative International Pesticides Analytic Council (CIPAC) digital code, development code, molecular formula, structural formula, isomer composition, relative molecular mass or molecular mass range (the release time of the international relative atomic mass table shall be provided)	●
	2. Strain description①		

	2.1 Strain source	Geographic distribution and life cycle in nature	●
	2.2 Host range	Describe the host type and range	●
	2.3 Spread ability	Relationship with the known pathogenic bacteria of plants or animals; Tolerance in different environmental conditions and spread ability in nature	●
	2.4 History and application		●
	2.5 Strain preservation	Preservation in domestic and international authoritative Microbiological Culture Collection Centers	●
	3. Production process		
	3.1 Raw material description		●
	3.2 Production process description	Describe the actual production units in sequence	●
	3.3 Production flow chart		●
	3.4 Production unit process flow chart and description		●
	3.5 In-process quality control description		●
	4. Physicochemical properties	(1) The physicochemical properties include: Appearance (color, material, odor), density, stability and corrosion to packaging materials, of which, stability includes: -sensitivity to temperature changes: Provide the survival rate of active ingredients after storage for some time under different temperature conditions, to evaluate the storage and transport	●

		conditions of the product; ——sensitivity to light: Provide the survival rate of active ingredients after storage for some time under different light conditions, to evaluate the package and application conditions of the product; ——sensitivity to pH value: Provide the survival rate of active ingredients after storage for some time under different pH conditions, to evaluate the technical indexes of the product; (2) Provide physicochemical property test report based on characteristics of the product and in accordance with the *Guideline on Pesticide Physiochemical Property Test*.	
	5. Component analysis report	Including but not limited to the following: Qualitative analysis of the active ingredients, microbial contaminants (other bacteria), detrimental impurities (metabolites and chemicals boasting toxicological significance to human, livestock or environmental organisms) and other chemical components of one batch of products, and quantitative analysis of the active ingredients, microbial contaminants (other bacteria), detrimental impurities (metabolites and chemicals boasting toxicological	●

		significance to human, livestock or environmental organisms) and other chemical components of five batches of products.	
	6. Product quality specifications		
	6.1 Appearance	Describe the color, physical state and odor of the product.	●
	6.2 Content of active ingredients	(1) Usually expressed in the number of microorganisms in the product per unit mass or volume, and the units of microbial content defined based on different determination measures include endospore number, spore number, international toxicity unit (ITU), international unit (IU), colony forming unit (CFU), and inclusion body (IB or OB); (2) Define the minimum content of active ingredients.	●
	6.3 Content of microbiological contaminants and detrimental impurities	For products containing microbiological contaminants and detrimental impurities, define their maximum content.	●
	6.4 Content of other restrictive components	For products containing safeners, stabilizers, synergists or any other restrictive components, their content shall consist of the marked content and the allowable fluctuation range. The latter	●

		shall be determined according to the chemical pesticide preparation requirements.	
	6.5 Acidity, alkalinity or pH range	Express the acidity or alkalinity in the mass fraction of sulfuric acid or sodium hydroxide, regardless of its actual existence form.	●
	6.6 Insoluble matter	Define the maximum allowable content, which is expressed in mass fraction (%).	●
	6.7 Water or heating loss	Define the maximum allowable content, which is expressed in mass fraction (%).	●
	7. Detection methods corresponding to product quality control items and method validation		
	7.1 Identification method for active ingredients in products	Describe morphological features, physiological and biochemical reaction characteristics, serological reactions and molecular biology (proteins and DNA), and provide necessary maps, photographs or sequences, etc	●
	7.2 Methods for detection of active ingredients, microbiological contaminants and detrimental impurities, safeners, stabilizers, synergists and other restrictive components and method validation	(1) Detection method: Provide a complete set of detection method, which typically includes the method summary, principle, sample information, standard information, instruments, reagent, solution preparation, operation conditions, detection procedures, result calculation, statistical method and allowable tolerance; (2) Method validation Comply with the	●

		Guideline on Validation of Pesticide Product Quality Analysis Method.	
	7.3 Methods for detection of other technical indexes	Comply with the *Guideline on Validation of Pesticide Product Quality Analysis Method*.	●
	8. Product quality specification description	Give necessary descriptions about the basis for setting the technical indexes and its reasonability.	●
	9. Product quality test report and test method validation report②	(1) The product quality test report shall include all items specified in the product quality specifications; (2) Methods for detection of active ingredients, microbiological contaminants, detrimental impurities, safeners, stabilizers, synergists and other restrictive components shall be validated by the registration testing institute responsible for issuing the product quality test report, which will issue a test method validation report after completion of validation; the detection method designed for other control items may be not validated; (3) The test method validation report shall include: Testing conditions provided by the entrusting party, actual testing	●

		conditions adopted by the registration testing institute (such as the chromatographic conditions, culture conditions and sample preparation), descriptions about any alteration, results of parallel measurements, standard deviation, typical spectrograms (including standards and samples), and evaluation of the method feasibility.	
	10. Package (material, shape, size, net content), storage and transportation, and safety warning, etc.		
	10.1 Package, storage and transportation	The applicant shall choose proper packaging materials, and proper package size and transportation tools by taking into account the hazard classification of products, and compile the transportation and storage attentions in accordance with relevant safe production and transportation laws, regulations and standards of the state.	●
	10.2 Safety warning	Evaluate, classify and label the hazard degree of products based on their physicochemical properties and in accordance with the *Chemical Hazard Classification Standards*, and make it known to the public in form of Material Safety Data Sheet (MSDS).	●

Toxicology	1. Proof that any active ingredient is not any known pathogene found in human or any other mammals.		●
	2. Basic toxicology test data		
	2.1 Acute oral toxicity test data		●
	2.2 Acute percutaneous toxicity test data		●
	2.3 Acute inhalation toxicity test data		●
	2.4 Eye irritation test data/infection test data		●
	2.5 Sensitization test, investigation data about sensitization of exposed personnel, and reports on sensitization cases at home and abroad		●
	2.6 Acute oral pathogenicity test data		●
	2.7 Acute respiratory tract pathogenicity test data		●
	2.8 Acute injection pathogenicity test data	Conduct intravenous injection tests on bacteria and viruses Conduct intraperitoneal injection test on fungi or protozoa	●
	2.9 Cell culture test data	This test is required for viruses, viroids, some bacteria and protozoa.	●
	3. Supplementary toxicology test data	If any microbial pesticide is found to produce any toxin, or give rise to any obvious infection symptom or persistently exist, supplement data about acute neurotoxicity, chronic toxicity, mutagenicity, reproductive toxicity, chronic toxicity, carcinogenicity, endocrine disrupting effect, immune deficiency and primate pathogenicity tests as needed.	●

	4. Human exposure investigation data		◐
	5. Toxic symptoms, first aid and treatment measures		●
Environmental impact③	1. Bird toxicity test data		●
	2. Bee toxicity test data④		◐
	3. Silkworm toxicity test data②④		◐
	4. Fish toxicity test data		●
	5. Daphnia magna test data		●
	6. Microbial proliferation test data⑤		●

Note:

① For genetically modified microorganisms, the applicant also needs to submit data about the genetic engineering technology adopted, the gene fragments inserted or knocked out (base sequence or restriction enzyme map), new features compared with those of parent strains, genetic stability in natural environment, GMO safety certificate and transgene-related genetic background.

② It shall be completed within the territory of China in accordance with Article 16 of the *Measures on management of Pesticide Registration*.

③ If adequate data prove that the pesticide is less likely to be exposed to certain environmental organisms, relevant data may be exempted upon application, but relevant supporting documents shall be submitted. For pesticides produced exclusively for use in protection areas or indoors (such as pesticides used to inhibit the sprouting of harvested potatoes), the environmental data may not be provided.

④ For pesticides produced exclusively for direct use in ponds, rivers, lakes or other water bodies (such as pesticides produced for lotus roots), such data may not be provided.

⑤ If the maximum lethal dose in the above ecotoxicity test does not lead to death or give rise to any irreversible symptom, the test can be exempted.

4 Botanical pesticide TKs (TCs)

Pesticide Classes	1. Class A: New pesticide TKs (TCs), including pesticides that have been registered but are not in a valid state, and pesticides that have not been authorized within the 6-year registration protection period; 2. Class C: Non-me-too TKs (TCs) Note: "●" means Yes，"✖"means No，"◐"means No for rodenticides.

Data classification	Items	Interpretation and description	A	C
General data	1. Application form	Complete the application form issued by the Ministry of Agriculture	●	

	2. The applicant's certificates	(1) Copies of the production permit, the business license and the unified social credit code stamped with the common seal of the pesticide producer; (2) Descriptions about the pesticide registration application by the new pesticide developer; (3) ID paper of the overseas producer, descriptions about the registration and application of the product in relevant regions and jurisdictions, descriptions about is offices or agencies in China and the business license.	●
	3. The applicant's statement	A statement that the application data are true and legal.	●
	4. Product overview	(1) Copies of the production permit, the business license and the unified social credit code stamped with the common seal of the pesticide producer; (2) Descriptions about the pesticide registration application by the new pesticide developer; (3) ID paper of the overseas producer, descriptions about the registration and application of the product in relevant regions and jurisdictions, descriptions about is offices or agencies in China and the business license.	●
	5. Labels and manuals	Specimen of labels and manuals prepared in accordance with the *Measures on Management of Pesticide Labels and Manuals*	●

	6. Other registration-supporting documents	(1) Product chemistry, toxicology, or environmental impact data or comprehensive reports currently available in other countries or jurisdictions; (2) Basis for naming active ingredients of a new pesticide	●
	7. Product safety datasheet		●
	8. References	Please give their source	●
Product chemistry ①	1. Product identification		
	1.1 Product name	For a botanical pesticide extracted from a plant, it may be named after its active ingredients, or be expressed in the "common name of the source plant + extract", with its symbolic active ingredients clearly marked. For a botanical pesticide extracted from the mixture of multiple plants, it shall be named after its symbolic active ingredients.	●
	1.2 Identification of active ingredients or symbolic active ingredients, stabilizers, synergists and other restrictive components	(1) Common names of active ingredients or symbolic active ingredients, safeners, stabilizers, synergists and other restrictive components, names approved by the international organization for standardization (ISO), common names adopted by other international organizations and nations, chemical names, Chemical Abstracts Service (CAS) registry number, Collaborative International Pesticides Analytic Council (CIPAC) digital code, development code,	●

		molecular formula, structural formula, isomer composition, relative molecular mass or molecular mass range (the release time of the international relative atomic mass table shall be provided) (2) When an active ingredient exists in the form of any salt, data about the identification of relevant derivatives shall be provided.	
	2. Production process		
	2.1 Raw material description	(1) Describe the name of the source plant, the parts of the plant used (seed, fruit, leaf, root, bark, stem and trunk, etc.), place of origin and growth conditions (including artificial cultivation or wild plant), harvest time or conditions (such as size), storage time and conditions and the Latin name of the source plant, which should be in line with the *International Rules for Botanical Nomenclature* (ICBN); (2) Chemical names of main solvents involved in the extraction process, CAS registry number, technical specifications and sources, etc.	●
	2.2 Production process description	Including the source plant processing process, extraction method and purification process.	●
	2.3 Production flow chart		●
	2.4 Production unit process flow chart and description		●
	2.5 In-process quality control description		●
	3. Physicochemical properties		

	3.1 Physicochemical properties of active ingredients or symbolic active ingredients	Conduct management and submit physicochemical property determination reports based on classes of such ingredients. (1) Class A botanical pesticide TKs: For plants that have been long and widely used, data about the physicochemical properties of active ingredients or symbolic active ingredients may not be provided; (2) Class B botanical pesticide TKs: For plants that have not been widely used, data about the physicochemical properties of active ingredients or symbolic active ingredients must be provided and made accessible, together with references, including: Appearance (color, physical state, odor), melting point/melting range, boiling point, solubility in water and in organic solvents (polar, nonpolar and aromatic solvents), density, hydrolysis, in-water photolysis, ultraviolet/visible light absorption and specific rotation, etc	●	✖
	3.2 Physicochemical properties of TKs	(1) The physicochemical properties of TKs include: Appearance (color, physical state, odor), stability (heat, metal and metal ions), combustibility, corrosion to packaging materials and specific rotation, etc; (2) Provide physicochemical property test report based on characteristics of the product and in accordance with the *Guideline on Pesticide Physiochemical Property Test*.	●	

	4. Component analysis		
	4.1 Component analysis report	Conduct management and submit component analysis reports based on classes of such ingredients. (1) Class A botanical pesticide TKs: For plants that have been long and widely used, submit the TK component analysis report, which shall at least include the active ingredients or symbolic active ingredients, relevant impurities, qualitative and quantitative analysis data about solvents and chemical fingerprints of five batches of products. (2) Class B botanical pesticide TKs: For plants that have not been widely used, submit a complete set of TK component analysis report, which shall at least include active ingredients or symbolic active ingredients, relevant impurities, ingredients with the peak area ⩾ 10% of the main peak area, ingredients with the content ⩾ 1, qualitative and quantitative analysis data about solvents and chemical fingerprints of five batches of products. The total content of all ingredients obtained from the quantitative analysis shall be no lower than 80%; (3) The test method and test reports shall be in compliance with the *Guideline on Full Component Analysis for Technical Materials in Pesticide Registration*.	●

	4.2 Content of active ingredients or symbolic active ingredients and limit of relevant impurities	Define the marked content of active ingredients or symbolic active ingredients in TK and the maximum content of relevant impurities. Describe the statistics based on which the limits are established.	●
	5. Product quality specifications		
	5.1 Appearance	Describe the color, physical state and odor of the product.	●
	5.2 Content of active ingredients or symbolic active ingredients	(1) The content of active ingredients or symbolic active ingredients typically consists of the marked content and the allowable fluctuation range; the marked content is the mean value of five batches of representative samples detected, and the allowable function range is ±25% of the marked content; (2) If an active ingredient exists in the form of any salt, the product name and mass fraction shall be expressed in its actual existence form, and marked with the content of the active ingredient and of paired countra-ions.	●
	5.3 Content of relevant impurities	For products containing relevant impurities, define the maximum content of such impurities, which is expressed in mass fraction.	●
	5.4 Content of other restrictive components	For products containing safeners, stabilizers, synergists or any other restrictive components, their content shall consist of the marked content and the allowable fluctuation range. The latter shall be determined according to the chemical pesticide preparation requirements.	●

	5.5 Acidity, alkalinity or pH range	Express the acidity or alkalinity in the mass fraction of sulfuric acid or sodium hydroxide, regardless of its actual existence form.	●
	5.6 Insoluble matter	Define the maximum allowable content, which is expressed in mass fraction (%).	●
	6. Detection methods corresponding to product quality control items and method validation		
	6.1 Product identification method②	Use the characteristic peak and the retention time in the chemical fingerprints to identify the product③	●
	6.2 Methods for detection of active ingredients or symbolic active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and method validation	(1) Detection method: Provide a complete set of detection method, which typically includes the method summary, principle, sample information, standard information, instruments, reagent, solution preparation, operation conditions, detection procedures, result calculation, statistical method and allowable tolerance; (2) Method validation Comply with the *Guideline on Validation of Pesticide Product Quality Analysis Method*.	●
	6.3 Methods for detection of other technical indexes	Comply with the *Guideline on Validation of Pesticide Product Quality Analysis Method*.	●
	7. Product quality specification description	Give necessary descriptions about the basis for setting the technical indexes and its reasonability.	●

	8. Product quality test report and test method validation report④	(1) The product quality test report shall include all items specified in the product quality specifications; (2) Methods for detection of active ingredients or symbolic active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components shall be validated by the registration testing institute responsible for issuing the product quality test report, which will issue a test method validation report after completion of validation; the detection method designed for other control items may be not validated; (3) The test method validation report shall include: Testing conditions provided by the entrusting party, actual testing conditions adopted by the registration testing institute (such as the chromatographic conditions and sample preparation), descriptions about any alteration, results of parallel measurements, standard deviation, typical spectrograms (including standards and samples), and method feasibility evaluation.	●
	9. Package (material, shape, size, net content), storage and transportation, and safety warning, etc.		
	9.1 Package, storage and transportation	The applicant shall choose proper packaging materials, and proper package size and transportation tools by taking into account the hazard classification of products, and compile	●

		the transportation and storage attentions in accordance with relevant safe production and transportation laws, regulations and standards of the state.	
	9.2 Safety warning	Evaluate, classify and label the hazard degree of products based on their physicochemical properties and in accordance with the *Chemical Hazard Classification Standards*, and make it known to the public in the form of Material Safety Data Sheet (MSDS).	●
Toxicology⑤	1. Acute toxicity test data		
	1.1 Acute oral toxicity test data		●
	1.2 Acute percutaneous toxicity test data		●
	1.3 Acute inhalation toxicity test data		●
	1.4 Eye irritation test data		●
	1.5 Skin irritation test data		●
	1.6 Skin sensitization test data		●
	2. Acute neurotoxicity test data		●
	3. Delayed neurotoxicity test data	Applicable to organophosphorus pesticides, or pesticides having a chemical structure similar to that of the substance resulting in delayed neurotoxicity	●
	4. Sub-chronic (acute) toxicity test data		
	4.1 Sub-chronic oral toxicity test data	90-day oral toxicity test	●
	4.2 Sub-chronic (acute) percutaneous toxicity test data	28-day or 90-day percutaneous toxicity test	●
	4.3 Sub-chronic (acute) inhalation toxicity test data	28-day or 90-day inhalation toxicity test	●

	5. Mutagenicity test data	(1) Mutagenicity composite tests include: a Salmonella typhimurium/reverse mutation test b In vitro mammalian cell gene mutation test c In vitro mammalian cell chromosomal aberration test d In vivo mammalian marrow cell micronucleus test (2) If either test in clauses a through c produces a positive result, and the test in clause d produces a negative result, add another in vivo test (such as mammalian cell UDS test); if each test in clauses a through c produces a negative result, and the test in clause produces a positive result, add in vivo mammalian germ cell chromosome aberration test or dominant lethal test.	●
	6. Reproductive toxicity test data		●
	7. Teratogenicity test data	Submit data about teratogenicity test of two types of mammals, preferably rats and rabbits	●
	8. Chronic toxicity and carcinogenicity test data⑥	Submit data about carcinogenicity test of two types of rodents, preferably rats and mice	●
	9. Metabolic and toxicokinetics test data		◐
	10. Endocrine disrupting effect test data	If the chronic toxicity or reproductive toxicity test shows that the product is toxic to the endocrine system, provide the test report on endocrine disrupting effect.	◐
	11. Human exposure investigation data		◐

	12. Relevant impurities and main metabolite/degradation product toxicity		◐	
	13. Acceptable daily intake (ADI) and acute reference dosage (ARFD)		◐	
	14. Toxic symptoms, first aid and treatment measures		●	
Environmental impact	1. Hydrolysis test data	Data about hydrolysis tests in buffer solutions at 25°C, with ph values of 4, 7 and 9	●	✖
	2. In-water photolysis test data	Data about photolysis test in pure water or buffer solutions.	●	✖
	3. Soil aerobic degradation test data	Conduct aerobic degradation test in at least four types of representative soil	●	✖
	4. Soil adsorption (leaching) test data	Provide soil adsorption (batch equilibrium method) test data; if it is impossible to conduct the soil adsorption test using the batch equilibrium method when the adsorption rate of the pesticide in soil is <20% at the water to soil water ratio of 1:1, conduct the soil column leaching test. The batch equilibrium method or column leaching method shall produce the soil adsorption coefficient in at least four types of representative soil (including at least one soil containing organic matter＜1%); if the pesticide is unstable in soil-calcium chloride solution or insoluble in water, provide soil adsorption (high performance liquid chromatography) test data. If the test results or relevant data show that the adsorption of the pesticide in soil is dependent on the pH value of soil, the four types of representative test oil	●	✖

		shall include one red oil and one soil with a higher pH value (such as black soil, moisture soil or brown soil) or the like.		
	5. Bird acute oral toxicity test data	The high or extremely high toxicity to one type of bird (LD50≤50mg a.i./kg body weight) needs to be confirmed by the test of another type of bird	●	●
	6. Fish acute toxicity test data	The test shall be conducted with at least one type of cold water fish (such as rainbow trout) and at least one type of warm water fish (such as zebra fish and medaka);	●	●
	7. Daphnia magna acute activity inhibition test data		●	●
	8. Bee acute oral toxicity test data		◐	◐
	9. Bee acute exposure toxicity test data		◐	◐
	10. Silkworm acute toxicity test data④		◐	◐
	11. Parasitic natural enemy acute toxicity test data	Provide the acute toxicity test data about at least one type of parasitic natural enemy	◐	◐
	12. Predatory natural enemy acute toxicity test data	Provide the acute toxicity test data about at least one type of predatory natural enemy	◐	◐
	13. Other advanced-stage test data required for environmental risk assessment	If the primary risk assessment shows that the risk posed by the pesticide to a particular	●	●

		protection object is unacceptable, provide data about corresponding advanced-stage tests		

Note:

① The data requirements for registration of botanical pesticide TCs are the same as those for chemical pesticide TCs, except for requirements in relation to the production process as follows:

-Describe the name of the source plant (common name, English name and Latin name), the parts of the plant used (seed, fruit, leaf, root, bark, stem and trunk, etc.), place of origin and growth conditions (including artificial cultivation or wild plant), harvest time or conditions (such as size), and storage time and conditions; the Latin name of the source plant should be in line with the International Rules for Botanical Nomenclature (ICBN);

-Chemical names of main solvents involved in the extraction process, CAS registry number, technical specifications and sources, etc.

-the production process descriptions shall include the source plant processing process, extraction method and purification process.

② Symbolic active ingredients refer to substances that appear to be stable in the "chemical fingerprints" of a botanical pesticide, or substances that have been reported or confirmed by the laboratory to be a potential source of activity. The symbolic active ingredients can be composed of one or more components and serve as the quality control index for botanical pesticides.

③ “Chemical fingerprints” "refer to a set of spectrums or chromatograms of a botanical pesticide, which shall be in match with corresponding spectrums or chromatograms of the control or standard samples qualitatively and quantitatively and are used to identify samples and compare the consistency between the samples and the control samples.

④ The test shall be completed within the territory of China in accordance with Article 16 of the *Measures on management of Pesticide Registration*.

⑤ Test data about reproductive toxicity, teratogenicity, chronic toxicity and carcinogenicity, metabolism and toxicokinetics, and the endocrine disrupting effect may not be provided if the pesticide concerned has been approved by the competent department of state to be registered and used as a food additive, a health-care food or a pharmaceutical ingredient, and the review based on proof and test literature provided by relevant department has confirmed that the pesticide meets relevant safety requirements.

⑥ For rodenticides, submit data about the 6-month chronic toxicity test.

category	2. Category E: Products of unregistered formulation type; 3. Category F: Products of unregistered active ingredient content; 4. Category G: New ready-mixtures; 5. Category H: Products of unregistered application scope; 6. Category I: Products of unregistered application method; 7. Category J: Me-too formulations, same application scope and method; 8. Category K: Me-too formulations, different application scope and method; 9. Category L: Similar formulations, same application scope and method; 10. Category M: Similar formulations, different application scope and method. Note: "●" means required, and "✖" means not required.

Data classification	Data item	Interpretation and description	D	E	F	G	H	I	J	K	L	M
General data	1. Application form	Adopt the application form issued by the Ministry of Agriculture.					●					
	2. Proof documents of the applicant	(1) A pesticide producer should submit the photocopies of production permit, business license and uniform social credit code bearing its official seal; (2) A developer of new pesticides should provide description of the application for pesticide registration; (3) A foreign enterprise should provide identification paper, description of the registration and use status in related countries and regions, description of the establishment of offices or agencies in China and business license.					●					
	3. Applicant statement	Statement on the authenticity and legality of application materials.					●					
	4. Summary report											
	4.1 Product overview	Include brief introduction to place of production, product chemistry, efficacy, residue, toxicology, environmental impact and overseas registration.					●					
	4.2 Summary of risk assessment	Summary of product risk assessment in the aspects of diet, occupational health, environment, etc.					●					
	4.3 Summary of benefit analysis	Summary of the analysis on the economic, social and environmental benefits of the product.					●					
	5. Labels and manuals	Specimens of labels and manuals prepared according to the Measures for the Administration of Pesticide Labels and Manuals.					●					
	6. Other registration-related proof documents	(1) Data of product chemistry, efficacy, residue, toxicology and environmental impact or comprehensive query reports available in other countries or regions; (2) Naming basis of the active ingredients of the new pesticide; (3) For a new formulation type not specified in the national standards, the applicant should submit a naming basis and appraisal report of the formulation type; (4) Description of the source of TC.					●					
	7. MSDS						●					
	8. References	Their sources should be indicated.					●					

Product chemistry	1. Identification of active ingredients, safeners, stabilizers, synergists and other restrictive components	(1) The common names, names approved by ISO, common names adopted by other international organizations and countries, chemical names, CAS registry numbers, CIPAC numeric codes, development numbers, molecular formulae, structural formulae, isomer composition, relative molecular weight and molecular mass ranges of the active ingredients, safeners, stabilizers, synergists and other restrictive components (indicating the issue date of IUPAC Periodic Table of the Elements); (2) If an active ingredient exists in a form of a specific salt (such as glyphosate sodium), the identification information of the corresponding derivatives should also be provided.	●
	2. Basic information of TC (TK)	Basic information of the producer, registration, quality control items and indexes of the TC (TK) used.	●
	3. Product composition	(1) The chemical names, CAS registry numbers, molecular formulae, structural formulae, contents and functions of the components used in formulation processing. For mixed solvents and mixed adjuvants expressed with codes, their compositions, sources, safety [such as MSDS] and other related information should also be provided; for some adjuvants with special functions, such as safeners, stabilizers and synergists, their quality specifications, basic physic-chemical properties, sources, safety [such as MSDS] and use at home and abroad, etc. should also be provided; (2) For a separately packaged adjuvant (designated adjuvant) added during on-site preparation of a solution, its composition and the above information should be provided separately.	●
	4. Description of processing method		
	4.1 Process flow diagram		●
	4.2 Addition amount and sequence of components		●
	4.3 Main equipment and operating conditions		●
	4.4 Description of quality control measures in the production process		●
	5. Physic-chemical properties	(1) The physic-chemical properties include: appearance (color, physical state and odor), density, viscosity, oxidation and reduction properties, corrosiveness to packing material, compatibility with non-polar organic solvents (applicable to the formulations diluted by organic solvents), explosibility and combustibility; for a product to which a designated adjuvant needs to be added, data about the compatibility between the product and the designated adjuvant must be submitted; (2) A test report of physic-chemical properties should be provided according to the Guidelines for Determination of Physic-Chemical Properties of Pesticides. If specific parameters are not applicable to the product, explanation should be given.	●
	6. Product quality specification	In the quality warranty period, the product quality specification shall meet the following requirements.	

	6.1 Appearance	The definite color, physical state and odor of the product should be described.	●
	6.2 Content of active ingredients	(1) The content of an active ingredient includes indicated content and acceptable range of fluctuation. Its requirements are shown in Note ①. For other special products, the range of content of active ingredients should be determined in reference to Note ①; (2) The content of an active ingredient generally is expressed with mass fraction (%). The content of an active ingredient in a liquid formulation may be expressed with mass concentration (g/L) or mass fraction (%). When it is expressed with mass concentration, mass fraction should be stated at the same time; (3) When an active ingredient has isomers, the names and proportion of such isomers in the formulation should be consistent with the used TC. When an active ingredient has isomers, if a definition has been given in the common name, there is no need to specify isomer proportion in the control items again. If the common name does not define the mixture of which registration is applied for, the isomer proportion should be specified; (4) If an active ingredient exists in a form of a salt (such as glyphosate sodium and copper compounds), the name and mass fraction of the product should be expressed in the form of actual existence and meanwhile the content of the active part and paired counterions is stated.	●
	6.3 Content of relevant impurities	If a product contains relevant impurities, their maximum content should be specified, and expressed with mass fraction.	●
	6.4 Content of other restrictive components	If a product contains safeners, stabilizers, synergists and other restrictive components, their content should include indicated content and acceptable range of fluctuation. The acceptable range of fluctuation is determined in reference to Note ①.	●
	6.5 Other control items and indexes related to formulation type ②③	(1) For each formulation type, technical indexes tallying with its features should be set; (2) The formulation types not specified in the Requirements may refer to the specification requirements of FAO and WHO. The control items of an innovative formulation type may be determined in comprehensive consideration of the features of active ingredients, application method, safety and other factors and meanwhile the data for formulation type appraisal test should be submitted.	●
	7. Test methods corresponding to product quality control items and validation thereof		
	7.1 Test methods for identification of active ingredients in the product	There should be at least one test method to identify active ingredients. When chemical identification is adopted, at least two identification test methods should be provided. When an active ingredient exists in a form of a salt, the identification test method should be able to identify the type of the salt.	●

	7.2 Test methods of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and validation thereof	(1) Test methods: Complete methods should be provided. A test method usually includes method summary, principle, sample information, standard specimen information, instruments, reagents, solution preparation, operating conditions, test procedures, result calculation, statistical method and allowable deviation; (2) Method validation: comply with the Guidelines for Validation of Agrochemical Analysis Methods.	●		
	7.3 Test methods of other technical indexes	Comply with the Guidelines for Validation of Agrochemical Analysis Methods.	●		
	8. Determination of product quality specification	Give necessary explanation on the basis and reasonableness for formulation of technical indexes.	●		
	9. Data of normal-temperature storage stability test	(1) Data of normal-temperature storage stability test for at least one batch of samples should be provided; (2) If same products adopt different packing materials, separate normal-temperature storage stability tests should be done; (3) In general, normal-temperature storage stability test requires that the samples shall be stored under determined conditions for two years.	●	✖	●
	10. Product quality test report and test method validation report④	(1) The product quality test report should include all the items specified in the product quality specification; (2) The test methods for the content of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components should be validated by the registration testing institution, which issues the product quality test report. Moreover, a test method validation report should be issued. For other control items, it is not required to validate the test methods; (3) The test method validation report includes: test conditions provided by the client, the test conditions adopted by the registration testing institution (such as chromatographic condition and sample preparation) and changes, all results of parallel determination, standard deviation and typical spectra (including standard specimens and samples). The feasibility of the method is evaluated.	●		
	11. Package (material, shape, size and net content), transportation, storage, safety alerts, quality warranty period, etc.				
	11.1 Package and transportation	The applicant should select correct packing material, package size and means of transportation based on hazard classification of products and should determine the precautions of transportation and storage according to national laws, regulations and standards regarding to work safety, storage and transportation.	●		
	11.2 Safety alerts	The hazard level of the product is evaluated and classified according to the data of the physical and chemical properties of the product and the standards for hazard classification of chemicals and is disclosed in form of label and/or MSDS.	●		
	11.3 Quality warranty period	A reasonable product quality warranty period should be specified according to the data of normal-temperature storage stability test.	●		
Toxicology	1. Data of acute oral toxicity test		●	✖	●

	2. Data of acute dermal toxicity test		●	✖		●			
	3. Data of acute inhalation toxicity test ⑤		●	✖		●			
	4. Data of eye irritation test		●	✖		●			
	5. Data of skin irritation test		●	✖		●			
	6. Data of skin sensitization test		●	✖		●			
	7. Data of advanced tests that health risk assessment needs④	If the primary health risk assessment indicates that the health risk of pesticides to human body is unacceptable, the data of advanced tests (including, but not limited to: pesticide user field exposure level test) may be provided.	●	✖	●	✖	●		
	8. Health risk assessment report	A pesticide user health risk assessment report should be submitted.	●	✖	●	✖	●		
Efficacy	1. Benefit analysis								
	1.1 Overview of the crop applying for registration and target organisms	Planting area, commercial value and national distribution of the applying crop; distribution, rules of occurrence, way of harm and economic loss of the target organisms.	●						
	1.2 Substitutability analysis and benefit analysis report	Purpose and use method of the product applying for registration, and its adaptability to the current condition of agricultural production; use cost of the product applying for registration, and expected economic loss that can be recovered and influence on the income of growers; analysis of comparison with existing registered products or chemicals commonly used during production; effect on the resistance management of existing registered products; possibility of substituting pesticides with a higher risk.	●						
	2. Data of efficacy trial								
	2.1 Data of laboratory bioactivity test	Action mode, action spectrum, action mechanism or predicative analysis of action mechanism (only for new pesticide formulations); laboratory activity test report (for formulations with single active ingredient involving new target objects); purpose of making mixtures and laboratory ingredients screening report (for mixtures).	●					✖	✖	●	✖	●
	2.2 Data of laboratory crop safety test	Laboratory crop safety test report (only for products involving new crops).	●					✖	✖	●	✖	●
	2.3 Data of plot efficacy trial④	(1) For insecticides and fungicides, a report of plot efficacy trial conducted in four provincial-level administrative regions in China for two years should be provided; for herbicides and plant growth regulators, a report of plot efficacy trial conducted in five provincial-level administrative regions in China for two years should be provided; for herbicide with a long residual effect, a report of safety trial of main aftercrops should also be provided; (2) For crops planted in localized regions, or diseases, insects and weeds limited to localized regions, a report of plot efficacy trial conducted in three provincial-level administrative regions in China for two years may be provided; (3) For sterilant herbicide or forest pesticide, a report of plot efficacy trial conducted in three provincial-level administrative regions in China for two years should be provided; (4) For pesticide used in relevantly stable environmental conditions, such as for storage, antiseptic, and preservation purpose, a report of efficacy trial conducted	●	●⑥	●⑥	●	●	●	✖	●⑥	●⑦	●⑥

		over two periods in two provincial-level administrative regions in China or over one period in four provincial-level administrative regions in China may be provided.										
	2.4 Data of regional efficacy trial ④	(1) Provide a report of regional efficacy trial conducted in two provincial-level administrative regions in China for one year; (2) For pesticide used in relevantly stable environmental conditions, such as for storage, antiseptic, and preservation purpose, no report is required.	●	✖								
	3. Data of resistance risk assessment											
	3.1 Data of laboratory resistance risk test	Target organism sensitivity test method, sensitivity baseline, cross resistance, resistance risk assessment result, risk management measures, etc.	●	●⑧		✖	✖	●⑧	✖	●⑧		
	3.2 Field resistance risk monitoring method	Field sampling method, sample size, sample storage and transport conditions, resistance test method, etc.	●	✖								
	4. Other data	Description of site selection of plot test (needed if not included in the Guidelines for Field Efficacy Trial Areas for Pesticide Registration); influence on major predators and parasites in the field; influence on neighboring crops; registration and application status of this crop or target objects at abroad (for products of unregistered application scope); product features and application precautions; other data relevant with this pesticide variety and application scope.	●									
	5. Comprehensive assessment report	Recapitulative summary of all efficacy data.	●									
Residue ⑨	1. Data of plant metabolism test ⑩	(1) At least one type of crops is selected from five types of crops, including: tuber, leaf, fruit, oil plant and grain to do metabolism tests. If the data indicates this pesticide has the same metabolic pathways in three types of crops, no other metabolism tests are required. Otherwise the data of the metabolism tests of all of the five types of crops should be submitted; (2) If the pesticide can be used only in one type of the crops, reasons should be provided and the data of the metabolism test of this type of crops should be submitted (for concrete requirements, please refer to the Guidelines for Crop Metabolism Test of Pesticides).	●	✖								
	2. Data of animal metabolism test ⑪	Data of livestock and poultry metabolism test of radioactively labeled pesticides.	●	✖								
	3. Data of environmental metabolism test ⑫	Data of environmental metabolism test of pesticides.	●	✖								

	4. Data of pesticide residue storage stability test	(1) Submit the data for the stability of active ingredient matrix and metabolites with toxicological significance when they are stored in the corresponding substrate (for concrete requirements, please refer to the Guidelines for Pesticide Residue Storage Stability Test); (2) The data should cover the period from sampling to sample testing.	●	●⑬	●⑬	●⑬	●⑬	✖	✖	●⑬	✖	●⑬
	5. Residue analysis method	Test method for residual quantity of active ingredient matrix and metabolites with toxicological significance in the corresponding substrate (for concrete requirements, please refer to the Guidelines for Pesticide Residue Tests).	●	●	●	●	●	●	●	●	●	●
	6. Data of pesticide residue test in crops ④	Data of residue test of active ingredient matrix and metabolites with toxicological significance in the crop applying for registration (for concrete requirements, please refer to the Guidelines for Pesticide Residue Tests and the Requirements on Number of Locations of Residue Test for Pesticide Registration).	●	●	●⑭	●	●	●	●⑮	●	●⑮	●
	7. Data of pesticide residue test in processed agricultural products	(1) Data of changes of active ingredient matrix and metabolites with toxicological significance during processing of agricultural products; (2) Limited to the agricultural products whose pesticide residue quantity may increase after processing, such as representative crops: oil plants: soybean, peanut and rapeseed; fruit: citrus and apple (for concrete requirements, please refer to the Guidelines for Pesticide Residue Test in Processed Agricultural Products); (3) If there is queried data, its source should be stated, and the data for comparison with Chinese agricultural product processing technology should be submitted.	●	●	●	●	●	✖	✖	●	✖	●
	8. Data of crops registered in other countries and MRLs	Crops registered in other countries and determination of maximum residue limits of pesticides.	●	✖								
	9. Dietary risk assessment report	Dietary risk assessment report of the active ingredient in registered crops and crops applying for registration.	●	●	●	●	●	●	✖	●	✖	●
Environmental impact ⑯	1. Summary of environmental data of TC (TK)		●						✖	✖	✖	✖
	2. Data of bird acute oral toxicity test ⑰	The birds used in the test should be a more sensitive species in the bird acute oral toxicity test of TC.	●						✖	✖	●⑱	●⑱
	3. Data of fish acute toxicity test ⑰⑲	The fish used in the test should be a more sensitive species in the fish acute toxicity test of TC.	●						✖	✖	●	●
	4. Data of Daphnia magna acute immobilisation test ⑰⑲		●	●	●	●	●	●	✖	✖	●	●
	5. Data of green algae growth inhibition test ⑰⑲		●	●	●	●	●	●	✖	✖	✖	✖
	6. Data of honeybee acute oral toxicity test ⑰⑳		●	●	●	●	●	●	✖	✖	●	●
	7. Data of honeybee acute contact toxicity test ⑰⑳		●	●	●	●	●	●	✖	✖	✖	✖
	8. Data of silkworm acute toxicity test ④⑰⑳		●	●	●	●	●	●	✖	✖	✖	✖

	9. Data of silkworm chronic toxicity test ④	Apply to only the formulations directly used on mulberry trees (except the pesticides for farm cleanup in winter) and provide silkworm chronic toxicity test of TC or formulations.	●	●	●	●	●	●	×	×	×	×
	10. Data of mulberry leaf maximum residue test ④	Apply to only the formulations directly used on mulberry trees (except the pesticides for farm cleanup in winter) and provide mulberry leaf ultimate residue test conducted at least at three test locations.	●	●	●	●	●	●	×	×	×	×
	11. Data of parasite acute toxicity test ⑰⑳		●	●	●	●	●	●	×	×	×	×
	12. Data of predator acute toxicity test ⑰⑳		●	●	●	●	●	●	×	×	×	×
	13. Data of earthworm acute toxicity test		●	●	●	●	●	●	×	×	●	●
	14. Data of other advanced tests that environmental risk assessment needs	When the primary health risk assessment indicates that the risk of pesticides to a specific protected object is unacceptable, data of advanced tests may be provided.	●	●	●	●	●	●	×	×	×	×
	15. Environmental risk assessment report	Possible environmental risk is assessed during use according to the recommended GAP.	●	●	●	●	●	●	×	×	×	×

Attachment 2.

Interpretation and Specification of the Data Requirements for Pesticide Formulation Registration

1 Chemical pesticide formulations

Note:

① Requirements for the range of active ingredient content (X, % or g/100mL, 20℃±2℃) in the product.

X≤2.5 ±15%X (applicable to EC, SE, SP and other uniform formulations)

±25%X (applicable to G, WDG and other non-uniform formulations)

2.5<X≤10 ±10%X

10<X≤25 ±6%X

25<X≤50 ±5%X

X>50 ±2.5% or 2.5g/100mL

② The general test condition for thermal storage stability test is (54±2) ℃, 2 weeks. The alternative condition is: (50±2) ℃, 4 weeks; (45±2) ℃, 6 weeks; (40±2) ℃, 8 weeks; (35±2) ℃, 12 weeks; (30±2) ℃, 18 weeks. If an alternative condition is selected, the reason should be provided.

③ The freezing and thawing stability test generally should complete four cycles between (-10±2) ℃ and (20±2) ℃. Each cycle consists of 18 hours' freezing and 6 hours' thawing.

④ According to Article 16 of the Measures for the Administration of Pesticide Registration, it should be completed in China.

⑤ If a product meets one of the following conditions, data of acute inhalation toxicity test should be provided:

a. gas or liquefied gas;

b. smoke generating or fumigant formulation;

c. formulation applied by atomization equipment;

d. vapor releasing formulation;

e. aerosol;

f. formulation containing a certain proportion (weight percentage >1%) of particles smaller than 50μm in diameter;

g. formulation that might cause inhalation exposure while being applied from an aircraft;

h. formulation that contains active ingredients with vapor pressure >1×10-2Pa, and might be used in enclosed space, such as warehouse or greenhouses;

i. formulation that might produce a certain proportion (weight percentage >1%) of particles or drops smaller than 50μm in diameter depending on use method.

⑥ For a product not involving new application scope or new application method, a 1-year field efficacy trial report may be provided.

⑦ Provide a 1-year field efficacy trial report.

⑧ For a product involving new target objects, data for resistance research should be provided, including target organism sensitivity test, drug resistance monitoring method, drug resistance risk assessment, etc.

⑨ For a product for use in non-food crops or non-feed crops, data of residue test is required; for low-toxic or slightly-toxic TC seed treatment (including seed mixing, coating and soaking formulations), data of residue test is not required. For a formulation containing a new pesticide in the protection period, complete data of residue test or data of authorized residue test should be submitted.

⑩ If complete data of plant metabolism has been submitted for a new pesticide, or the submitted data of metabolism covers the type of the crops applying for registration, no data of plant metabolism needs to be submitted

⑪ If the registered crops don't involve animal feed, no data of animal metabolism needs to be submitted.

⑫ If the data for this part has been submitted in the environmental data, there is no need to submit it again.

⑬ Queried data may be submitted, indicating sources.

⑭ For a product of unregistered active ingredient content relative to the registered products of the company (including ready-mixtures with change in content of active ingredients in an equal proportion), if the registered crops, dosage, application period, application frequency, application method and preharvest interval are not changed, the data of residue test may be exempted or reduced; if the registered crops and application method are not changed, but dosage, application period, application frequency and preharvest interval are changed, and may result in the rise of residue risk, data of residue test conducted at a halved number of locations should be submitted, but the minimum number of locations is two.

⑮ If the change in dosage, application frequency and preharvest interval won't increase residue risk, the data of residue test may be exempted or reduced; if the change may result in the rise of residue risk, data of residue test conducted at a halved number of locations should be submitted, but the minimum number of locations is two.

⑯ If available data can fully prove the possibility of biological exposure of this pesticide to a specific environment is extremely low, exemption or reduction of biological test data for this environment may be applied for. For pesticides injected into or smeared onto tree trunks or formulations used only in an indoor environment (e.g. formulations that inhibit germination of potato after harvesting), no environmental data is required.

⑰ For formulations used only in the protected areas, it is not required.

⑱ For seed treatment, and granules or baits applied by spreading, it is required.

⑲ If TC test result indicates it is sensitive to one of the three test organisms: fish, Daphnia and alga (above 100 times more sensitive than to other two organisms), only the test on the sensitive organism is required; for seed treatment for dryland and granules applied in furrows or holes, it is not required.

⑳ For seed treatment, granules, soil treatment and other formulations used not by spraying, it is not required.

For formulations only directly used in ponds, rivers, lakes and other waters (e.g. formulations used in lotus roots), it is not required.

For formulations used only in the outdoor environment in residential areas, it is not required.

For the registration categories except D, H and I, the applicant should compare them with the application method and ecological toxicity of the registered products of the company. If the dosage and application frequency are not higher than those of the registered products of the company, the application interval is not shorter than that of the registered products of the company and the ecological toxicity is not higher than that of the registered products of the company, it is not required.

2 Biochemical pesticide formulations

Registration category	1. Category D: New pesticide formulations, including those not obtaining the first authorization in the 6-year protection period; 2. Category E: Products of unregistered formulation type; 3. Category F: Products of unregistered active ingredient content; 4. Category G: New ready-mixtures; 5. Category H: Products of unregistered application scope; 6. Category I: Products of unregistered application method; 7. Category J: Me-too formulations, same application scope and method; 8. Category K: Me-too formulations, different application scope and method; 9. Category L: Similar formulations, same application scope and method; 10. Category M: Similar formulations, different application scope and method. Note: "●" means required, and "✖" means not required.

Data classification	Data item	Interpretation and description	D	E	F	G	H	I	J	K	L	M
General data	1. Application form	Adopt the application form issued by the Ministry of Agriculture.						●				
	2. Proof documents of the applicant	(1) A pesticide producer should submit the photocopies of production permit, business license and uniform social credit code bearing its official seal; (2) A developer of new pesticides should provide description of the application for pesticide registration; (3) A foreign enterprise should provide identification paper, description of the registration and use status in related countries and regions, description of the establishment of offices or agencies in China and business license.						●				
	3. Applicant statement	Statement on the authenticity and legality of application materials.						●				
	4. Summary report											
	4.1 Product overview	Include brief introduction to place of production, product chemistry, efficacy, residue, toxicology, environmental impact and overseas registration.						●				
	4.2 Summary of risk assessment	Summary of product risk assessment in the aspects of diet, occupational health, environment, etc.						●				
	4.3 Summary of benefit analysis	Summary of the analysis on the economic, social and environmental benefits of the product.						●				
	5. Labels and manuals	Specimens of labels and manuals prepared according to the Measures for the Administration of Pesticide Labels and Manuals.						●				
	6. Other registration-related proof documents	(1) Data of product chemistry, efficacy, residue, toxicology and environmental impact or comprehensive query reports available in other countries or regions; (2) Naming basis of the active ingredients of the new pesticide;						●				

		(3) For a new formulation type not specified in the national standards, the applicant should submit a naming basis and appraisal report of the formulation type; (4) Description of the source of TC.	
	7. MSDS		●
	8. References	Their sources should be indicated.	●
Product chemistry①	1. Identification of active ingredients, safeners, stabilizers, synergists and other restrictive components	(1) The common names, names approved by ISO, common names adopted by other international organizations and countries, chemical names, CAS registry numbers, CIPAC numeric codes, development numbers, molecular formulae, structural formulae, isomer composition, relative molecular weight and molecular mass ranges of the active ingredients, safeners, stabilizers, synergists and other restrictive components (indicating the issue date of IUPAC Periodic Table of the Elements); (2) If an active ingredient exists in a form of a specific salt, the identification information of the corresponding derivatives should also be provided.	●
	2. Basic information of TC (TK)	Basic information of the producer, registration, quality control items and indexes of the TC (TK) used.	●
	3. Product composition	(1) The chemical names, CAS registry numbers, molecular formulae, structural formulae, contents and functions of the components used in formulation processing. For mixed solvents and mixed adjuvants expressed with codes, their compositions, sources, safety [such as MSDS] and other related information should also be provided; for some adjuvants with special functions, such as safeners, stabilizers and synergists, their quality specifications, basic physic-chemical properties, sources, safety [such as MSDS] and use at home and abroad, etc. should also be provided; (2) For a separately packaged adjuvant (designated adjuvant) added during on-site preparation of a solution, its composition and the above information should be provided separately.	●
	4. Description of processing method		
	4.1 Process flow diagram		●
	4.2 Addition amount and sequence of components		●
	4.3 Main equipment and operating conditions		●
	4.4 Description of quality control measures in the production process		●

	5. Physic-chemical properties	(1) The physic-chemical properties include: appearance (color, physical state and odor), density, viscosity, oxidation and reduction properties, corrosiveness to packing material, compatibility with non-polar organic solvents (applicable to the formulations diluted by organic solvents), explosibility and combustibility; for a product to which a designated adjuvant needs to be added, data about the compatibility between the product and the designated adjuvant must be submitted; (2) A test report of physic-chemical properties should be provided according to the Guidelines for Determination of Physic-Chemical Properties of Pesticides. If specific parameters are not applicable to the product, explanation should be given.	●
	6. Product quality specification	In the quality warranty period, the product quality specification shall meet the following requirements.	●
	6.1 Appearance	The definite color, physical state and odor of the product should be described.	●
	6.2 Content of active ingredients	(1) The content of an active ingredient includes indicated content and acceptable range of fluctuation. Its requirements may refer to chemical pesticide formulations. For other special products, the range of content of active ingredients may be determined in reference to the requirements for chemical pesticide formulations; (2) The content of an active ingredient generally is expressed with mass fraction (%). The content of an active ingredient in a liquid formulation may be expressed with mass concentration (g/L) or mass fraction (%). When it is expressed with mass concentration, mass fraction should be stated at the same time; (3) When an active ingredient has isomers, the names and proportion of such isomers in the formulation should be consistent with the used TC. When an active ingredient has isomers, if a definition has been given in the common name, there is no need to specify isomer proportion in the control items again. If the common name does not define the mixture of which registration is applied for, the isomer proportion should be specified; (4) If an active ingredient exists in a form of a salt, the name and mass fraction of the product should be expressed in the form of actual existence and meanwhile the content of the active part and paired counterions is stated.	●
	6.3 Content of relevant impurities	If a product contains relevant impurities, their maximum content should be specified, and expressed with mass fraction.	●
	6.4 Content of other restrictive components	If a product contains safeners, stabilizers, synergists and other restrictive components, their content should include indicated content and acceptable range of fluctuation. The acceptable range of fluctuation is determined in reference to the requirements for chemical pesticide formulations.	●

	6.5 Other control items and indexes related to formulation type②③	(1) For each formulation type, technical indexes tallying with its features should be set; (2) The formulation types not specified in the Requirements may refer to the specification requirements of FAO and WHO. The control items of an innovative formulation type may be determined in comprehensive consideration of the features of active ingredients, application method, safety and other factors and meanwhile the data for formulation type appraisal test should be submitted.	●		
	7. Test methods corresponding to product quality control items and validation thereof				
	7.1 Test methods for identification of active ingredients in the product	There should be at least one test method to identify active ingredients. When chemical identification is adopted, at least two identification test methods should be provided. When an active ingredient exists in a form of a salt, the identification test method should be able to identify the type of the salt.	●		
	7.2 Test methods of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components and validation thereof	(1) Test methods: Complete methods should be provided. A test method usually includes method summary, principle, sample information, standard specimen information, instruments, reagents, solution preparation, operating conditions, test procedures, result calculation, statistical method and allowable deviation; (2) Method validation: comply with the Guidelines for Validation of Agrochemical Analysis Methods.	●		
	7.3 Test methods of other technical indexes	Comply with the Guidelines for Validation of Agrochemical Analysis Methods.	●		
	8. Determination of product quality specification	Give necessary explanation on the basis and reasonableness for formulation of technical indexes.	●		
	9. Data of normal-temperature storage stability test	(1) Data of normal-temperature storage stability test for at least one batch of samples should be provided; (2) If same products adopt different packing materials, separate normal-temperature storage stability tests should be done; (3) In general, normal-temperature storage stability test requires that the samples shall be stored under determined conditions for two years.	●	✖	●
	10. Product quality test report and test method validation report④	(1) The product quality test report should include all the items specified in the product quality specification; (2) The test methods for the content of active ingredients, relevant impurities, safeners, stabilizers, synergists and other restrictive components should be validated by the registration testing institution, which issues the product quality test report. Moreover, a test method validation report should be issued. For other control items, it is not required to validate the test methods;	●		

		(3) The test method validation report includes: test conditions provided by the client, the test conditions adopted by the registration testing institution (such as chromatographic condition and sample preparation) and changes, all results of parallel determination, standard deviation and typical spectra (including standard specimens and samples). The feasibility of the method is evaluated.					
	11. Package (material, shape, size and net content), transportation, storage, safety alerts, quality warranty period, etc.		●				
	11.1 Package and transportation	The applicant should select correct packing material, package size and means of transportation based on hazard classification of products and should determine the precautions of transportation and storage according to national laws, regulations and standards regarding to work safety, storage and transportation.	●				
	11.2 Safety alerts	The hazard level of the product is evaluated and classified according to the data of the physical and chemical properties of the product and the standards for hazard classification of chemicals and is disclosed in form of label and/or MSDS.	●				
	11.3 Quality warranty period	A reasonable product quality warranty period should be specified according to the data of normal-temperature storage stability test.	●				
Toxicology	1. Data of acute oral toxicity test		●	✖		●	
	2. Data of acute dermal toxicity test		●	✖		●	
	3. Data of acute inhalation toxicity test⑤		●	✖		●	
	4. Data of eye irritation test		●	✖		●	
	5. Data of skin irritation test		●	✖		●	
	6. Data of skin sensitization test		●	✖		●	
	7. Data of advanced tests that health risk assessment needs ④	If biochemical pesticide TC requires submission of supplementary toxicological data and the primary health risk assessment indicates that the health risk of pesticides to human body is unacceptable, the data of advanced tests (including, but not limited to: pesticide user field exposure level test) may be provided.	●	✖	●	✖	●
	8. Health risk assessment report	If biochemical pesticide TC requires submission of supplementary toxicological data, this data (pesticide user health risk assessment report) should be provided in general.	●	✖	●	✖	●
	1. Benefit analysis						

	1.1 Overview of the crop applying for registration and target organisms	Planting area, commercial value and national distribution of the applying crop; distribution, rules of occurrence, way of harm and economic loss of the target organisms.	●								
	1.2 Substitutability analysis and benefit analysis report	Purpose and use method of the product applying for registration, and its adaptability to the current condition of agricultural production; use cost of the product applying for registration, and expected economic loss that can be recovered and influence on the income of growers; analysis of comparison with existing registered products or chemicals commonly used during production; effect on the resistance management of existing registered products; possibility of substituting pesticides with a higher risk.	●								
Efficacy	2. Data of efficacy trial										
	2.1 Data of laboratory bioactivity test	Action mode, action spectrum, action mechanism or predicative analysis of action mechanism (only for new pesticide formulations); laboratory activity test report (for formulations with single active ingredient involving new target objects); purpose of making mixtures and laboratory ingredients screening report (for mixtures).	●	●	●	●	●	×	×	●	×	●
	2.2 Data of laboratory crop safety test	Laboratory crop safety test report (only for natural plant growth regulator and natural plant inducer products).	●	●	●	●	●	×	×	●	×	●
	2.3 Data of plot efficacy trial④	(1) For insecticides and fungicides, a report of plot efficacy trial conducted in four provincial-level administrative regions in China for two years or eight provincial-level administrative regions in China for one year should be provided; for herbicides and plant growth regulators, a report of plot efficacy trial conducted in five provincial-level administrative regions in China for two years or ten provincial-level administrative regions in China for one year should be provided; for herbicide with a long residual effect, a report of safety trial of main aftercrops should also be provided; (2) For crops planted in localized regions, or diseases, insects and weeds limited to localized regions, a report of plot efficacy trial conducted in three provincial-level administrative regions in China for two years or six provincial-level administrative regions in China for one year may be provided; (3) For forest pesticide, a report of plot efficacy trial conducted in three provincial-level administrative regions in China for two years or six provincial-level administrative regions in China for one year should be provided; (4) For pesticide used in relevantly stable environmental conditions, such as for storage, antiseptic, and preservation purpose, a report of efficacy trial conducted over two periods in two provincial-level administrative regions in China or over one period in four provincial-level administrative regions in China may be provided; (5) For semiochemicals, a regional trial report may be used instead ⑧.	●	●⑥	●⑥	●	●	●	×	●⑥	●⑦	●⑥

	2.4 Data of regional efficacy trial ④	(1) Provide a report of regional efficacy trial conducted in two provincial-level administrative regions in China for one year; (2) For pesticide used in relevantly stable environmental conditions, such as for storage, antiseptic, and preservation purpose, no report is required.	●	×
	3. Other data	Description of site selection of plot test (needed if not included in the Guidelines for Field Efficacy Trial Areas for Pesticide Registration); influence on major predators and parasites in the field; influence on neighboring crops; registration and application status of this crop or target objects at abroad (for products of unregistered application scope); product features and application precautions; other data relevant with this pesticide variety and application scope.	●	
	4. Comprehensive assessment report	Recapitulative summary of all efficacy data.	●	
Residue ⑨	1. Data of plant metabolism test ⑩	(1) At least one type of crops is selected from five types of crops, including: tuber, leaf, fruit, oil plant and grain to do metabolism tests. If the data indicates this pesticide has the same metabolic pathways in three types of crops, no other metabolism tests are required. Otherwise the data of the metabolism tests of all of the five types of crops should be submitted; (2) If the pesticide can be used only in one type of the crops, reasons should be provided and the data of the metabolism test of this type of crops should be submitted (for concrete requirements, please refer to the Guidelines for Crop Metabolism Test of Pesticides).	●	×
	2. Data of animal metabolism test ⑪	Data of livestock and poultry metabolism test of radioactively labeled pesticides.	●	×
	3. Data of environmental metabolism test⑫	Data of environmental metabolism test of pesticides.	●	×
	4. Data of pesticide residue storage stability test	(1) Submit the data for the stability of active ingredient matrix and metabolites with toxicological significance when they are stored in the corresponding substrate (for concrete requirements, please refer to the Guidelines for Pesticide Residue Storage Stability Test); (2) The data should cover the period from sampling to sample testing.	●	●⑬ ●⑬ ●⑬ ●⑬ × × ●⑬ × ●⑬
	5. Residue analysis method	Test method for residual quantity of active ingredient matrix and metabolites with toxicological significance in the corresponding substrate (for concrete requirements, please refer to the Guidelines for Pesticide Residue Tests).	●	
	6. Data of pesticide residue test in crops ④	Data of residue test of active ingredient matrix and metabolites with toxicological significance in the crop applying for registration (for concrete requirements, please refer to the Guidelines for Pesticide Residue Tests and the Requirements on Number of Locations of Residue Test for Pesticide Registration).	●	● ●⑭ ● ● ● ●⑮ ● ●⑮ ●

	7. Data of pesticide residue test in processed agricultural products	(1) Data of changes of active ingredient matrix and metabolites with toxicological significance during processing of agricultural products; (2) Limited to the agricultural products whose pesticide residue quantity may increase after processing, such as representative crops: oil plants: soybean, peanut and rapeseed; fruit: citrus and apple (for concrete requirements, please refer to the Guidelines for Pesticide Residue Test in Processed Agricultural Products); (3) If there is queried data, its source should be stated.	●	×	×	●	×	●
	8. Data of crops registered in other countries and MRLs	Crops registered in other countries and determination of maximum residue limits of pesticides.	●	×				
	9. Dietary risk assessment report	Dietary risk assessment report of the active ingredient in registered crops and crops applying for registration.	●		×	●	×	●
Environmental impact ⑯	1. Data of bird acute oral toxicity test		●		×	×	●⑰	●⑰
	2. Data of honeybee acute oral toxicity test⑱		●		×	×	●	●
	3. Data of fish acute toxicity test ⑲		●		×	×	●	●
	4. Data of Daphnia magna acute immobilisation test⑲		●		×	×	●	●

Note:

① If a biochemical pesticide TC (TK) whose registration is exempted or reduced is used to process a formulation, a (complete) composition analysis and test report of the TC (TK) as well as complete processing process, quality control items and indexes should be submitted.

If the used biochemical pesticide TC (TK) has been approved and registered by drug, food and health product approval authorities, the above data is not required, but a photocopy of the registration certificate, the product quality standard and other related documents should be submitted.

② The general test condition for thermal storage stability test is (54±2) ℃, 2 weeks. The alternative condition is: (50±2) ℃, 4 weeks; (45±2) ℃, 6 weeks; (40±2) ℃, 8 weeks; (35±2) ℃, 12 weeks; (30±2) ℃, 18 weeks. If an alternative condition is selected, the reason should be provided.

③ The freezing and thawing stability test generally should complete four cycles between (-10±2) ℃ and (20±2) ℃. Each cycle consists of 18 hours' freezing and 6 hours' thawing.

④ According to Article 16 of the Measures for the Administration of Pesticide Registration, it should be completed in China.

⑤ If a product meets one of the following conditions, data of acute inhalation toxicity test should be provided:

a. gas or liquefied gas;

b. smoke generating or fumigant formulation;

c. formulation applied by atomization equipment;

d. vapor releasing formulation;

e. aerosol;

f. formulation containing a certain proportion (weight percentage >1%) of particles smaller than 50μm in diameter;

g. formulation that might cause inhalation exposure while being applied from an aircraft;

h. formulation that contains active ingredients with vapor pressure >1×10-2Pa, and might be used in enclosed space, such as warehouse or greenhouses;

i. formulation that might produce a certain proportion (weight percentage >1%) of particles or drops smaller than 50μm in diameter depending on use method.

⑥ For a product not involving new application scope or new application method, a report of field efficacy trial conducted in three regions for one year (forest pesticides, crops planted in localized regions, and diseases, insects and weeds limited to localized regions) or in four regions for one year (insecticides and fungicides) or in five regions for one year (herbicides and plant growth regulators) may be provided.

⑦ Provide a report of field efficacy trial conducted in three regions for one year (forest pesticides, crops planted in localized regions, and diseases, insects and weeds limited to localized regions) or in four regions for one year (insecticides and fungicides) or in five regions for one year (herbicides and plant growth regulators).

⑧ For semiochemical product, a report of regional trial conducted in two provincial-level administrative regions in China for two years or four provincial-level administrative regions in China for one year may be provided; data of application at home and abroad may be provided subject to need. For a product of unregistered formulation type or unregistered active ingredient content or similar formulation not involving new application scope and new application method, a report of regional trial conducted in two regions for one year may be provided.

⑨ For a product for use in non-food crops or non-feed crops, no data of residue test is required; for low-toxic or slightly-toxic TC seed treatment (including seed mixing, coating and soaking formulations), no data of residue test is required. For a formulation containing a new pesticide in the protection period, complete data of residue test or data of authorized residue test should be submitted.

⑩ If complete data of plant metabolism has been submitted for a new pesticide, or the submitted data of metabolism covers the type of the crops applying for registration, no data of plant metabolism needs to be submitted.

⑪ If the registered crops don't involve animal feed, no data of animal metabolism needs to be submitted.

⑫ If the data for this part has been submitted in the environmental data, there is no need to submit it again.

⑬ Queried data may be submitted, indicating sources.

⑭ For a product of unregistered active ingredient content relative to the registered products of the company (including ready-mixtures with change in content of active ingredients in an equal proportion), if the registered crops, dosage, application period, application frequency, application method and preharvest interval are not changed, the data of residue test may be exempted or reduced; if the registered crops and application method are not changed, but dosage, application period, application frequency and preharvest interval are changed, and may result in the rise of residue risk, data of residue test conducted at a halved number of locations should be submitted, but the minimum number of locations is two.

⑮ If the change in dosage, application frequency and preharvest interval won't increase residue risk, the data of residue test may be exempted or reduced; if the change may result in the rise of residue risk, data of residue test conducted at a halved number of locations should be submitted, but the minimum number of locations is two.

⑯ If test result of TC in any item indicates there is moderate or higher ecological toxicity, then the formulations using this TC during processing should provide test reports and data according to the data requirements for chemical pesticide formulations; if available data can fully prove the possibility of biological exposure of this pesticide to a specific environment is extremely low, exemption or reduction of this test may be applied for. For formulations used only in the protected areas, formulations used only in an indoor environment (e.g. formulations that inhibit germination of potato after harvesting) and pesticides injected into or smeared onto tree trunks, it is not required.

⑰ For seed treatment, and granules or baits, it is required.

⑱ For seed treatment, granules, soil treatment and other formulations used not by spraying, it is not required; for formulations only directly used in ponds, rivers, lakes and other waters (e.g. formulations used in lotus roots), it is not required.

⑲ For seed treatment for dryland and granules applied in furrows or holes, it is not required.

3 Microbial pesticide formulations

Registration category	1. Category D: New pesticide formulations, including those not obtaining the first authorization in the 6-year protection period; 2. Category E: Products of unregistered formulation type; 3. Category F: Products of unregistered active ingredient content; 4. Category G: New ready-mixtures; 5. Category H: Products of unregistered application scope; 6. Category I: Products of unregistered application method; 7. Category L: Similar formulations, same application scope and method; 8. Category M: Similar formulations, different application scope and method. Note: "●" means required, and "✖" means not required.

Data classification	Data item	Interpretation and description	D	E	F	G	H	I	L	M
General data	1. Application form	Adopt the application form issued by the Ministry of Agriculture.				●				
	2. Proof documents of the applicant	(1) A pesticide producer should submit the photocopies of production permit, business license and uniform social credit code bearing its official seal; (2) A developer of new pesticides should provide description of the application for pesticide registration; (3) A foreign enterprise should provide identification paper, description of the registration and use status in related countries and regions, description of the establishment of offices or agencies in China and business license.				●				
	3. Applicant statement	Statement on the authenticity and legality of application materials.				●				
	4. Summary report									
	4.1 Product overview	Include brief introduction to place of production, product chemistry, efficacy, residue, toxicology, environmental impact and overseas registration.				●				
	4.2 Summary of risk assessment	Summary of product risk assessment in the aspects of diet, occupational health, environment, etc.				●				
	4.3 Summary of benefit analysis	Summary of the analysis on the economic, social and environmental benefits of the product.				●				
	5. Labels and manuals	Specimens of labels and manuals prepared according to the Measures for the Administration of Pesticide Labels and Manuals.				●				
	6. Other registration-related proof documents	(1) Data of product chemistry, efficacy, residue, toxicology and environmental impact or comprehensive query reports available in other countries or regions; (2) Naming basis of the active ingredients of the new pesticide; (3) For a new formulation type not specified in the national standards, the applicant should submit a naming basis and appraisal report of the formulation type; (4) Description of the source of TC.				●				
	7. MSDS					●				

	8. References	Their sources should be indicated.	●
Product chemistry and biological features ①	1. Identification and biological features of active ingredients, and identification of safeners, stabilizers, synergists and other restrictive components	(1) The common names, international common names (Latin scientific names normally) and taxonomic status (such as family, genus, species, subspecies, strain, serotype, pathovar or other names relevant with microorganisms) of the active ingredients; (2) The common names, names approved by ISO, common names adopted by other international organizations and countries, chemical names, CAS registry numbers, CIPAC numeric codes, development numbers, molecular formulae, structural formulae, isomer composition, relative molecular weight and molecular mass ranges of the safeners, stabilizers, synergists and other restrictive components (indicating the issue date of IUPAC Periodic Table of the Elements).	●
	2. Basic information of TK	Basic information of the producer, registration, quality control items and indexes of the TK used.	●
	3.Product composition	(1) The chemical names, CAS registry numbers, molecular formulae, structural formulae, contents and functions of the components used in formulation processing. For mixed solvents and mixed adjuvants expressed with codes, their compositions, sources, safety [such as MSDS] and other related information should also be provided; for some adjuvants with special functions, such as safeners, stabilizers and synergists, their quality specifications, basic physic-chemical properties, sources, safety [such as MSDS] and use at home and abroad, etc. should also be provided; (2) For a separately packaged adjuvant (designated adjuvant) added during on-site preparation of a solution, its composition and the above information should be provided separately.	●
	4. Description of processing method		
	4.1 Process flow diagram		●
	4.2 Addition amount and sequence of components		●
	4.3 Main equipment and operating conditions		●
	4.4 Description of quality control measures in the production process		●
	5. Physic-chemical properties	(1) The physic-chemical properties include: appearance (color, physical state and odor), density, corrosiveness to packing material; for a product to which a designated adjuvant needs to be added, data about the compatibility between the product and the designated adjuvant must be submitted; (2) A test report of physic-chemical properties should be provided according to the Guidelines for Determination of Physic-Chemical Properties of Pesticides.	●
	6. Product quality specification	In the quality warranty period, the product quality specification shall meet the following requirements.	

	6.1 Appearance	The definite color, physical state and odor of the product should be described.	●
	6.2 Content of active ingredients	(1) Normally, it is expressed with the quantity of microbes in a unit mass or volume of the product. Based on different determination methods, different units of microorganism content are specified, such as bacillus number, spore number, ITU, CFU, and IB or OB; (2) The minimum content of active ingredients should be specified.	●
	6.3 Content of microorganic contaminants and detrimental impurities	If a product contains microorganic contaminants and detrimental impurities, their maximum content should be specified.	●
	6.4 Content of other restrictive components	If a product contains safeners, stabilizers, synergists and other restrictive components, their content should include indicated content and acceptable range of fluctuation. The acceptable range of fluctuation is determined in reference to the requirements for chemical pesticide formulations.	●
	6.5 Other control items and indexes related to formulation type	(1) For each formulation type, technical indexes tallying with its features should be set; (2) The formulation types not specified in the Requirements may refer to the specification requirements of FAO and WHO. The control items of an innovative formulation type may be determined in comprehensive consideration of the features of active ingredients, application method, safety and other factors and meanwhile the data for formulation type appraisal test should be submitted.	●
	7. Test methods corresponding to product quality control items and validation thereof		
	7.1 Test methods for identification of active ingredients in the product	Make description or provide necessary spectra, photos or sequences from the perspectives of morphological characteristics, physiological and biochemical reaction characteristics, serological reaction and molecular biology (protein and DNA).	●
	7.2 Test methods of active ingredients, microorganic contaminants, detrimental impurities, safeners, stabilizers, synergists and other restrictive components and validation thereof	(1) Test methods: Complete methods should be provided. A test method usually includes method summary, principle, sample information, standard specimen information, instruments, reagents, solution preparation, operating conditions, test procedures, result calculation, statistical method and allowable deviation; (2) Method validation: comply with the Guidelines for Validation of Agrochemical Analysis Methods.	●
	7.3 Test methods of other technical indexes	Comply with the Guidelines for Validation of Agrochemical Analysis Methods.	●
	8. Determination of product quality specification	Give necessary explanation on the basis and reasonableness for formulation of technical indexes.	●
	9. Storage stability	(1) Data of storage stability test at specific temperature for at least one batch of samples should be provided, e.g. store at 20-25℃ for one year or at 0-5℃ for two years; (2) If same products adopt different packing materials, separate storage stability tests should be done; (3) In general, no data of thermal storage stability test needs to be submitted.	●

	10. Product quality test report and test method validation report②	(1) The product quality test report should include all the items specified in the product quality specification; (2) The test methods for the content of active ingredients, microorganic contaminants, detrimental impurities, safeners, stabilizers, synergists and other restrictive components should be validated by the registration testing institution, which issues the product quality test report. Moreover, a test method validation report should be issued. For other control items, it is not required to validate the test methods; (3) The test method validation report includes: test conditions provided by the client, the test conditions adopted by the registration testing institution (such as chromatographic condition, cultivation condition and sample preparation) and changes, all results of parallel determination, standard deviation and typical spectra (including standard specimens and samples). The feasibility of the method is evaluated.	●		
	11. Package (material, shape, size and net content), transportation, storage, safety alerts, quality warranty period, etc.				
	11.1 Package and transportation	The applicant should select correct packing material, package size and means of transportation based on hazard classification of products and should determine the precautions of transportation and storage according to national laws, regulations and standards regarding to work safety, storage and transportation.	●		
	11.2 Safety alerts	The hazard level of the product is evaluated and classified according to the data of the physical and chemical properties and biological features of the product and the standards for hazard classification of biological and chemicals and is disclosed in form of label and/or MSDS.	●		
	11.3 Quality warranty period	A reasonable product quality warranty period should be specified according to the characteristics of the product.	●		
Toxicology	1. Data of acute oral toxicity test		●		
	2. Data of acute dermal toxicity test		●		
	3. Data of acute inhalation toxicity test③		●		
	4. Data of eye irritation test		●		
	5. Data of skin irritation test		●		
	6. Data of skin sensitization test		●		
	7. Data of advanced tests that health risk assessment needs ②	If microbial pesticide TK requires submission of supplementary toxicological data and the primary health risk assessment indicates that the health risk of pesticides to human body is unacceptable, the data of advanced tests (including, but not limited to: pesticide user field exposure level test) may be provided.	●	✖	●

	8. Health risk assessment report	If microbial pesticide TK requires submission of supplementary toxicological data, this data (pesticide user health risk assessment report) should be provided in general.			●				✖	●
Efficacy	1. Benefit analysis										
	1.1 Overview of the crop applying for registration and target organisms	Planting area, commercial value and national distribution of the applying crop; distribution, rules of occurrence, way of harm and economic loss of the target organisms.			●						
	1.2 Substitutability analysis and benefit analysis report	Purpose and use method of the product applying for registration, and its adaptability to the current condition of agricultural production; use cost of the product applying for registration, and expected economic loss that can be recovered and influence on the income of growers; analysis of comparison with existing registered products or chemicals commonly used during production; effect on the resistance management of existing registered products; possibility of substituting pesticides with a higher risk.			●						
	2. Data of efficacy trial										
	2.1 Data of laboratory bioactivity test	Action mode, action spectrum, action mechanism or predicative analysis of action mechanism (only for new pesticide formulations); laboratory activity test report (for formulations with single active ingredient involving new target objects); purpose of making mixtures and laboratory ingredients screening report (for mixtures).	●	●	●	●	●	✖	✖	●
	2.2 Data of laboratory crop safety test	A laboratory crop safety test report is submitted subject to the need.			●						
	2.3 Data of plot efficacy trial②	(1) For insecticides and fungicides, a report of plot efficacy trial conducted in four provincial-level administrative regions in China for two years or eight provincial-level administrative regions in China for one year should be provided; for herbicides and plant growth regulators, a report of plot efficacy trial conducted in five provincial-level administrative regions in China for two years or ten provincial-level administrative regions in China for one year should be provided; for herbicide with a long residual effect, a report of safety trial of main aftercrops should also be provided; (2) For crops planted in localized regions, or diseases, insects and weeds limited to localized regions, a report of plot efficacy trial conducted in three provincial-level administrative regions in China for two years or six provincial-level administrative regions in China for one year may be provided; (3) For forest pesticide, a report of plot efficacy trial conducted in three provincial-level administrative regions in China for two years or six provincial-level administrative regions in China for one year should be provided; (4) For pesticide used in relevantly stable environmental conditions, such as for storage, antiseptic, and preservation purpose, a report of efficacy trial conducted over two periods in two provincial-level administrative regions in China or over one period in four provincial-level administrative regions in China may be provided.	●	● ④	● ④	●	●	● ⑤	● ④

	2.4 Data of regional efficacy trial ②	(1) Provide a report of regional efficacy trial conducted in two provincial-level administrative regions in China for one year; (2) For pesticide used in relevantly stable environmental conditions, such as for storage, antiseptic, and preservation purpose, no report is required.	●	✖	
	3. Other data	Description of site selection of plot test (needed if not included in the Guidelines for Field Efficacy Trial Areas for Pesticide Registration); influence on major predators and parasites in the field; influence on neighboring crops; registration and application status of this crop or target objects at abroad (for products of unregistered application scope); product features and application precautions; other data relevant with this pesticide variety and application scope.	●		
	4. Comprehensive assessment report	Recapitulative summary of all efficacy data.	●		
Residue	1. Data of residue test	If toxicological determination indicates there is toxicological significance, data of residue of this substance in agricultural products should be submitted according to the requirements of the National Pesticide Registration Review Committee.	✖		
Environmental impact ⑥	1. Data of bird toxicity test		●	●	●
	2. Data of honeybee toxicity test ⑦		●	●	●
	3. Data of silkworm toxicity test②⑦		●	●	●
	4. Data of fish toxicity test⑧		●	●	●
	5 Data of Daphnia magna toxicity test ⑧		●	●	●

Note:

① If a microbial TK whose registration is exempted or reduced is used to process a formulation, a culture appraisal report, strain code, culture description, complete production process, a composition analysis and test report, stability test data (sensitivity to temperature changes, light and pH value), quality control items and indexes of this TK should be submitted.

If the used microbial pesticide TK has been approved and registered by drug, food and health product approval authorities, the above data is not required, but a photocopy of the registration certificate, the product quality standard and other related documents should be submitted.

② According to Article 16 of the Measures for the Administration of Pesticide Registration, it should be completed in China.

③ If a product meets one of the following conditions, data of acute inhalation toxicity test should be provided:

a. gas or liquefied gas;

b. smoke generating or fumigant formulation;

c. formulation applied by atomization equipment;

d. vapor releasing formulation;

e. aerosol;

f. formulation containing a certain proportion (weight percentage >1%) of particles smaller than 50μm in diameter;

g. formulation that might cause inhalation exposure while being applied from an aircraft;

h. formulation that contains active ingredients with vapor pressure >1×10-2Pa, and might be used in enclosed space, such as warehouse or greenhouses;

i. formulation that might produce a certain proportion (weight percentage >1%) of particles or drops smaller than 50μm in diameter depending on use method.

④ For a product not involving new application scope or new application method, a report of field efficacy trial conducted in three regions for one year (forest pesticides, crops planted in localized regions, and diseases, insects and weeds limited to localized regions) or in four regions for one year (insecticides and fungicides) or in five regions for one year (herbicides and plant growth regulators) may be provided.

⑤ Provide a report of field efficacy trial conducted in three regions for one year (forest pesticides, crops planted in localized regions, and diseases, insects and weeds limited to localized regions) or in four regions for one year (insecticides and fungicides) or in five regions for one year (herbicides and plant growth regulators).

⑥ If available data can fully prove the possibility of biological exposure of this pesticide to a specific environment is extremely low, exemption or reduction of this test may be applied for. For pesticides injected into or smeared onto tree trunks, formulations used only in the protected areas and formulations used only in an indoor environment (e.g. formulations that inhibit germination of potato after harvesting), no environmental data needs to be provided.

⑦ For seed treatment, granules, soil treatment and other formulations used not by spraying, it is not required; for formulations only directly used in ponds, rivers, lakes and other waters (e.g. formulations used in lotus roots), it is not required.

⑧ For seed treatment for dryland and granules applied in furrows or holes, it is not required.

4 Botanical pesticide formulations

Registration category	1. Category D: New pesticide formulations, including those not obtaining the first authorization in the 6-year protection period; 2. Category E: Products of unregistered formulation type; 3. Category F: Products of unregistered active ingredient content; 4. Category G: New ready-mixtures; 5. Category H: Products of unregistered application scope; 6. Category I: Products of unregistered application method; 7. Category L: Similar formulations, same application scope and method; 8. Category M: Similar formulations, different application scope and method. Note: "●" means required, and "✖" means not required.

Data classification	Data item	Interpretation and description	D	E	F	G	H	I	L	M
General data	1. Application form	Adopt the application form issued by the Ministry of Agriculture.					●			
	2. Proof documents of the applicant	(1) A pesticide producer should submit the photocopies of production permit, business license and uniform social credit code bearing its official seal; (2) A developer of new pesticides should provide description of the application for pesticide registration; (3) A foreign enterprise should provide identification paper, description of the registration and use status in related countries and regions, description of the establishment of offices or agencies in China and business license.					●			
	3. Applicant statement	Statement on the authenticity and legality of application materials.	●							
	4. Summary report		●							
	4.1 Product overview	Include brief introduction to place of production, product chemistry, efficacy, residue, toxicology, environmental impact and overseas registration.	●							
	4.2 Summary of risk assessment	Summary of product risk assessment in the aspects of diet, occupational health, environment, etc.	●							
	4.3 Summary of benefit analysis	Summary of the analysis on the economic, social and environmental benefits of the product.	●							
	5. Labels and manuals	Specimens of labels and manuals prepared according to the Measures for the Administration of Pesticide Labels and Manuals.	●							
	6. Other registration-related proof documents	(1) Data of product chemistry, efficacy, residue, toxicology and environmental impact or comprehensive query reports available in other countries or regions; (2) Naming basis of the active ingredients of the new pesticide; (3) For a new formulation type not specified in the national standards, the applicant should submit a naming basis and appraisal report of the	●							

		formulation type; (4) Description of the source of TC.	
	7. MSDS		●
	8. References	Their sources should be indicated.	●
Product chemistry ①	1. Product identification		
	1.1 Product name	A botanical pesticide extracted from a plant may be named after an active ingredient, or expressed with “common name of the raw material plant+extract”, but the symbolic active ingredient should be stated; a botanical pesticide extracted from multiple plants in a mixed manner should be named after the symbolic active ingredient.	●
	1.2 Identification of active ingredients or symbolic active ingredient, safeners, stabilizers, synergists and other restrictive components	(1) The common names, names approved by ISO, common names adopted by other international organizations and countries, chemical names, CAS registry numbers, CIPAC numeric codes, development numbers, molecular formulae, structural formulae, isomer composition, relative molecular weight and molecular mass ranges of the active ingredients or symbolic active ingredient, safeners, stabilizers, synergists and other restrictive components (indicating the issue date of IUPAC Periodic Table of the Elements); (2) If an active ingredient exists in a form of a specific salt, the identification information of the corresponding derivatives should also be provided.	●
	2. Basic information of TC (TK)	Basic information of the producer, registration, quality control items and indexes of the TC (TK) used.	●
	3. Product composition	(1) The chemical names, CAS registry numbers, molecular formulae, structural formulae, contents and functions of the components used in formulation processing. For mixed solvents and mixed adjuvants expressed with codes, their compositions, sources, safety [such as MSDS] and other related information should also be provided; for some adjuvants with special functions, such as safeners, stabilizers and synergists, their quality specifications, basic physic-chemical properties, sources, safety [such as MSDS] and use at home and abroad, etc. should also be provided; (2) For a separately packaged adjuvant (designated adjuvant) added during on-site preparation of a solution, its composition and the above information should be provided separately.	●
	4. Description of processing method		

	4.1 Process flow diagram		●
	4.2 Addition amount and sequence of components		●
	4.3 Main equipment and operating conditions		●
	4.4 Description of quality control measures in the production process		●
	5. Physic-chemical properties	(1) The physic-chemical properties include: appearance (color, physical state and odor), density, viscosity, oxidation and reduction properties, corrosiveness to packing material, compatibility with non-polar organic solvents (applicable to the formulations diluted by organic solvents), explosibility and combustibility; for a product to which a designated adjuvant needs to be added, data about the compatibility between the product and the designated adjuvant must be submitted; (2) A test report of physic-chemical properties should be provided according to the Guidelines for Determination of Physic-Chemical Properties of Pesticides. If specific parameters are not applicable to the product, explanation should be given.	●
	6. Product quality specification	In the quality warranty period, the product quality specification shall meet the following requirements.	
	6.1 Appearance	The definite color, physical state and odor of the product should be described.	●
	6.2 Content of active ingredients or symbolic active ingredient	(1) The content of an active ingredient or symbolic active ingredient includes indicated content and acceptable range of fluctuation. The acceptable range of fluctuation does not exceed ±25% of the indicated content; (2) If an active ingredient exists in a form of a salt, the name and mass fraction of the product should be expressed in the form of actual existence and meanwhile the content of the active part and paired counterions is stated.	●
	6.3 Content of relevant impurities	If a product contains relevant impurities, their maximum content should be specified, and expressed with mass fraction.	●
	6.4 Content of other restrictive components	If a product contains safeners, stabilizers, synergists and other restrictive components, their content should include indicated content and acceptable range of fluctuation. The acceptable range of fluctuation is determined in reference to the requirements for chemical pesticide formulations.	●
	6.5 Other control items and indexes related to formulation type	(1) For each formulation type, technical indexes tallying with its features should be set; (2) The formulation types not specified in the Requirements may refer to the specification requirements of FAO and WHO. The control items of an innovative formulation type may be determined in comprehensive consideration of the features of active ingredients, application method,	●

		safety and other factors and meanwhile the data for formulation type appraisal test should be submitted.	
	7. Test methods corresponding to product quality control items and validation thereof		
	7.1 Test methods for identification of active ingredients or symbolic active ingredient in the product	(1) If TC is used to process a formulation, there should be at least one test method to identify active ingredients. When chemical identification is adopted, at least two identification test methods should be provided; (2) If TK is used to process a formulation, the characteristic peak and retention time in the "chemical fingerprint" spectrum of the formulation should be used to identify the product.	●
	7.2 Test methods of active ingredients or symbolic active ingredient, relevant impurities, safeners, stabilizers, synergists and other restrictive components and validation thereof	(1) Test methods: Complete methods should be provided. A test method usually includes method summary, principle, sample information, standard specimen information, instruments, reagents, solution preparation, operating conditions, test procedures, result calculation, statistical method and allowable deviation; (2) Method validation: comply with the Guidelines for Validation of Agrochemical Analysis Methods.	●
	7.3 Test methods of other technical indexes	Comply with the Guidelines for Validation of Agrochemical Analysis Methods.	●
	8. Determination of product quality specification	Give necessary explanation on the basis and reasonableness for formulation of technical indexes.	●
	9. Data of normal-temperature storage stability test	(1) Data of normal-temperature storage stability test for at least one batch of samples should be provided; (2) If same products adopt different packing materials, separate normal-temperature storage stability tests should be done; (3) In general, normal-temperature storage stability test requires that the samples shall be stored under determined conditions for two years.	●
	10. Product quality test report and test method validation report②	(1) The product quality test report should include all the items specified in the product quality specification; (2) The test methods for the content of active ingredients or symbolic active ingredient, relevant impurities, safeners, stabilizers, synergists and other restrictive components should be validated by the registration testing institution, which issues the product quality test report. Moreover, a test method validation report should be issued. For other control items, it is not required to validate the test methods; (3) The test method validation report includes: test conditions provided by the client, the test conditions adopted by the registration testing institution (such as chromatographic condition and sample preparation) and changes, all results of parallel determination, standard deviation and typical spectra	●

		(including standard specimens and samples). The feasibility of the method is evaluated.			
	11. Package (material, shape, size and net content), transportation, storage, safety alerts, quality warranty period, etc.				
	11.1 Package and transportation	The applicant should select correct packing material, package size and means of transportation based on hazard classification of products and should determine the precautions of transportation and storage according to national laws, regulations and standards regarding to work safety, storage and transportation.	●		
	11.2 Safety alerts	The hazard level of the product is evaluated and classified according to the data of the physical and chemical properties of the product and the standards for hazard classification of chemicals and is disclosed in form of label and/or MSDS.	●		
	11.3 Quality warranty period	A reasonable product quality warranty period should be specified according to the data of normal-temperature storage stability test.	●		
Toxicology	1. Data of acute oral toxicity test		●		
	2. Data of acute dermal toxicity test		●		
	3. Data of acute inhalation toxicity test③		●		
	4. Data of eye irritation test		●		
	5. Data of skin irritation test		●		
	6. Data of skin sensitization test		●		
	7. Data of advanced tests that health risk assessment needs ②	If botanical TC (TK) requires submission of a complete set of toxicological data and the primary health risk assessment indicates that the health risk of pesticides to human body is unacceptable, the data of advanced tests (including, but not limited to: pesticide user field exposure level test) may be provided.	●	✖	●
	8. Health risk assessment report	If botanical TC (TK) requires submission of a complete set of toxicological data, this data (pesticide user health risk assessment report) should be provided in general.	●	✖	●
Efficacy	1. Benefit analysis				

	1.1 Overview of the crop applying for registration and target organisms	Planting area, commercial value and national distribution of the applying crop; distribution, rules of occurrence, way of harm and economic loss of the target organisms.	●						
	1.2 Substitutability analysis and benefit analysis report	Purpose and use method of the product applying for registration, and its adaptability to the current condition of agricultural production; use cost of the product applying for registration, and expected economic loss that can be recovered and influence on the income of growers; analysis of comparison with existing registered products or chemicals commonly used during production; effect on the resistance management of existing registered products; possibility of substituting pesticides with a higher risk.	●						
	2. Data of efficacy trial								
	2.1 Data of laboratory bioactivity test	Action mode, action spectrum, action mechanism or predicative analysis of action mechanism; botanical pesticides of which TK (TC) registration is exempted or reduced, a laboratory activity test report (for products involving new target objects) should be provided; purpose of making mixtures and laboratory ingredients screening report (for mixtures)	●	●	●	●	●	✖	✖	●
	2.2 Data of laboratory crop safety test	Laboratory crop safety test report (only for products involving new crops).	●	●	●	●	●	✖	✖	●
	2.3 Data of plot efficacy trial②	(1) For insecticides and fungicides, a report of plot efficacy trial conducted in four provincial-level administrative regions in China for two years or eight provincial-level administrative regions in China for one year should be provided; for herbicides and plant growth regulators, a report of plot efficacy trial conducted in five provincial-level administrative regions in China for two years or ten provincial-level administrative regions in China for one year should be provided; for herbicide with a long residual effect, a report of safety trial of main aftercrops should also be provided; (2) For crops planted in localized regions, or diseases, insects and weeds limited to localized regions, a report of plot efficacy trial conducted in three provincial-level administrative regions in China for two years or six provincial-level administrative regions in China for one year may be provided; (3) For forest pesticide, a report of plot efficacy trial conducted in three provincial-level administrative regions in China for two years or six provincial-level administrative regions in China for one year should be provided; (4) For pesticide used in relevantly stable environmental conditions, such as for storage, antiseptic, and preservation purpose, a report of efficacy trial conducted over two periods in two provincial-level administrative regions in China or over one period in four provincial-level administrative regions in China may be provided.	●	●④	●④	●	●	●⑤	●④

	2.4 Data of regional efficacy trial ②	(1) Provide a report of regional efficacy trial conducted in two provincial-level administrative regions in China for one year; (2) For pesticide used in relevantly stable environmental conditions, such as for storage, antiseptic, and preservation purpose, no report is required.	●	✖
	3. Other data	Description of site selection of plot test (needed if not included in the Guidelines for Field Efficacy Trial Areas for Pesticide Registration); influence on major predators and parasites in the field; influence on neighboring crops; registration and application status of this crop or target objects at abroad (for products of unregistered application scope); product features and application precautions; other data relevant with this pesticide variety and application scope.	●	
	4. Comprehensive assessment report	Recapitulative summary of all efficacy data.	●	
Residue	1. Data of residue test	If toxicological determination indicates there is toxicological significance, data of residue of this substance in agricultural products should be submitted according to the requirements of the National Pesticide Registration Review Committee.	✖	
Environmental impact ⑥	1. Summary of environmental data of TC (TK)		●	✖ ✖
	2. Data of bird acute oral toxicity test	The birds used in the test should be a more sensitive species in the bird acute oral toxicity test of TC (TK).	●	●⑦ ●⑦
	3. Data of fish acute toxicity test ⑧	The fish used in the test should be a more sensitive species in the fish acute toxicity test of TC (TK).	●	● ●
	4. Data of Daphnia magna acute immobilisation test ⑧		●	● ●
	5. Data of honeybee acute oral toxicity test ⑨⑩		●	● ●
	6. Data of honeybee acute contact toxicity test ⑨⑩		●	✖ ✖
	7. Data of silkworm acute toxicity test ②⑨⑩		●	✖ ✖
	8. Data of parasite acute toxicity test ⑨⑩⑪		●	✖ ✖
	9. Data of predator acute toxicity test ⑨⑩⑪		●	✖ ✖

Note:

① If a botanical TK (TC) whose registration is exempted or reduced is used to process a formulation, the complete production process, a composition analysis and test report, quality control items and indexes of this TK (TC) should be submitted.

If the used botanical pesticide TK (TC) has been approved and registered by drug, food and health product approval authorities, the above data is not required, but a photocopy of the registration certificate, the product quality standard and other related documents should be submitted.

② According to Article 16 of the Measures for the Administration of Pesticide Registration, it should be completed in China.

③ If a product meets one of the following conditions, data of acute inhalation toxicity test should be provided:

a. gas or liquefied gas;

b. smoke generating or fumigant formulation;

c. formulation applied by atomization equipment;

d. vapor releasing formulation;

e. aerosol;

f. formulation containing a certain proportion (weight percentage >1%) of particles smaller than 50μm in diameter;

g. formulation that might cause inhalation exposure while being applied from an aircraft;

h. formulation that contains active ingredients with vapor pressure >1×10-2Pa, and might be used in enclosed space, such as warehouse or greenhouses;

i. formulation that might produce a certain proportion (weight percentage >1%) of particles or drops smaller than 50μm in diameter depending on use method.

④ For a product not involving new application scope or new application method, a report of field efficacy trial conducted in three regions for one year (forest pesticides, crops planted in localized regions, and diseases, insects and weeds limited to localized regions) or in four regions for one year (insecticides and fungicides) or in five regions for one year (herbicides and plant growth regulators) may be provided.

⑤ Provide a report of field efficacy trial conducted in three regions for one year (forest pesticides, crops planted in localized regions, and diseases, insects and weeds limited to localized regions) or in four regions for one year (insecticides and fungicides) or in five regions for one year (herbicides and plant growth regulators).

⑥ If available data can fully prove the possibility of biological exposure of this pesticide to a specific environment is extremely low, exemption or reduction of this test may be applied for. For pesticides injected into or smeared onto tree trunks, formulations used only in the protected areas and formulations used only in an indoor environment (e.g. formulations that inhibit germination of potato after harvesting), no environmental data needs to be provided.

⑦ For seed treatment, and granules or baits applied by spreading, it is required.

⑧ For seed treatment for dryland and granules applied in furrows or holes, it is not required.

⑨ For seed treatment, granules, soil treatment and other formulations used not by spraying, it is not required.

⑩ For formulations only directly used in ponds, rivers, lakes and other waters (e.g. formulations used in lotus roots), it is not required.

⑪ For formulations used only in the outdoor environment in residential areas, it is not required.

Attachment 3.

Interpretation and Specification of the Data Requirements for Sanitation-oriented Pesticide Formulation Registration

1. Sanitation-oriented chemical pesticide formulation

Registration Category	1. Type D: New agrochemical formulations, including the ones which have not been authorized for the first time within the 6-year protection period; 2. Type E: New dosage form; 3. Type F: New content; 4. Type G: New mixed formulation; 5. Type H: New use scope; 6. Type I: New use method; 7. Type J: Same formulation and same use scope and use method; 8. Type K: Same formulation but different use scopes and use methods; 9. Type L: Similar formulation and same use scope and use method; 10. Type M: Similar formulation but different use scope and use method. Note: "●" indicates "Necessary", and "✖" means "Unnecessary".

Data Classification	Data Item	Explanation and Description	D	E	F	G	H	I	J	K	L	M
Basic Data	1. Application form	It shall be filled according to the application form issued by the Ministry of Agriculture.					●					
	2. Documents of the applicant	(1) The copies of the production license and the business license with the official seal and the standard social credit codes submitted by agrochemical producers; (2) The information about new agrochemical developers' application for agrochemical registration; (3) The identification document of overseas enterprises, the information about the registration and use in relevant countries and regions, the information about the establishment of offices or agencies in China and the business license.					●					
	3. Declaration of the applicant	The declaration for the reliability and legality of the application materials.					●					
	4. Summary report											
	4.1 Introduction to products	The brief introduction including the place of origin, chemistry, effect, toxicology, environmental impact, and overseas registration of products.					●					
	4.2 Summary of the risk evaluation report	The risk evaluation summary including the occupational health and environment of products.					●					
	4.3 Summary of the benefit analysis report	The summary including the analysis of the economic, social and environmental benefits of products.					●					
	5. Label and instruction	The samples of the label and instruction made in accordance with Regulations on the Label and Instruction of Agrochemicals.					●					

	6. Other documents related to the registration	(1) The data about the chemistry, efficacy, residual, toxicology and environmental impact of products or the comprehensive inquiry report in other countries or regions; (2) The basis of the naming of the active ingredients of new agrochemicals;(3) For the new dosage forms which have not be stipulated in the national standards, the applicant shall submit the basis of naming and the appraisal report;(4) The information about the sources of technical.	●
	7. Material safety data sheet		●
	8. References	The sources of quotations shall be given.	●
Product Chemistry	1. Identification of active ingredients and other restrictive components like safener, stabilizer and synergist	(1) The general names of active ingredients and other restrictive components like safener, stabilizer and synergist; the names approved by the International Standard Organization (ISO) and the general names, chemical names and the accession number of American Chemical Abstracts (CAS number) in other international organizations and countries; the digital codes, development numbers, molecular formula, structural formula, isomer composition, relative molecular mass or molecular mass scope (with the issuance time of the International relative atomic mass index for the calculation) of the Collaborative International Pestricides Analytical Committee (CAPAC); (2) If the active ingredients exist in the form of certain salt, the data about the identification of corresponding derivatives shall be offered.	●
	2. Basic information about technical (TK)	The information about the producer, registration, quality control item and index of the adopted technical (TK).	●
	3. Product composition	(1) The chemical names, numbers of American Chemical Abstracts (CAS number), molecular formula, structural formula, contents and functions of the components for the processing of the formulation. For the mixed solvents and assistants represented with codes, the information about their composition, sources and safety (such as the material safety data sheet (MSDS)) shall be offered. For the assistants with special functions, including safener, stabilizer and synergist, the information about their quality specification, basic physicochemical properties, sources, safety (such as the material safety data sheet (MSDS)) and domestic and overseas use shall be offered; (2) For the separately-wrapped assistants (designated ones) added in the on-site solution preparation, their composition and the above information shall be separately offered.	●
	4. Description of the processing method		
	4.1 Process flow chart		●
	4.2 Quantity of components and the sequence of their use		●
	4.3 Main equipment and operation conditions		●
	4.4 Description of the quality control measures in the production		●

	5. Physicochemical properties	(1) Physicochemical properties include appearance (color, state and smell), density, viscosity, oxidizability/reducibility, the corrosiveness to packing materials, the compatibility with nonpolar organic solvents (applicable to the dosage form for the dilution with organic solvents), explosiveness, and combustibility. For the products which require designated assistants in their use, the information about the mixture of the products and the designated assistants must be offered.(2) The measurement report on the physicochemical properties shall be offered in accordance with the Guidelines of the Measurement Test on Physicochemical Properties of Agrochemicals. If specific parameters are not suitable for products, the explanation shall be offered.	●
	6. Production quality specification	The product quality specification shall meet the following requirements during the quality assurance period.	
	6.1 Appearance	The color, state and smell of products shall be clearly described.	●
	6.2 Content of active ingredient	(1) The content of active ingredient consists of labeled content and the scope of acceptable fluctuation. Its requirements are shown in Annotation ①. The requirements on the content scope of other special products can be made according to Annotation ①; (2) The content of active ingredient is usually represented with quality percentage (%). The content of active ingredient of liquid formulation can be represented with quality concentration (g/L) or quality percentage (%). If it is represented with quality concentration, its quality percentage shall be offered at the same time; (3) If active ingredient exists in the isomer, the name and proportion of the isomer in the formulation shall be the same with that of the technical. If general name is adopted to define the active ingredient in the isomer, it will be unnecessary to repeatedly specify the isomer proportion in the control item; if general name has not defined the mixture to be registered, the isomer proportion needs to be specified. (4) If active ingredient exists in the form of certain salt, the name and quality percentage of products will be represented with the actual existence. Meanwhile, the active parts and the content of paired counter-ions shall be labeled. (5) There is an acceptable fluctuation scope for the content of the products whose content is represented with effective dose (for example, the content of electro-thermal mosquito repellent incense slice is represented with “mg/slice”). First, the content is converted into quality percentage; then, an appropriate corresponding value is chosen from Annotation ①; (6) As far as incense coil is concerned, the acceptable fluctuation scope of the content of its active ingredient shall not be higher than 40% or lower than 20% of the labeled content.	●
	6.3 Content of relevant impurities	The maximum content of the products with relevant impurities shall be specified and represented with quality percentage.	●
	6.4 Content of other restrictive components	The content of the products with other restrictive components like safener, stabilizer and synergist shall consist of labeled content and acceptable fluctuation content. The acceptable fluctuation scope is shown in Annotation ①.	●
	6.5 Other control items and indexes ②③ related to dosage form	(1) Different dosage forms need the technical indexes consistent with their features; (2) The dosage forms that are not specified in this requirement can be specified according to the specification requirements by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The control items of innovative dosage forms can be defined according to the features, utilization method and safety of active ingredients. Meanwhile, the information	●

		about the appraisal test on dosage form shall be submitted.			
	7. Test methods for the quality control items of products and method confirmation				
	7.1 Test methods of identifying the active ingredients of products④	At least one test method shall be adopted to identify active ingredients. If the chemical method is used for the identification, at least two identification test methods shall be offered. If active ingredients exist in the form of certain salt, the identification test method shall be able to identify the type of salt.	●		
	7.2 Methods of testing active ingredients, relevant impurities, and other restrictive components like safener, stabilizer and synergist and method confirmation	(1) Test methods: Complete test methods shall be provided. The test methods usually include method summary, principle, information about samples, reference materials, apparatus, agents, solution preparation, operation conditions, test procedure, calculation for results, statistical methods, and allowable deviation; (2) Method confirmation: It shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●		
	7.3 Test methods of other technical indexes	They shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●		
	8. Information about the confirmation of quality specification of products	Make necessary explanation for the basis and rationality of technical indexes.	●		
	9. Data of the test on the stability of storage at the room temperature	(1) The data of the test on the stability at the room temperature of at least a batch of samples shall be provided; (2) The same products wrapped with different materials should be tested for the stability at the room temperature respectively; (3) Usually, samples are stored under specific conditions for two years in the test on the stability at the room temperature.	●	×	●
	10. Product quality test report and the test method demonstration report⑤	(1) The product quality test report shall include all the items as specified in the product quality specification; (2) The methods of testing the contents of active ingredients, relevant impurities and other restrictive components like safener, stabilizer and synergist should be demonstrated by the registration test unit which issues the product quality test report. Meanwhile, the test method demonstration report shall also be issued. The test methods of other control items can be exempted from the method demonstration. (3) The test method demonstration report includes the test conditions proposed by the consignor, the test conditions (such as chromatographic condition and sample preparation) of the registration test unit and the explanation for any change, and all the results, standard deviation and typical map (including reference materials and samples) of the parallel test. Meanwhile, the feasibility of the test methods shall be evaluated.	●		

	11. Packing (material, shape, size and net content), storage and transport, safety warning, and quality assurance period										
	11.1 Packing and storage and transport	The applicant shall select appropriate packing materials, package sizes and transport tools according to the hazard category of products. The matters worthy of attention for the transport and storage shall be defined according to the state laws and regulations on safe production, storage and transport.					●				
	11.2 Safety warning	The hazard degree of products is evaluated and classified according to the data about the physicochemical properties of products and the hazard classification standards of chemicals. Moreover, it is made public in the form of label and material safety data sheet (MSDS).					●				
	11.3 Quality assurance period	An appropriate product quality assurance period is defined according to the data of the test on the stability at the room temperature.					●				
Toxicology	1. Data of the test on acute oral toxicity⑥					●				×	●
	2. Data of the test on acute percutaneous toxicity⑥					●				×	●
	3. Data of the test on acute inhalation toxicity⑥⑦					●				×	●
	4. Data of the test on eye irritation⑥					●				×	●
	5. Data of the test on skin irritation⑥					●				×	●
	6. Data of the test on skin sensitization⑥					●				×	●
	7. The data of the advanced test for the health risk evaluation⑤	According to the preliminary health risk evaluation, if the risk of agrochemicals on human health is unacceptable, the corresponding data of the advanced test can be offered. The advanced test data about household health pesticides include but not limited to the resident exposure model test, and the advanced test data about the environmental health pesticides include but not limited to the pesticide user exposure test.				●				×	●
	8. Heath risk evaluation report	For the household health pesticides, the resident health risk evaluation report shall be submitted. For the environmental health pesticides, the pesticide user health risk evaluation report shall be submitted.				●				×	●
Efficacy	1. Benefit analysis										
	1.1 Application for use site and the information about target organisms	The features and harm of target organisms, their distribution in China, the rules of occurrence, and their threat to human health.					●				

	1.2 Analysis of the value and strength of products	The method and cost of using the products to be registered and the benefits the products bring to human health, safety and environment; the function and use of the products to be registered and the mutual compatibility between the products and the current measures for controlling harmful organisms; the information about the existing registered products whose functions are to be registered; the comparative analysis with existing registered products or common medicine; the role in the resistance management of existing registered products; the possibility to substitute the agrochemicals with higher risk.	●					
	2. Data of the efficacy test							
	2.1 Data of the test on indoor bioactivity	Action method, action spectrum, action mechanism or action mechanism prediction analysis (for the formulation of new agrochemicals only); indoor activity test report (for the single-dose products involving new targets of prevention and treatment); the purpose of mixture and the report on indoor formula selection (for the mixture formulation).	●	×	●	×	●	
	2.2 Report on the indoor efficacy measurement test⑤	The report on the 1-year indoor efficacy measurement test in two provincial administrative regions in China.	●⑧					
	2.3 Report on the simulated on-site test⑤	The report on the 1-year simulated on-site test in two provincial administrative regions in China.	●⑨					
	2.4 Report on the on-site test⑤	The report on the 1-year on-site test in two provincial administrative regions in China (one in South China and the other in North China; in case of harmful organisms in some regions, both can either be in South China or North China).	●⑩					
	3. Research report on resistance risk	It includes the test on the sensitivity of target organisms, the methods of monitoring the resistance to drugs, and the risk evaluation of the resistance to drugs (for the products involving new targets of prevention and treatment).	●	×	×	●	×	●
	4. Features of utilization	Product features and the matters worthy of attention in the use.	●					
	5. Comprehensive evaluation report	Summary of all the data about efficacy.	●					
Environmental impact⑪	1. Summary of the environmental data about the technical (TK)		●	×	●			
	2. Data of the test on the acute oral toxicity for birds	The birds in the test shall be the ones which are sensitive in the technical test on the acute oral toxicity for birds.	●	×	●			
	3. Data of the test on the acute toxicity of fishes⑫	The fishes in the test shall be the one which are sensitive in the technical test on the acute oral toxicity for fishes.	●	×	●			
	4. Data of the test on the acute activity inhibition for daphnia magna⑫		●	×	●			
	5. Data of the test on the growth inhibition of green alga⑫		●	×	●			
	6. Data of the test on the oral toxicity for bees⑬		●	×	●			

	7. Data of the test on the acute contact toxicity of bees ⑬		●	×	●
	8. Data of the test on the acute toxicity for silkworms ⑤⑬		●	×	●
	9. Other data of the advanced tests for the environmental risk evaluation	According to the preliminary environmental risk evaluation, if the risk of agrochemicals on certain target of protection is unacceptable, the corresponding data of the advanced test need to be offered.	●	×	●
	10. Report on environmental risk evaluation⑪⑭	The possible environmental risk caused by the use of the recommended GAP is evaluated.	●	×	

Notes:

① Requirement on the content scope (X, % or g/100mL, 20℃±2℃) of active ingredients in the products.

X≤2.5 ±15%X (suitable for well-proportioned formulations like missible oil, suspension concentrate and soluble concentrate)
±25%X (suitable for poor-proportioned formulations like granules and water dispersible granule)

2.5<X≤10 ±10%X

10<X≤25 ±6%X

25<X≤50 ±5%X

X>50 ±2.5%或 2.5g/100mL

② The common test condition of thermal storage stability is (54±2)℃ for 2 weeks. The alternative conditions as follows: (50±2)℃ for 4 weeks; (45±2)℃ for 6 weeks; (40±2)℃ for 8 weeks; (35±2)℃ for 12 weeks; (30±2)℃ for 18 weeks. Reasons should be given if the alternative conditions are chosen.

③ Normally, the freezing and melting stability test should be cycled for four times between (-10±2)℃ and (20±2)℃. Each cycle includes 18 hours of freezing and 6 hours of melting.

④ If the sanitation-oriented agrochemical preparation with a content of lower than 1% involves isomer resolution and there is the information about the discrimination test on active ingredients of products (including the discrimination of isomer), it is unnecessary to provide corresponding isomer resolution methods and the method demonstration report. However, the submitted data shall include the following information:

- If the content of active ingredient in the product refers to certain isomer, the content of active ingredient should be result of multiplying the total content with the proportion coefficient of active isomer in the adopted technical or TK;
- If active ingredient consists of more than one isomer of different proportions, the total content and the proportions of different isomers should be specified;
- The discrimination test should specify the proportion scope of isomer in technical or TK as well as the resolution method and chromatogram of technical or TK isomer.

⑤ It shall be finished in China in accordance with Article 16 of the Agrochemical Registration Management Measures.

⑥ As for sanitation-oriented agrochemicals, the data of the toxicological test shall be provided according to dosage form. The specific requirements are as follows:

a. Mosquito-repellent incense and electro-thermal mosquito repellent incense slice: acute inhalation toxicity;

b. Aerosol: acute inhalation toxicity, eye irritation and skin irritation;

c. Electro-thermal mosquito repellent liquid: acute oral toxicity, acute percutaneous toxicity and acute inhalation toxicity;

d. Repellent: acute oral toxicity, acute percutaneous toxicity, acute inhalation toxicity, eye irritation, and several skin irritation and sensitization tests;

e. Other dosage forms: acute oral toxicity, acute percutaneous toxicity, acute inhalation toxicity, eye irritation, skin irritation and sensitization tests.

Corresponding test items can be added or reduced according to special dosage form and active ingredient.

⑦ For the products which meet one of the following conditions, the data of the test on acute inhalation toxicity shall be provided:

a. Gas or liquefied gas;

b. Fuming preparation or steaming preparation;

c. The preparation which adopts nebulization equipment for agrochemical application;

d. Steam release preparation;

e. Aerosol;

f. The preparation whose particles (with a diameter of less than 50um) account for a large proportion (weight>1%);

g. Airplane-based agrochemical application may generate inhalable preparation;

h. The preparation whose vapor pressure of active ingredient is higher than 1×10-2Pa and which may be used in confined space like warehouses or greenhouses;

i. The preparation whose particles (with a diameter of less than 50μm) or small drops which account for a large proportion (weight>1%) can be generated according to the use.

⑧ It is unnecessary to provide the products that cannot be used for the indoor efficacy test, including the ultra-low volume spray and hot fogging concentrate spray.

⑨ It is unnecessary to provide the products for the indoor residual spraying after coating, spreading, repelling, mothproof and dilution or the products which cannot be used in the simulated on-site test.

⑩ The on-site test reports on snail killer, termite control agent, grain storage pest control agent, ultra-low volume preparation, hot fogging concentrate, outdoor mosquito (larva) repellent, fly (larva) and other preparations for exterior use need to be provided. That of other products is provided according to need.

⑪ Adequate data have shown that if the possibility of contact between agrochemical and certain environmental organism is extremely low, the test can be exempted through application. The environmental data of the pesticides for indoor use and the mosquito-repelling products which can be rubbed on human body can be exempted.

⑫ According to the results of the technical test, one of the three test organisms (fish, daphnia and algae) was sensitive (more sensitive than the other two for over 100 times). Then, only the sensitive organism was chosen for the test.

⑬ It is unnecessary to provide the sanitation-oriented agrochemicals not for spraying, including granules, soil treatment herbicides and baits.

⑭ For the registration types beyond Types D, H and I, the applicant shall compare them with the registered products in terms of use and eco-toxicity. If the dose and frequency of application of the products to be registered are no higher than that of the registered products, if the application interval is no shorter than that of the registered products, and if the eco-toxicity is no stronger than that of the registered products, it is unnecessary to provide them.

2. Sanitation-oriented biochemical pesticide formulation

Registration Category	1. Type D: New agrochemical formulations, including the one which have not been authorized for the first time within the 6-year protection period; 2. Type E: New dosage form; 3. Type F: New content; 4. Type G: New mixed formulation; 5. Type H: New use scope; 6. Type I: New use method; 7. Type J: Same formulation and same use scope and use method; 8. Type K: Same formulation but different use scopes and use methods; 9. Type L: Similar formulation and same use scope and use method; 10. Type M: Similar formulation but different use scope and use method. Note: "●" indicates "Necessary", and "✖" means "Unnecessary".

Data Category	Data Item	Explanation and Description	D	E	F	G	H	I	J	K	L	M
Basic data	1. Application form	It shall be filled according to the application form issued by the Ministry of Agriculture.						●				
	Data Item	Explanation and Description						●				
	1. Application form	It shall be filled according to the application form issued by the Ministry of Agriculture.	●									
	2. Documents of the applicant	(1) The copies of the production license and the business license with the official seal and the standard social credit codes submitted by agrochemical producers; (2) The information about new agrochemical developers' application for agrochemical registration; (3) The identification document of overseas enterprises, the information about the registration and use in relevant countries and regions, the information about the establishment of offices or agencies in China and the business license.										
	3. Declaration of the applicant	The declaration for the reliability and legality of the application materials.	●									
	4. Summary report	Summary of the risk evaluation report on the meal, occupational health and environment of products.	●									
	4.1 Introduction to products	The brief introduction including the place of origin, chemistry, effect, toxicology, environmental impact, and overseas registration of products.	●									

	4.2 Summary of the risk evaluation report	The risk evaluation summary including the occupational health and environment of products.	●
	4.3 Summary of the benefit analysis report	The summary including the analysis of the economic, social and environmental benefits of products.	●
	5. Label and instruction	The samples of the label and instruction made in accordance with Regulations on the Label and Instruction of Agrochemicals.	●
	6. Other documents related to the registration	(1) The information about the chemistry, efficacy, residual, toxicology and environmental impact of products or the comprehensive inquiry report in other countries or regions; (2) The basis of the naming of the active ingredients of new agrochemicals; (3) For the new dosage forms which have not be stipulated in the national standards, the applicant shall submit the basis of naming and the appraisal report; (4) The information about the sources of technical.	●
Product chemistry ①	8. References	The sources of quotations shall be given.	●
	2. Basic information about technical (TK)	Provide the information about the producers, registration, quality control items and indexes of the adopted technical (TK).	●
	1. Identification of active ingredients and safener, stabilizer, synergist and other restrictive components	(1) The general names of active ingredients and other restrictive components like safener, stabilizer and synergist; the names approved by the International Standard Organization (ISO) and the general names, chemical names and the accession number of American Chemical Abstracts (CAS number) in other international organizations and countries; the digital codes, development numbers, molecular formula, structural formula, isomer composition, relative molecular mass or molecular mass scope (with the issuance time of the International relative atomic mass	●

		index for the calculation) of the Collaborative International Pestricides Analytical Committee (CIPAC);(2) If the active ingredients exist in the form of certain salt, the data about the identification of corresponding derivatives shall be offered.	
	4. Description of the processing method		
	4.1 Process flow chart		●
	4.2 Quantity of components and the sequence of their use		●
	4.3 Main equipment and operation conditions		●
	4.4 Description of the quality control measures in the production		●
	5. Physicochemical properties	(1) Physicochemical properties include appearance (color, state and smell), density, viscosity, oxidizability/reducibility, the corrosiveness to packing materials, the compatibility with nonpolar organic solvents (applicable to the dosage form for the dilution with organic solvents), explosiveness, and combustibility. For the products which require designated assistants in their use, the information about the mixture of the products and the designated assistants must be offered. (2) The measurement report on the physicochemical properties shall be offered in accordance with the Guidelines of the Measurement Test on Physicochemical Properties of Agrochemicals. If specific parameters are not suitable for products, the explanation shall be offered.	●
	6. Production quality specification	The product quality specification shall meet the following requirements during the quality assurance period.	
	6.1 Appearance	The color, state and smell of products shall be clearly described.	●

	6.2 Content of active ingredient	(1) The content of active ingredient consists of labeled content and the scope of acceptable fluctuation. Its requirements are shown in Annotation ②. The requirements on the content scope of other special products can be made according to Annotation ②; (2) The content of active ingredient is usually represented with quality percentage (%). The content of active ingredient of liquid formulation can be represented with quality concentration (g/L) or quality percentage (%). If it is represented with quality concentration, its quality percentage shall be offered at the same time; (3) If active ingredient exists in the isomer, the name and proportion of the isomer in the formulation shall be the same with that of the technical. If general name is adopted to define the active ingredient in the isomer, it will be unnecessary to repeatedly specify the isomer proportion in the control item; if general name has not defined the mixture to be registered, the isomer proportion needs to be specified. (4) If active ingredient exists in the form of certain salt, the name and quality percentage of products will be represented with the actual existence. Meanwhile, the active parts and the content of paired counter-ions shall be labeled. (5) There is an acceptable fluctuation scope for the content of the products whose content is represented with effective dose (for example, the content of electro-thermal mosquito repellent incense slice is represented with “mg/slice”). First, the content is converted into quality percentage; then, an appropriate corresponding value is chosen from Annotation ②; (6) As far as incense coil is concerned, the acceptable fluctuation scope of the content of its active ingredient shall not be higher than 40% or lower than 20% of the labeled content.	●
	6.3 Content of relevant impurities	The maximum content of the products with relevant impurities shall be specified and represented with quality percentage.	●
	6.4 Content of other restrictive components	The content of the products with other restrictive components like safener, stabilizer and synergist shall consist of labeled content and acceptable fluctuation content. The acceptable fluctuation scope is shown in	●

		Annotation ②.			
	6.5 Other control items and indexes ③④ related to dosage form	(1) Different dosage forms need the technical indexes consistent with their features; (2) The dosage forms that are not specified in this requirement can be specified according to the specification requirements by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The control items of innovative dosage forms can be defined according to the features, utilization method and safety of active ingredients. Meanwhile, the information about the appraisal test on dosage form shall be submitted.	●		
	7. Test methods for the quality control items of products and method confirmation				
	7.1 Test methods of identifying the active ingredients of products⑤	At least one test method shall be adopted to identify active ingredients. If the chemical method is used for the identification, at least two identification test methods shall be offered. If active ingredients exist in the form of certain salt, the identification test method shall be able to identify the type of salt.	●		
	7.2 Methods of testing active ingredients, relevant impurities, and other restrictive components like safener, stabilizer and synergist and method confirmation	(1) Test methods: Complete test methods shall be provided. The test methods usually include method summary, principle, information about samples, reference materials, apparatus, agents, solution preparation, operation conditions, test procedure, calculation for results, statistical methods, and allowable deviation; (2) Method confirmation: It shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●		
	7.3 Test methods of other technical indexes	They shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●		
	8. Information about the confirmation of quality specification of products	Make necessary explanation for the basis and rationality of technical indexes.	●		
	9. Data of the test on the stability of storage at the room temperature	(1) The data of the test on the stability at the room temperature of at least a batch of samples shall be provided;	●	×	●

		(2) The same products wrapped with different materials shall be tested for the stability at the room temperature respectively; (3) Usually, samples are stored under specific conditions for two years in the test on the stability at the room temperature.			
	10. Product quality test report and the test method demonstration report⑥	(1) The product quality test report shall include all the items as specified in the product quality specification; (2) The methods of testing the contents of active ingredients, relevant impurities and other restrictive components like safener, stabilizer and synergist shall be demonstrated by the registration test unit which issues the product quality test report. Meanwhile, the test method demonstration report shall also be issued. The test methods of other control items can be exempted from the method demonstration. (3) The test method demonstration report includes the test conditions proposed by the consignor, the test conditions (such as chromatographic condition and sample preparation) of the registration test unit and the explanation for any change, and all the results, standard deviation and typical map (including reference materials and samples) of the parallel test. Meanwhile, the feasibility of the test methods shall be evaluated.	●		
	11. Packing (material, shape, size and net content), storage and transport, safety warning, and quality assurance period				
	11.1 Packing and storage and transport	The applicant shall select appropriate packing materials, package sizes and transport tools according to the hazard category of products. The matters worthy of attention for the transport and storage shall be defined according to the state laws and regulations on safe production, storage and transport.	●		
	11.2 Safety warning	The hazard degree of products is evaluated and classified according to the data about the physicochemical properties of products and the hazard classification standards of chemicals. Moreover, it is made public in the form of label and material safety data sheet (MSDS).	●		
	11.3 Quality assurance period	An appropriate product quality assurance period is defined according to the data of the test on the stability	●		

		at the room temperature.				
Toxicology	1. Data of the test on acute oral toxicity⑦		●	×	●	
	2. Data of the test on acute percutaneous toxicity⑦		●	×	●	
	3. Data of the test on acute inhalation toxicity⑦⑧		●	×	●	
	4. Data of the test on eye irritation⑦		●	×	●	
	5. Data of the test on skin irritation⑦		●	×	●	
	6. Data of the test on skin sensitization⑦		●	×	●	
	7. The advanced test for the health risk evaluation⑥	If the supplementary toxicological data require biochemical agrochemical technical and, according to the preliminary health risk evaluation, if the risk of agrochemicals on human health is unacceptable, the corresponding data of the advanced test can be offered. The advanced test data about household health pesticides include but not limited to the resident exposure model test, and the advanced test data about the environmental health pesticides include but not limited to the pesticide user exposure test.	●	×	●	×	●
	8. Heath risk evaluation report	If the supplementary toxicological data require biochemical agrochemical technical, the data shall be offered. For the household health pesticides, the resident health risk evaluation report shall be submitted. For the environmental health pesticides, the pesticide user health risk evaluation report shall be submitted.	●	×	●	×	●
Efficacy	1. Benefit analysis					
	1.1 Application for use site and the information about target organisms	The features and harm of target organisms, their distribution in China, the rules of occurrence, and their threat to human health.	●				
	1.2 Analysis of the value and strength of products	The method and cost of using the products to be registered and the benefits the products bring to human health, safety and environment; the function and use of the products to be registered and the mutual compatibility between the products and the current	●				

		measures for controlling harmful organisms; the information about the existing registered products whose functions are to be registered; the comparative analysis with existing registered products or common medicine; the role in the resistance management of existing registered products; the possibility to substitute the agrochemicals with higher risk.					
	2. Data of the efficacy test						
	2.1 Data of the test on indoor bioactivity	Action method, action spectrum, action mechanism or action mechanism prediction analysis (for the formulation of new agrochemicals only); indoor activity test report (for the single-dose products involving new targets of prevention and treatment); the purpose of mixture and the report on indoor formula selection (for the mixture formulation).	●	×	●	×	●
	2.2 Report on the indoor efficacy measurement test⑥	The report on the 1-year indoor efficacy measurement test in two provincial administrative regions in China.	●⑨				
	2.3 Report on the simulated on-site test⑥	The report on the 1-year simulated on-site test in two provincial administrative regions in China.	●⑩				
	2.4 Report on the on-site test⑥	The report on the 1-year on-site test in two provincial administrative regions in China (one in South China and the other in North China; in case of harmful organisms in some regions, both can either be in South China or North China).	●⑪				
	3.Features of utilization	Product features and the matters worthy of attention in the use.	●				
	4.Comprehensive evaluation report	Summary of all the data about efficacy.	●				
Environmental impact ⑫	1.Data of the test on the acute oral toxicity for birds		●	×	●		
	2.Data of the test on the acute contact toxicity for bees⑬		●	×	●		
	3.Data of the test on the acute toxicity for fishes		●	×	●		
	4.Data of the test on the acute activity inhibition for daphnia magna		●	×	●		

Notes:

① If the biochemical agrochemical technical (TK) which is exempted from registration is used for the processing of formulation, the (full) component analysis test report of the technical (TK) and the complete processing and quality control items and their indexes shall be submitted. If the registration of the adopted biochemical agrochemical technical (TK) has been approved by the examining and approving organizations of medicine, food and health products, the submission of the above data will not be compulsory; however, the copy of the registration certificate and the product quality standards shall be submitted.

② Requirement on the content scope (X, % or g/100mL, 20℃±2℃) of active ingredients in the products.

X≤2.5	±15%X (suitable for well-proportioned formulations like missible oil, suspension concentrate and soluble concentrate)
	±25%X (suitable for poor-proportioned formulations like granules and water dispersible granule)
2.5<X≤10	±10%X
10<X≤25	±6%X
25<X≤50	±5%X
X>50	±2.5%或 2.5g/100mL

③The common test condition of thermal storage stability is (54±2)℃ for 2 weeks. The alternative conditions as follows: (50±2)℃ for 4 weeks; (45±2)℃ for 6 weeks; (40±2)℃ for 8 weeks; (35±2)℃ for 12 weeks; (30±2)℃ for 18 weeks. Reasons should be given if the alternative conditions are chosen.

④Normally, the freezing and melting stability test should be cycled for four times between (-10±2)℃ and (20±2)℃. Each cycle includes 18 hours of freezing and 6 hours of melting.

⑤If the sanitation-oriented agrochemical preparation with a content of lower than 1% involves isomer resolution and there is the information about the discrimination test on active ingredients of products (including the discrimination of isomer), it is unnecessary to provide corresponding isomer resolution methods and the method demonstration report. However, the submitted data shall include the following information:

-If the content of active ingredient in the product refers to certain isomer, the content of active ingredient should be result of multiplying the total content with the proportion coefficient of active isomer in the adopted technical or TK;

-If active ingredient consists of more than one isomer of different proportions, the total content and the proportions of different isomers should be specified;

-The discrimination test should specify the proportion scope of isomer in technical or TK as well as the resolution method and chromatogram of technical or TK isomer.

⑥It shall be finished in China in accordance with Article 16 of the Agrochemical Registration Management Measures.

⑦As for sanitation-oriented agrochemicals, the data of the toxicological test shall be provided according to dosage form. The specific requirements are as follows:

a. Mosquito-repellent incense and electro-thermal mosquito repellent incense slice: acute inhalation toxicity;

b. Aerosol: acute inhalation toxicity, eye irritation and skin irritation;

c. Electro-thermal mosquito repellent liquid: acute oral toxicity, acute percutaneous toxicity and acute inhalation toxicity;

d. Repellent: acute oral toxicity, acute percutaneous toxicity, acute inhalation toxicity, eye irritation, and several skin irritation and sensitization tests;

e. Other dosage forms: acute oral toxicity, acute percutaneous toxicity, acute inhalation toxicity, eye irritation, skin irritation and sensitization tests.

Corresponding test items can be added or reduced according to special dosage form and active ingredient.

⑧For the products which meet one of the following conditions, the data of the test on acute inhalation toxicity shall be provided:

a. Gas or liquefied gas;

b. Fuming preparation or steaming preparation;

c. The preparation which adopts nebulization equipment for agrochemical application;

d. Steam release preparation;

e. Aerosol;

f. The preparation whose particles (with a diameter of less than 50um) account for a large proportion (weight>1%);

g. Airplane-based agrochemical application may generate inhalable preparation;

h. The preparation whose vapor pressure of active ingredient is higher than 1×10-2Pa and which may be used in confined space like warehouses or greenhouses;

i. The preparation whose particles (with a diameter of less than 50μm) or small drops which account for a large proportion (weight>1%) can be generated according to the use.

⑨It is unnecessary to provide the products that cannot be used for the indoor efficacy test, including the ultra-low volume spray and hot fogging concentrate spray.

⑩It is unnecessary to provide the products for the indoor residual spraying after coating, spreading, repelling, mothproof and dilution or the products which cannot be used in the simulated on-site test.

⑪The on-site test reports on snail killer, termite control agent, grain storage pest control agent, ultra-low volume preparation, hot fogging concentrate, outdoor mosquito (larva) repellent, fly (larva) and other preparations for exterior use need to be provided. That of other products is provided according to need.

⑫Adequate data have shown that if the possibility of contact between agrochemical and certain environmental organism is extremely low, the test can be exempted through application. The environmental data of the pesticides for indoor use and the mosquito-repelling products which can be rubbed on human body can be exempted.

⑬It is unnecessary to provide the sanitation-oriented agrochemicals not for spraying, including granules, soil treatment herbicides and baits.

3. Sanitation-oriented microbial pesticide formulation

Registration Category	1. Type D: New agrochemical formulations, including the one which have not been authorized for the first time within the 6-year protection period; 2. Type E: New dosage form; 3. Type F: New content; 4. Type G: New mixed formulation; 5. Type H: New use scope; 6. Type I: New use method; 7. Type L: Similar formulation and same use scope and use method; 8. Type M: Similar formulation but different use scope and use method. Note: "●" indicates "Necessary", and "✖" means "Unnecessary".

Data Category	Data Item	Explanation and Description	D	E	F	G	H	I	L	M
Basic data	1. Application form	It shall be filled according to the application form issued by the Ministry of Agriculture.					●			
	Data Item	Explanation and Description					●			
	1. Application form	It shall be filled according to the application form issued by the Ministry of Agriculture.					●			
	2. Documents of the applicant	(1) The copies of the production license and the business license with the official seal and the standard social credit codes submitted by agrochemical producers; (2) The information about new agrochemical developers' application for agrochemical registration; (3) The identification document of overseas enterprises, the information about the registration and use in relevant countries and regions, the information about the establishment of offices or agencies in China and the business license.								
	3. Declaration of the applicant	The declaration for the reliability and legality of the application materials.					●			
	4. Summary report	Summary of the risk evaluation report on the meal, occupational health and environment of products.					●			
	4.1 Introduction to products	The brief introduction including the place of origin, chemistry, effect, toxicology, environmental impact, and overseas registration of products.					●			
	4.2 Summary of the risk evaluation report	The risk evaluation summary including the occupational health and environment of products.					●			

	4.3 Summary of the benefit analysis report	The summary including the analysis of the economic, social and environmental benefits of products.	●
	5. Label and instruction	The samples of the label and instruction made in accordance with Regulations on the Label and Instruction of Agrochemicals.	●
	6. Other documents related to the registration	(1) The information about the chemistry, efficacy, residual, toxicology and environmental impact of products or the comprehensive inquiry report in other countries or regions; (2) The basis of the naming of the active ingredients of new agrochemicals; (3) For the new dosage forms which have not be stipulated in the national standards, the applicant should submit the basis of naming and the appraisal report; (4) The information about the sources of technical.	●
Product chemistry and biological features①	8. References	The sources of quotations should be given.	●
	2.Basic information about TK	Provide the information about the producers, registration, quality control items and indexes of the adopted TK.	●
	1. Identification of active ingredients and safener, stabilizer, synergist and other restrictive components	(1) The general names of active ingredients and other restrictive components like safener, stabilizer and synergist; the names approved by the International Standard Organization (ISO) and the general names, chemical names and the accession number of American Chemical Abstracts (CAS number) in other international organizations and countries; the digital codes, development numbers, molecular formula, structural formula, isomer composition, relative molecular mass or molecular mass scope (with the issuance time of the International relative atomic mass	●

		index for the calculation) of the Collaborative International Pestricides Analytical Committee (CIPAC); (2) If the active ingredients exist in the form of certain salt, the data about the identification of corresponding derivatives shall be offered.	
	4.Description of the processing method		
	4.1 Process flow chart		●
	4.2 Quantity of components and the sequence of their use		●
	4.3 Main equipment and operation conditions		●
	4.4 Description of the quality control measures in the production		●
	5. Physicochemical properties	(1) Physicochemical properties include appearance (color, state and smell), density, and the corrosiveness to packing materials. For the products which require designated assistants in their use, the information about the mixture of the products and the designated assistants must be offered. (2) The measurement report on relevant physicochemical properties shall be offered according to product features and in accordance with the Guidelines of the Measurement Test on Physicochemical Properties of Agrochemicals.	●
	6. Production quality specification	The product quality specification shall meet the following requirements during the quality assurance period.	
	6.1 Appearance	The color, state and smell of products shall be clearly described.	●
	6.2 Content of active ingredient	(1) It is usually represented with the quantity of the microorganisms in the unit quality or volume products. The microorganism content units are defined according to measurement methods, including the quantity of spore, international toxicity unit (ITU), international unit (IU), Colony-Forming Units (CFU) and inclusion body (IB) or occlusion body (OB); (2) The minimum content of active ingredient shall be specified.	●

	6.3 Content of micro-organic pollutants and harmful impurities	The maximum content of micro-organic pollutants and harmful impurities in products shall be specified.	●
	6.4 Content of other restrictive components	The content of the products with other restrictive components like safener, stabilizer and synergist shall consist of labeled content and acceptable fluctuation content. The acceptable fluctuation scope meets the requirement on sanitation-oriented chemical pesticides.	●
	6.5 Other control items and indexes related to dosage form	(1) Different dosage forms need the technical indexes consistent with their features; (2) The dosage forms that are not specified in this requirement can be specified according to the specification requirements by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The control items of innovative dosage forms can be defined according to the features, utilization method and safety of active ingredients. Meanwhile, the information about the appraisal test on dosage form shall be submitted.	●
	7. Test methods for the quality control items of products and method confirmation		
	7.1 Test methods of identifying the active ingredients of products	Necessary maps, photos or sequences shall be described and provided from such aspects as morphological characteristics, physiological and biochemical response characteristics, serological reaction, and molecular biology (protein and DNA).	●
	7.2 Methods of testing active ingredients, micro-organic pollutants and harmful impurities, and other restrictive components like safener, stabilizer and synergist and method confirmation	(1) Test methods: Complete test methods shall be provided. The test methods usually include method summary, principle, information about samples, reference materials, apparatus, agents, solution preparation, operation conditions, test procedure, calculation for results, statistical methods, and allowable deviation;(2) Method confirmation: It shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●
	7.3 Test methods of other technical indexes	They shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●
	8. Information about the confirmation of quality specification of products	Make necessary explanation for the basis and rationality of technical indexes.	●

	9.Stability of storage	(1) The data of the test on the storage stability at the room temperature of at least a batch of samples shall be provided, such as one-year storage at 20-25℃ or two-year storage at 0-5℃. (2) The same products wrapped with different materials shall be tested for the storage stability at the room temperature respectively; (3) Usually, it is unnecessary to submit the data of the test on thermal storage stability.	●
	10. Product quality test report and the test method demonstration report②	(1) The product quality test report shall include all the items as specified in the product quality specification; (2) The methods of testing the contents of active ingredients, mirco-organic pollutants, harmful impurities and other restrictive components like safener, stabilizer and synergist shall be demonstrated by the registration test unit which issues the product quality test report. Meanwhile, the test method demonstration report shall also be issued. The test methods of other control items can be exempted from the method demonstration. (3) The test method demonstration report includes the test conditions proposed by the consignor, the test conditions (such as chromatographic condition and sample preparation) of the registration test unit and the explanation for any change, and all the results, standard deviation and typical map (including reference materials and samples) of the parallel test. Meanwhile, the feasibility of the test methods shall be evaluated.	●
	11. Packing (material, shape, size and net content), storage and transport, safety warning, and quality assurance period		
	11.1 Packing and storage and transport	The applicant shall select appropriate packing materials, package sizes and transport tools according to the hazard category of products. The matters worthy of attention for the transport and storage shall be defined according to the state laws and regulations on safe production, storage and transport.	●
	11.2 Safety warning	The hazard degree of products is evaluated and classified according to the data about the physicochemical properties of products and the hazard classification standards of chemicals. Moreover, it is	●

		made public in the form of label and material safety data sheet (MSDS).			
	11.3 Quality assurance period	An appropriate product quality assurance period is defined according to the data of the test on the stability at the room temperature.	●		
Toxicology	1. Data of the test on acute oral toxicity③		●		
	2. Data of the test on acute percutaneous toxicity③		●		
	3. Data of the test on acute inhalation toxicity③④		●		
	4. Data of the test on eye irritation③		●		
	5. Data of the test on skin irritation③		●		
	6. Data of the test on skin sensitization③		●		
	7. The advanced test for the health risk evaluation②	If the supplementary toxicological data require biochemical agrochemical technical and, according to the preliminary health risk evaluation, if the risk of agrochemicals on human health is unacceptable, the corresponding data of the advanced test can be offered. The advanced test data about household health pesticides include but not limited to the resident exposure model test, and the advanced test data about the environmental health pesticides include but not limited to the pesticide user exposure test.	●	✖	●
	8. Heath risk evaluation report	If the supplementary toxicological data require biochemical agrochemical technical, the data shall be offered. For the household health pesticides, the resident health risk evaluation report shall be submitted. For the environmental health pesticides, the pesticide user health risk evaluation report shall be submitted.	●	✖	●
Efficacy	1. Benefit analysis				
	1.1 Application for use site and the information about target organisms	The features and harm of target organisms, their distribution in China, the rules of occurrence, and their	●		

		threat to human health.				
	1.2 Analysis of the value and strength of products	The method and cost of using the products to be registered and the benefits the products bring to human health, safety and environment; the function and use of the products to be registered and the mutual compatibility between the products and the current measures for controlling harmful organisms; the information about the existing registered products whose functions are to be registered; the comparative analysis with existing registered products or common medicine; the role in the resistance management of existing registered products; the possibility to substitute the agrochemicals with higher risk.	●			
	2. Data of the efficacy test					
	2.1 Data of the test on indoor bioactivity	Action method, action spectrum, action mechanism or action mechanism prediction analysis (for the formulation of new agrochemicals only); indoor activity test report (for the single-dose products involving new targets of prevention and treatment); the purpose of mixture and the report on indoor formula selection (for the mixture formulation).	●	✖	✖	●
	2.2 Report on the indoor efficacy measurement test②	The report on the 1-year indoor efficacy measurement test in two provincial administrative regions in China.	●⑤			
	2.3 Report on the simulated on-site test②	The report on the 1-year simulated on-site test in two provincial administrative regions in China.	●⑥			
	2.4 Report on the on-site test②	The report on the 1-year on-site test in two provincial administrative regions in China (one in South China and the other in North China; in case of harmful organisms in some regions, both can either be in South China or North China).	●⑦			
	3.Features of utilization	Product features and the matters worthy of attention in the use.	●			
	4.Comprehensive evaluation report	Summary of all the data about efficacy.	●			
Environmental impact⑧	1.Data of the test on the acute oral toxicity for birds		●			●
	2.Data of the test on the acute contact toxicity for bees⑨		●			●
	3.Data of the test on the acute toxicity for silkworms②⑨		●			●

	4.Test on the acute toxicity for fishes		●	●
	5.Test on the acute activity inhibition for daphnia magna		●	●

Notes:

① If the micro-organic TK which is exempted from registration is used for the processing of formulation, the strain appraisal report, strain code and strain description of the TK, the complete production technology, the component analysis test report and the data of the test on stability (sensitivity to temperature and pH value), quality control items and their indexes shall be submitted.

If the registration of the adopted micro-organic TK has been approved by the examining and approving organizations of medicine, food and health products, the submission of the above data will not be compulsory; however, the copy of the registration certificate and the product quality standards shall be submitted.

② It shall be finished in China in accordance with Article 16 of the Agrochemical Registration Management Measures.

③ As for sanitation-oriented agrochemicals, the data of the toxicological test shall be provided according to dosage form. The specific requirements are as follows:

a. Mosquito-repellent incense and electro-thermal mosquito repellent incense slice: acute inhalation toxicity;

b. Aerosol: acute inhalation toxicity, eye irritation and skin irritation test;

c. Electro-thermal mosquito repellent liquid: acute oral toxicity, acute percutaneous toxicity and acute inhalation toxicity;

d. Repellent: acute oral toxicity, acute percutaneous toxicity, acute inhalation toxicity, eye irritation, and several skin irritation and sensitization tests;

e. Other dosage forms: acute oral toxicity, acute percutaneous toxicity, acute inhalation toxicity, eye irritation, skin irritation and sensitization tests.
Corresponding test items can be added or reduced according to special dosage form and active ingredient.

④ For the products which meet one of the following conditions, the data of the test on acute inhalation toxicity shall be provided:

a. Gas or liquefied gas;

b. Fuming preparation or steaming preparation;

c. The preparation which adopts nebulization equipment for agrochemical application;

d. Steam release preparation;

e. Aerosol;

f. The preparation whose particles (with a diameter of less than 50um) account for a large proportion (weight>1%);

g. Airplane-based agrochemical application may generate inhalable preparation;

h. The preparation whose vapor pressure of active ingredient is higher than 1×10-2Pa and which may be used in confined space like warehouses or greenhouses;

i. The preparation whose particles (with a diameter of less than 50μm) or small drops which account for a large proportion (weight>1%) can be generated according to the use.

⑤ It is unnecessary to provide the products that cannot be used for the indoor efficacy test, including the ultra-low volume spray and hot fogging concentrate spray.

⑥ It is unnecessary to provide the products for the indoor residual spraying after coating, spreading, repelling, mothproof and dilution or the products which cannot be used in the simulated on-site test.

⑦ The on-site test reports on snail killer, termite control agent, grain storage pest control agent, ultra-low volume preparation, hot fogging concentrate, outdoor mosquito (larva) repellent, fly (larva) and other preparations for exterior use need to be provided. That of other products is provided according to need.

⑧ Adequate data have shown that if the possibility of contact between agrochemical and certain environmental organism is extremely low, the test can be exempted through application. The environmental data of the sanitation-oriented pesticides for indoor use can be exempted.

⑨ It is unnecessary to provide the sanitation-oriented agrochemicals not for spraying, including granules, soil treatment herbicides and baits.

4. Sanitation-oriented botanical pesticide formulation

Registration Category	1. Type D: New agrochemical formulations, including the one which have not been authorized for the first time within the 6-year protection period; 2. Type E: New dosage form; 3. Type F: New content; 4. Type G: New mixed formulation; 5. Type H: New use scope; 6. Type I: New use method; 7. Type L: Similar formulation and same use scope and use method; 8. Type M: Similar formulation but different use scope and use method. Note: "●" indicates "Necessary", and "✖" means "Unnecessary".

Data Category	Data Item	Explanation and Description	D	E	F	G	H	I	L	M
Basic data	1. Application form	It shall be filled according to the application form issued by the Ministry of Agriculture.					●			
	2. Documents of the applicant	(1) The copies of the production license and the business license with the official seal and the standard social credit codes submitted by agrochemical producers; (2) The information about new agrochemical developers' application for agrochemical registration; (3) The identification document of overseas enterprises, the information about the registration and use in relevant countries and regions, the information about the establishment of offices or agencies in China and the business license.								
	3. Declaration of the applicant	The declaration for the reliability and legality of the application materials.					●			
	4. Summary report	Summary of the risk evaluation report on the meal, occupational health and environment of products.					●			
	4.1 Introduction to products	The brief introduction including the place of origin, chemistry, effect, toxicology, environmental impact, and overseas registration of products.					●			
	4.2 Summary of the risk evaluation report	The risk evaluation summary including the occupational health and environment of products.					●			
	4.3 Summary of the benefit analysis report	The summary including the analysis of the economic, social and environmental benefits of products.					●			
	5. Label and instruction	The samples of the label and instruction made in accordance with Regulations on the Label and Instruction of Agrochemicals.					●			

	6. Other documents related to the registration	(1) The information about the chemistry, efficacy, residual, toxicology and environmental impact of products or the comprehensive inquiry report in other countries or regions; (2) The basis of the naming of the active ingredients of new agrochemicals; (3) For the new dosage forms which have not be stipulated in the national standards, the applicant should submit the basis of naming and the appraisal report; (4) The information about the sources of technical.	●
Product chemistry ①	8. References	The sources of quotations should be given.	
	1.1 Product name	For the botanical agrochemicals which are extracted from a plant, they can be named with the active ingredient or in the form “the general name of the plant used as the raw material + extract”. However, the representative active ingredient shall be marked. For those extracted from several plants, they shall be named with the representative active ingredient.	●
	1. Identification of active ingredients and safener, stabilizer, synergist and other restrictive components	(1) The general names of active ingredients and other restrictive components like safener, stabilizer and synergist; the names approved by the International Standard Organization (ISO) and the general names, chemical names and the accession number of American Chemical Abstracts (CAS number) in other international organizations and countries; the digital codes, development numbers, molecular formula, structural formula, isomer composition, relative molecular mass or molecular mass scope (with the issuance time of the International relative atomic mass index for the calculation) of the Collaborative International Pestricides Analytical Committee (CIPAC);(2) If the active ingredients exist in the form of certain salt, the data about the identification of corresponding derivatives shall be offered.	●
	2.Basic information about TK	Provide the information about the producers, registration, quality control items and indexes of the adopted TK.	●
	3.Product composition	(1) The chemical names, numbers of American Chemical Abstracts (CAS number), molecular formula, structural formula, contents and functions of the components for the processing of the formulation. For the mixed solvents and assistants represented with codes, the information about their composition, sources and safety (such as the material safety data sheet (MSDS)) shall be offered. For the assistants with special functions, including safener, stabilizer and synergist, the information about their quality specification, basic physicochemical properties, sources, safety (such as the material safety data sheet (MSDS)) and domestic and overseas use shall be offered; (2) For the separately-wrapped assistants (designated ones) added in the on-site solution preparation, their composition and the above information shall be separately offered.	●
	4.Description of the processing method		

	4.1 Process flow chart		●
	4.2 Quantity of components and the sequence of their use		●
	4.3 Main equipment and operation conditions		●
	4.4 Description of the quality control measures in the production		●
	5. Physicochemical properties	(1) Physicochemical properties include appearance (color, state and smell), density, viscosity, oxidizability/reducibility, the corrosiveness to packing materials, the compatibility with nonpolar organic solvents (applicable to the dosage form for the dilution with organic solvents), explosiveness, and combustibility. For the products which require designated assistants in their use, the information about the mixture of the products and the designated assistants must be offered. (2) The measurement report on the physicochemical properties shall be offered in accordance with the Guidelines of the Measurement Test on Physicochemical Properties of Agrochemicals. If specific parameters are not suitable for products, the explanation shall be offered.	●
	6. Production quality specification	The product quality specification shall meet the following requirements during the quality assurance period.	
	6.1 Appearance	The color, state and smell of products shall be clearly described.	●
	6.2 Content of active ingredient	(1) The content of active ingredient consists of labeled content and the scope of acceptable fluctuation. The acceptable fluctuation shall not exceed ±25% of the labeled content. (2) If active ingredient exists in the form of certain salt, the name and quality percentage of products will be represented with the actual existence. Meanwhile, the active parts and the content of paired counter-ions shall be labeled.	●
	6.3 Content of relevant impurities	The maximum content of the products with relevant impurities shall be specified and represented with quality percentage.	●
	6.4 Content of other restrictive components	The content of the products with other restrictive components like safener, stabilizer and synergist shall consist of labeled content and acceptable fluctuation content. The acceptable fluctuation scope meets the requirement on sanitation-oriented chemical pesticides.	●
	6.5 Other control items and indexes related to dosage form	(1) Different dosage forms need the technical indexes consistent with their features; (2) The dosage forms that are not specified in this requirement can be specified according to the specification requirements by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The control items of innovative dosage forms can be defined according to the features, utilization method and safety of active ingredients. Meanwhile, the information about the appraisal test on dosage form shall be submitted.	●

	7. Test methods for the quality control items of products and method confirmation		
	7.1 Test methods of identifying the active ingredients or the representative ones of products	(1) At least one test method shall be adopted to identify the active ingredients of technical for the processing of formulation. If the chemical method is used for the identification, at least two identification test methods shall be offered. (2) If TK is used for the processing of formulation, the characteristic peak and retention time in the "chemical fingerprint" map of the formulation shall be adopted for the identification of products.	●
	7.2 Methods of testing active ingredients or representative ones, relevant impurities, and other restrictive components like safener, stabilizer and synergist and method confirmation	(1) Test methods: Complete test methods shall be provided. The test methods usually include method summary, principle, information about samples, reference materials, apparatus, agents, solution preparation, operation conditions, test procedure, calculation for results, statistical methods, and allowable deviation;(2) Method confirmation: It shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●
	7.3 Test methods of other technical indexes	They shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●
	8. Information about the confirmation of quality specification of products	Make necessary explanation for the basis and rationality of technical indexes.	●
	9. Data of the test on the stability of storage at the room temperature	(1) The data of the test on the storage stability at the room temperature of at least a batch of samples shall be provided. (2) The same products wrapped with different materials shall be tested for the storage stability at the room temperature respectively; (3) Usually, samples are stored under specific conditions for two years in the test on the stability at the room temperature.	●
	10. Product quality test report and the test method demonstration report②	(1) The product quality test report shall include all the items as specified in the product quality specification; (2) The methods of testing the contents of active ingredients or representative ones, relevant impurities and other restrictive components like safener, stabilizer and synergist shall be demonstrated by the registration test unit which issues the product quality test report. Meanwhile, the test method demonstration report shall also be issued. The test methods of other control items can be exempted from the method demonstration. (3) The test method demonstration report includes the test conditions proposed by the consignor, the test conditions (such as chromatographic condition and sample preparation) of the registration test unit and the explanation for any change, and all the results, standard deviation and typical map (including reference materials and samples) of the parallel test. Meanwhile, the feasibility of the test methods shall be evaluated.	●
	11. Packing (material, shape, size and net content), storage and transport, safety warning, and quality assurance period		

	11.1 Packing and storage and transport	The applicant shall select appropriate packing materials, package sizes and transport tools according to the hazard category of products. The matters worthy of attention for the transport and storage shall be defined according to the state laws and regulations on safe production, storage and transport.	●		
	11.2 Safety warning	The hazard degree of products is evaluated and classified according to the data about the physicochemical properties of products and the hazard classification standards of chemicals. Moreover, it is made public in the form of label and material safety data sheet (MSDS).	●		
	11.3 Quality assurance period	An appropriate product quality assurance period is defined according to the data of the test on the stability at the room temperature.	●		
Toxicology	1. Data of the test on acute oral toxicity③		●		
	2. Data of the test on acute percutaneous toxicity③		●		
	3. Data of the test on acute inhalation toxicity③④		●		
	4. Data of the test on eye irritation③		●		
	5. Data of the test on skin irritation③		●		
	6. Data of the test on skin sensitization③		●		
	7. The data of the advanced test for the health risk evaluation②	If the botanical technical (TK) requires the whole set of toxicological data and, according to the preliminary health risk evaluation, if the risk of agrochemicals on human health is unacceptable, the corresponding data of the advanced test can be offered. The advanced test data about household health pesticides include but not limited to the resident exposure model test, and the advanced test data about the environmental health pesticides include but not limited to the pesticide user exposure test.	●	✖	●
	8. Heath risk evaluation report	If the botanical technical (TK) requires the whole set of toxicological data, the data shall be offered. For the household health pesticides, the resident health risk evaluation report shall be submitted. For the environmental health pesticides, the pesticide user health risk evaluation report shall be submitted.	●	✖	●
Efficacy	1. Benefit analysis				
	1.1 Application for use site and the information about target organisms	The features and harm of target organisms, their distribution in China, the rules of occurrence, and their threat to human health.	●		
	1.2 Analysis of the value and strength of products	The method and cost of using the products to be registered and the benefits the products bring to human health, safety and environment; the function and use of the products to be registered and the mutual compatibility between the products and the current measures for controlling harmful organisms; the information about the existing registered products whose functions are to be registered; the comparative analysis with existing registered products or common medicine; the	●		

		role in the resistance management of existing registered products; the possibility to substitute the agrochemicals with higher risk.				
	2. Data of the efficacy test					
	2.1 Data of the test on indoor bioactivity	Action method, action spectrum, action mechanism or action mechanism prediction analysis (for the formulation of new agrochemicals only); indoor activity test report (for the single-dose products involving new targets of prevention and treatment); the purpose of mixture and the report on indoor formula selection (for the mixture formulation).	●	✖	✖	●
	2.2 Report on the indoor efficacy measurement test②	The report on the 1-year indoor efficacy measurement test in two provincial administrative regions in China.	●⑤			
	2.3 Report on the simulated on-site test②	The report on the 1-year simulated on-site test in two provincial administrative regions in China.	●⑥			
	2.4 Report on the on-site test②	The report on the 1-year on-site test in two provincial administrative regions in China (one in South China and the other in North China; in case of harmful organisms in some regions, both can either be in South China or North China).	●⑦			
	3.Features of utilization	Product features and the matters worthy of attention in the use.	●			
	4.Comprehensive evaluation report	Summary of all the data about efficacy.	●			
Environmental impact⑧	1.Summary of the environmental data about TK (technical)		●	●		
	2.Data of the test on the acute oral toxicity for birds	The birds in the test shall be the ones which are sensitive in the technical test on the acute oral toxicity for birds.	●	●		
	3.Data of the test on the acute toxicity of fishes	The fishes in the test shall be the one which are sensitive in the technical test on the acute oral toxicity for fishes.	●	●		
	4. Data of the test on the acute activity inhibition for daphnia magna		●	●		
	5.Data of the test on the acute contact toxicity for bees⑨		●	●		
	6.Data of the test on the acute contact toxicity for bees⑨		●	●		
	7.Data of the test on the acute toxicity for silkworms②⑨		●	●		

Notes:

① If the TK of botanical agrochemicals, which is exempted from registration, is used for the processing of formulation, the complete production technology, the component analysis test report, quality control items and their indexes shall be submitted.

If the registration of the adopted TK of botanical agrochemicals has been approved by the examining and approving organizations of medicine, food and health products, the submission of the above data will not be compulsory; however, the copy of the registration certificate and the product quality standards shall be submitted.

② It shall be finished in China in accordance with Article 16 of the Agrochemical Registration Management Measures.

③ As for sanitation-oriented agrochemicals, the data of the toxicological test shall be provided according to dosage form. The specific requirements are as follows:

a. Mosquito-repellent incense and electro-thermal mosquito repellent incense slice: acute inhalation toxicity;

b. Aerosol: acute inhalation toxicity, eye irritation and skin irritation test;

c. Electro-thermal mosquito repellent liquid: acute oral toxicity, acute percutaneous toxicity and acute inhalation toxicity;

d. Repellent: acute oral toxicity, acute percutaneous toxicity, acute inhalation toxicity, eye irritation, and several skin irritation and sensitization tests;

e. Other dosage forms: acute oral toxicity, acute percutaneous toxicity, acute inhalation toxicity, eye irritation, skin irritation and sensitization tests.
Corresponding test items can be added or reduced according to special dosage form and active ingredient.

④ For the products which meet one of the following conditions, the data of the test on acute inhalation toxicity shall be provided:

a. Gas or liquefied gas;

b. Fuming preparation or steaming preparation;

c. The preparation which adopts nebulization equipment for agrochemical application;

d. Steam release preparation;

e. Aerosol;

f. The preparation whose particles (with a diameter of less than 50um) account for a large proportion (weight>1%);

g. Airplane-based agrochemical application may generate inhalable preparation;

h. The preparation whose vapor pressure of active ingredient is higher than 1×10-2Pa and which may be used in confined space like warehouses or greenhouses;

i. The preparation whose particles (with a diameter of less than 50μm) or small drops which account for a large proportion (weight>1%) can be generated according to the use.

⑤ It is unnecessary to provide the products that cannot be used for the indoor efficacy test, including the ultra-low volume spray and hot fogging concentrate spray.

⑥ It is unnecessary to provide the products for the indoor residual spraying after coating, spreading, repelling, mothproof and dilution or the products which cannot be used in the simulated on-site test.

⑦ The on-site test reports on snail killer, termite control agent, grain storage pest control agent, ultra-low volume preparation, hot fogging concentrate, outdoor mosquito (larva) repellent, fly (larva) and other preparations for exterior use need to be provided. That of other products is provided according to need.

⑧ Adequate data have shown that if the possibility of contact between agrochemical and certain environmental organism is extremely low, the test can be exempted through application. The environmental data of the sanitation-oriented pesticides for indoor use can be exempted.

⑨ It is unnecessary to provide the sanitation-oriented agrochemicals not for spraying, including granules, soil treatment herbicides and baits.

Attachment 4

Intertpretation and Specification of the Data Requirements for Rodenticide Formulation

1 Chemical rodenticide

Registration Category	1. Type D: New agrochemical formulations, including the one which have not been authorized for the first time within the 6-year protection period; 2. Type E: New dosage form; 3. Type F: New content; 4. Type G: New mixed formulation; 5. Type H: New use scope; 6. Type I: New use method; 7. Type J: Same formulation and same use scope and use method; 8. Type K: Same formulation but different use scopes and use methods; 9. Type L: Similar formulation and same use scope and use method; 10. Type M: Similar formulation but different use scope and use method. Note: "●" indicates "Necessary", and "✖" means "Unnecessary".											
Data Category	Data Item	Explanation and Description	D	E	F	G	H	I	J	K	L	M
Basic data	1. Application form	It shall be filled according to the application form issued by the Ministry of Agriculture.							●			
	2. Documents of the applicant	(1) The copies of the production license and the business license with the official seal and the standard social credit codes submitted by agrochemical producers; (2) The information about new agrochemical developers' application for agrochemical registration; (3) The identification document of overseas enterprises, the information about the registration and use in relevant countries and regions, the information about the establishment of offices or agencies in China and the business license.							●			
	3. Declaration of the applicant	The declaration for the reliability and legality of the application materials.										●
	4. Summary report											
	4.1 Introduction to products	The brief introduction including the place of origin, chemistry, effect, toxicology, environmental impact, and overseas registration of products.										●
	4.2 Summary of the risk evaluation report	The risk evaluation summary including the occupational health and environment of products.										●
	4.3 Summary of the benefit analysis report	The summary including the analysis of the economic, social and environmental benefits of products.										●
	5. Label and instruction	The samples of the label and instruction made in accordance with Regulations on the Label and Instruction of Agrochemicals.										●
	6. Other documents related to the registration	(1) The information about the chemistry, efficacy, residual, toxicology and environmental impact of products or the comprehensive inquiry report in other countries or regions; (2) The basis of the naming of the active ingredients of new agrochemicals; (3) For the new dosage forms which have not be stipulated in the national standards, the applicant shall submit the basis of naming and the appraisal report; (4) The information about the sources of technical.										●

	7. Material safety data sheet (MSDS)		●
	8. References	The sources of quotations shall be given.	●
Product chemistry	1. Identification of active ingredients and safener, stabilizer, synergist and other restrictive components	(1) The general names of active ingredients and other restrictive components like safener, stabilizer and synergist; the names approved by the International Standard Organization (ISO) and the general names, chemical names and the accession number of American Chemical Abstracts (CAS number) in other international organizations and countries; the digital codes, development numbers, molecular formula, structural formula, isomer composition, relative molecular mass or molecular mass scope (with the issuance time of the International relative atomic mass index for the calculation) of the Collaborative International Pestricides Analytical Committee (CIPAC); (2) If the active ingredients exist in the form of certain salt, the data about the identification of corresponding derivatives shall be offered.	●
	2. Basic information about technical (TK)	Provide the information about the producers, registration, quality control items and indexes of the adopted technical (TK).	●
	3. Product composition	(1) The chemical names, numbers of American Chemical Abstracts (CAS number), molecular formula, structural formula, contents and functions of the components for the processing of the formulation. For the mixed solvents and assistants represented with codes, the information about their composition, sources and safety (such as the material safety data sheet (MSDS)) shall be offered. For the assistants with special functions, including safener, stabilizer and synergist, the information about their quality specification, basic physicochemical properties, sources, safety (such as the material safety data sheet (MSDS)) and domestic and overseas use shall be offered; (2) For the separately-wrapped assistants (designated ones) added in the on-site solution preparation, their composition and the above information shall be separately offered.	●
	4. Description of the processing method		
	4.1 Process flow chart		●
	4.2 Quantity of components and the sequence of their use		●
	4.3 Main equipment and operation conditions		●
	4.4 Description of the quality control measures in the production		●
	5. Physicochemical properties	(1) Physicochemical properties include appearance (color, state and smell), density, viscosity, oxidizability/reducibility, the corrosiveness to packing materials, the compatibility with nonpolar organic solvents (applicable to the dosage form for the dilution with organic solvents), explosiveness, and combustibility. For the products which require designated assistants in their use, the information about the mixture of the products and the designated assistants must be offered. (2) The measurement report on the physicochemical properties shall be offered in accordance with the Guidelines of the Measurement Test on Physicochemical Properties of Agrochemicals. If specific parameters are not suitable for products, the explanation shall be offered.	●

	6. Production quality specification	The product quality specification should meet the following requirements during the quality assurance period.	
	6.1 Appearance	The color, state and smell of products shall be clearly described.	●
	6.2 Content of active ingredient	(1) The content of active ingredient consists of labeled content and the scope of acceptable fluctuation. Its requirements are shown in Annotation ①. The requirements on the content scope of other special products can be made according to Annotation ①; (2) The content of active ingredient is usually represented with quality percentage (%). The content of active ingredient of liquid formulation can be represented with quality concentration (g/L) or quality percentage (%). If it is represented with quality concentration, its quality percentage shall be offered at the same time; (3) If active ingredient exists in the isomer, the name and proportion of the isomer in the formulation shall be the same with that of the technical. If general name is adopted to define the active ingredient in the isomer, it will be unnecessary to repeatedly specify the isomer proportion in the control item; if general name has not defined the mixture to be registered, the isomer proportion needs to be specified. (4) If active ingredient exists in the form of certain salt, the name and quality percentage of products will be represented with the actual existence. Meanwhile, the active parts and the content of paired counter-ions shall be labeled.	●
	6.3 Content of relevant impurities	The maximum content of the products with relevant impurities shall be specified and represented with quality percentage.	●
	6.4 Content of other restrictive components	The content of the products with other restrictive components like safener, stabilizer and synergist shall consist of labeled content and acceptable fluctuation content. The acceptable fluctuation scope is shown in Annotation ①.	●
	6.5 Other control items and indexes ②③ related to dosage form	(1) Different dosage forms need the technical indexes consistent with their features; (2) The dosage forms that are not specified in this requirement can be specified according to the specification requirements by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The control items of innovative dosage forms can be defined according to the features, utilization method and safety of active ingredients. Meanwhile, the information about the appraisal test on dosage form shall be submitted.	●
	7. Test methods for the quality control items of products and method confirmation		
	7.1 Test methods of identifying the active ingredients of products	At least one test method shall be adopted to identify active ingredients. If the chemical method is used for the identification, at least two identification test methods shall be offered. If active ingredients exist in the form of certain salt, the identification test method shall be able to identify the type of salt.	●
	7.2 Methods of testing active ingredients, relevant impurities, and other restrictive components like safener, stabilizer and synergist and method confirmation	(1) Test methods: Complete test methods shall be provided. The test methods usually include method summary, principle, information about samples, reference materials, apparatus, agents, solution preparation, operation conditions, test procedure, calculation for results, statistical methods, and allowable deviation; (2) Method confirmation: It shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●

	7.3 Test methods of other technical indexes	They shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●		
	8. Information about the confirmation of quality specification of products	Make necessary explanation for the basis and rationality of technical indexes.	●		
	9. Data of the test on the stability of storage at the room temperature	(1) The data of the test on the stability at the room temperature of at least a batch of samples shall be provided; (2) The same products wrapped with different materials should be tested for the stability at the room temperature respectively; (3) Usually, samples are stored under specific conditions for two years in the test on the stability at the room temperature.	●	×	●
	10. Product quality test report and the test method demonstration report④	(1) The product quality test report shall include all the items as specified in the product quality specification; (2) The methods of testing the contents of active ingredients, relevant impurities and other restrictive components like safener, stabilizer and synergist should be demonstrated by the registration test unit which issues the product quality test report. Meanwhile, the test method demonstration report shall also be issued. The test methods of other control items can be exempted from the method demonstration. (3) The test method demonstration report includes the test conditions proposed by the consignor, the test conditions (such as chromatographic condition and sample preparation) of the registration test unit and the explanation for any change, and all the results, standard deviation and typical map (including reference materials and samples) of the parallel test. Meanwhile, the feasibility of the test methods shall be evaluated.	●		
	11. Packing (material, shape, size and net content), storage and transport, safety warning, and quality assurance period				
	11.1 Packing and storage and transport	The applicant shall select appropriate packing materials, package sizes and transport tools according to the hazard category of products. The matters worthy of attention for the transport and storage shall be defined according to the state laws and regulations on safe production, storage and transport.	●		
	11.2 Safety warning	The hazard degree of products is evaluated and classified according to the data about the physicochemical properties of products and the hazard classification standards of chemicals. Moreover, it is made public in the form of label and material safety data sheet (MSDS).	●		
	11.3 Quality assurance period	An appropriate product quality assurance period is defined according to the data of the test on the stability at the room temperature.	●		
Toxicology	1. Data of the test on acute oral toxicity		●	×	●
	2. Data of the test on acute percutaneous toxicity		●	×	●

	3. Data of the test on acute inhalation toxicity⑤		●		×		●	
	4. Data of the test on eye irritation		●		×		●	
	5. Data of the test on skin irritation		●		×		●	
	6. Data of the test on skin sensitization		●		×		●	
	7.Heath risk evaluation report		●		×	●	×	●
Efficacy	1. Benefit analysis							
	1.1 The information about the target organisms to be registered	The features and harm of target organisms, their distribution in China, the rules of occurrence, and their threat to human health.	●					
	1.2 Analysis of the value and strength of products	The method and cost of using the products to be registered and the benefits the products bring to human health, safety and environment; the function and use of the products to be registered and the mutual compatibility between the products and the current measures for controlling harmful organisms; the information about the existing registered products whose functions are to be registered; the comparative analysis with existing registered products or common medicine; the role in the resistance management of existing registered products; the possibility to substitute the agrochemicals with higher risk.	●					
	2. Data of the efficacy test							
	2.1 Data of the test on indoor bioactivity	Action method, action spectrum, action mechanism or action mechanism prediction analysis; other data are provided according to need.	●	×				
	2.2 Report of the indoor efficacy test④	The report of the 1-year indoor efficacy test on the poison for the prevention and treatment of commensal rodents in two provincial administrative regions.	●					
	2.3 Report on the simulated on-site test④	The report of the 1-year indoor efficacy test on the poison for the prevention and treatment of commensal rodents in two provincial administrative regions; the report of the 2-year indoor efficacy test on the poison for the prevention and treatment of field, wood and prairie rodents in two provincial administrative regions in China.	●	●⑥	●	●⑥	●	
	3. Features of utilization	Product features and the matters worthy of attention in the use.	●					
	4. Comprehensive evaluation report	Summary of all the data about efficacy.	●					
Residuals		It is unnecessary to provide the data about residuals, except the data about the rodenticides that are sprayed on an overall scale.	×					
Environmental impact⑦	1.Report on or summary of the technical environment test		●		×		●	

	2. Data of the test on the acute oral toxicity for birds	The birds in the test shall be the ones which are sensitive in the technical test on the acute oral toxicity for birds.	●	×	●
	3. Data of the test on the acute toxicity for fishes⑧	The fishes in the test shall be the one which are sensitive in the technical test on the acute oral toxicity for fishes.	●	×	●
	4. Other data of the advanced tests for the environmental risk evaluation	According to the preliminary environmental risk evaluation, if the risk of agrochemicals on certain target of protection is unacceptable, the corresponding data of the advanced test need to be offered.	●	×	●
	5. Report on environmental risk evaluation⑨	The possible environmental risk caused by the use of the recommended GAP is evaluated.	●	×	

Notes:

① Requirement on the content scope (X, % or g/100mL, 20℃±2℃) of active ingredients in the products.

X≤2.5 ±15%X (suitable for well-proportioned formulations like missible oil, suspension concentrate and soluble concentrate)
±25%X (suitable for poor-proportioned formulations like granules and water dispersible granule)

2.5<X≤10 ±10%X

10<X≤25 ±6%X

25<X≤50 ±5%X

X>50 ±2.5%或 2.5g/100mL

② The common test condition of thermal storage stability is (54±2)℃ for 2 weeks. The alternative conditions as follows: (50±2)℃ for 4 weeks; (45±2)℃ for 6 weeks; (40±2)℃ for 8 weeks; (35±2)℃ for 12 weeks; (30±2)℃ for 18 weeks. Reasons should be given if the alternative conditions are chosen.

③ Normally, the freezing and melting stability test should be cycled for four times between (-10±2)℃ and (20±2)℃. Each cycle includes 18 hours of freezing and 6 hours of melting.

④ It shall be finished in China in accordance with Article 16 of the Agrochemical Registration Management Measures.

⑤ For the products which meet one of the following conditions, the data of the test on acute inhalation toxicity shall be provided:

a. Gas or liquefied gas;

b. Fuming preparation or steaming preparation;

c. The preparation which adopts nebulization equipment for agrochemical application;

d. Steam release preparation;

e. Aerosol;

f. The preparation whose particles (with a diameter of less than 50um) account for a large proportion (weight>1%);

g. Airplane-based agrochemical application may generate inhalable preparation;

h. The preparation whose vapor pressure of active ingredient is higher than 1×10-2Pa and which may be used in confined space like warehouses or greenhouses;

i. The preparation whose particles (with a diameter of less than 50μm) or small drops which account for a large proportion (weight>1%) can be generated according to the use.

⑥ The 1-year report of the field efficacy test on the poison for the prevention and treatment of field, wood and prairie rodents in two places.

⑦ Adequate data have shown that if the possibility of contact between agrochemical and certain environmental organism is extremely low, the test can be exempted through application.

⑧ It is unnecessary to provide the rodenticides for the prevention and treatment of mice.

⑨ For the registration types beyond Types D, H and I, the applicant shall compare them with the registered products in terms of use and eco-toxicity. If the dose and frequency of application of the products to be registered are no higher than that of the registered products, if the application interval is no shorter than that of the registered products, and if the eco-toxicity is no stronger than that of the registered products, it is unnecessary to provide them.

2 Biochemical Rodenticide

Registration Category	1. Type D: New agrochemical formulations, including the one which have not been authorized for the first time within the 6-year protection period; 2. Type E: New dosage form; 3. Type F: New content; 4. Type G: New mixed formulation; 5. Type H: New use scope; 6. Type I: New use method; 7. Type L: Similar formulation and same use scope and use method; 8. Type M: Similar formulation but different use scope and use method. Note: "●" indicates "Necessary", and "✖" means "Unnecessary".

Data Classification	Data Item	Explanation and Description	D	E	F	G	H	I	L	M
Basic data	1. Application form	It shall be filled according to the application form issued by the Ministry of Agriculture.					●			
	2. Documents of the applicant	(1) The copies of the production license and the business license with the official seal and the standard social credit codes submitted by agrochemical producers; (2) The information about new agrochemical developers' application for agrochemical registration; (3) The identification document of overseas enterprises, the information about the registration and use in relevant countries and regions, the information about the establishment of offices or agencies in China and the business license.					●			
	3. Declaration of the applicant	The declaration for the reliability and legality of the application materials.					●			
	4. Summary report									
	4.1 Introduction to products	The brief introduction including the place of origin, chemistry, effect, toxicology, environmental impact, and overseas registration of products.					●			
	4.2 Risk evaluation report	The risk evaluation summary including the occupational health and environment of products.					●			
	4.3 Benefit analysis report	The summary including the analysis of the economic, social and environmental benefits of products.					●			
	5. Label and instruction	The samples of the label and instruction made in accordance with Regulations on the Label and Instruction of Agrochemicals.					●			
	6. Other documents related to the registration	(1) The information about the chemistry, efficacy, residual, toxicology and environmental impact of products or the comprehensive inquiry report in other countries or regions; (2) The basis of the naming of the active ingredients of new agrochemicals; (3) For the new dosage forms which have not be stipulated in the national standards, the applicant shall submit the basis of naming and the appraisal report; (4) The information about the sources of technical.					●			
	7. Material safety data sheet						●			

	8. References	The sources of quotations shall be given.	●
Product Chemistry ①	1. Identification of active ingredients and other restrictive components like safener, stabilizer and synergist	(1) The general names of active ingredients and other restrictive components like safener, stabilizer and synergist; the names approved by the International Standard Organization (ISO) and the general names, chemical names and the accession number of American Chemical Abstracts (CAS number) in other international organizations and countries; the digital codes, development numbers, molecular formula, structural formula, isomer composition, relative molecular mass or molecular mass scope (with the issuance time of the International relative atomic mass index for the calculation) of the Collaborative International Pestricides Analytical Committee (CAPAC); (2) If the active ingredients exist in the form of certain salt, the data about the identification of corresponding derivatives shall be offered.	●
	2. Basic information about technical (TK)	The information about the producer, registration, quality control item and index of the adopted technical (TK).	●
	3. Product composition	(1) The chemical names, numbers of American Chemical Abstracts (CAS number), molecular formula, structural formula, contents and functions of the components for the processing of the formulation. For the mixed solvents and assistants represented with codes, the information about their composition, sources and safety (such as the material safety data sheet (MSDS)) shall be offered. For the assistants with special functions, including safener, stabilizer and synergist, the information about their quality specification, basic physicochemical properties, sources, safety (such as the material safety data sheet (MSDS)) and domestic and overseas use shall be offered; (2) For the separately-wrapped assistants (designated ones) added in the on-site solution preparation, their composition and the above information shall be separately offered.	●
	4. Description of the processing method		
	4.1 Process flow chart		●
	4.2 Quantity of components and the sequence of their use		●
	4.3 Main equipment and operation conditions		●
	4.4 Description of the quality control measures in the production		●
	5. Physicochemical properties	(1) Physicochemical properties include appearance (color, state and smell), density, viscosity, oxidizability/reducibility, the corrosiveness to packing materials, the compatibility with nonpolar organic solvents (applicable to the dosage form for the dilution with organic solvents), explosiveness, and combustibility. For the products which require designated assistants in their use, the information about the mixture of the products and the designated assistants must be offered. (2) The measurement report on the physicochemical properties shall be offered in accordance with the Guidelines of the Measurement Test on Physicochemical Properties of Agrochemicals. If specific parameters are not suitable for products, the explanation shall be	●

		offered.	
	6. Production quality specification	The product quality specification shall meet the following requirements during the quality assurance period.	
	6.1 Appearance	The color, state and smell of products shall be clearly described.	●
	6.2 Content of active ingredient	(1) The content of active ingredient consists of labeled content and the scope of acceptable fluctuation, and the requirement is consistent with that on chemical rodenticide. The requirements on the content scope of other special products can be consistent with that on chemical rodenticide; (2) The content of active ingredient is usually represented with quality percentage (%). The content of active ingredient of liquid formulation can be represented with quality concentration (g/L) or quality percentage (%). If it is represented with quality concentration, its quality percentage shall be offered at the same time; (3) If active ingredient exists in the isomer, the name and proportion of the isomer in the formulation shall be the same with that of the technical. If general name is adopted to define the active ingredient in the isomer, it will be unnecessary to repeatedly specify the isomer proportion in the control item; if general name has not defined the mixture to be registered, the isomer proportion needs to be specified. (4) If active ingredient exists in the form of certain salt, the name and quality percentage of products will be represented with the actual existence. Meanwhile, the active parts and the content of paired counter-ions shall be labeled.	●
	6.3 Content of relevant impurities	The maximum content of the products with relevant impurities shall be specified and represented with quality percentage.	●
	6.4 Content of other restrictive components	The content of the products with other restrictive components like safener, stabilizer and synergist shall consist of labeled content and acceptable fluctuation content. The acceptable fluctuation scope is consistent with the requirement on chemical rodenticide.	●
	6.5 Other control items and indexes ②③ related to dosage form	(1) Different dosage forms need the technical indexes consistent with their features; (2) The dosage forms that are not specified in this requirement can be specified according to the specification requirements by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The control items of innovative dosage forms can be defined according to the features, utilization method and safety of active ingredients. Meanwhile, the information about the appraisal test on dosage form shall be submitted.	●
	7. Test methods for the quality control items of products and method confirmation		

	7.1 Test methods of identifying the active ingredients of products	At least one test method shall be adopted to identify active ingredients. If the chemical method is used for the identification, at least two identification test methods shall be offered. If active ingredients exist in the form of certain salt, the identification test method shall be able to identify the type of salt.	●
	7.2 Methods of testing active ingredients, relevant impurities, and other restrictive components like safener, stabilizer and synergist and method confirmation	(1) Test methods: Complete test methods shall be provided. The test methods usually include method summary, principle, information about samples, reference materials, apparatus, agents, solution preparation, operation conditions, test procedure, calculation for results, statistical methods, and allowable deviation; (2) Method confirmation: It shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●
	7.3 Test methods of other technical indexes	They shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●
	8. Information about the confirmation of quality specification of products	Make necessary explanation for the basis and rationality of technical indexes.	●
	9. Data of the test on the stability of storage at the room temperature	(1) The data of the test on the stability at the room temperature of at least a batch of samples shall be provided; (2) The same products wrapped with different materials should be tested for the stability at the room temperature respectively; (3) Usually, samples are stored under specific conditions for two years in the test on the stability at the room temperature.	●
	10. Product quality test report and the test method demonstration report④	(1) The product quality test report shall include all the items as specified in the product quality specification; (2) The methods of testing the contents of active ingredients, relevant impurities and other restrictive components like safener, stabilizer and synergist should be demonstrated by the registration test unit which issues the product quality test report. Meanwhile, the test method demonstration report shall also be issued. The test methods of other control items can be exempted from the method demonstration. (3) The test method demonstration report includes the test conditions proposed by the consignor, the test conditions (such as chromatographic condition and sample preparation) of the registration test unit and the explanation for any change, and all the results, standard deviation and typical map (including reference materials and samples) of the parallel test. Meanwhile, the feasibility of the test methods shall be evaluated.	●
	11. Packing (material, shape, size and net content), storage and transport, safety warning, and quality assurance period		
	11.1 Packing and storage and transport	The applicant shall select appropriate packing materials, package sizes and transport tools according to the hazard category of products. The matters worthy of attention for the transport and storage shall be defined according to the state laws and regulations on safe production, storage and transport.	●
	11.2 Safety warning	The hazard degree of products is evaluated and classified according to the data about the physicochemical properties of products and the hazard classification standards of chemicals.	●

		Moreover, it is made public in the form of label and material safety data sheet (MSDS).			
	11.3 Quality assurance period	An appropriate product quality assurance period is defined according to the data of the test on the stability at the room temperature.	●		
Toxicology	1. Data of the test on acute oral toxicity		●		
	2. Data of the test on acute percutaneous toxicity		●		
	3. Data of the test on acute inhalation toxicity⑤		●		
	4. Data of the test on eye irritation		●		
	5. Data of the test on skin irritation		●		
	6. Data of the test on skin sensitization		●		
	7. Heath risk evaluation report	If the technical requires supplementary toxicological data, the data shall be offered.	●	✖	●
Efficacy	1. Benefit analysis				
	1.1 The information about the target organisms to be registered	The features and harm of target organisms, their distribution in China, the rules of occurrence, and their threat to human health.	●		
	1.2 Analysis of the value and strength of products	The method and cost of using the products to be registered and the benefits the products bring to human health, safety and environment; the function and use of the products to be registered and the mutual compatibility between the products and the current measures for controlling harmful organisms; the information about the existing registered products whose functions are to be registered; the comparative analysis with existing registered products or common medicine; the role in the resistance management of existing registered products; the possibility to substitute the agrochemicals with higher risk.	●		
	2. Data of the efficacy test				
	2.1 Data of the test on indoor bioactivity	Action method, action spectrum, action mechanism or action mechanism prediction analysis.	●	✖	
	2.2 Report of the indoor efficacy test④	The report of the 1-year indoor efficacy test on the poison for the prevention and treatment of commensal rodents in two provincial administrative regions.	●		
	2.3 Report on the simulated on-site test④	The report of the 1-year indoor efficacy test on the poison for the prevention and treatment of commensal rodents in two provincial administrative regions; the report of the 2-year indoor efficacy test on the poison for the prevention and treatment of field, wood and prairie rodents in two provincial administrative regions in China.	●	●⑥	●
	3. Features of utilization	Product features and the matters worthy of attention in the use.	●		
	4. Comprehensive evaluation report	Summary of all the data about efficacy.	●		

Residuals		It is unnecessary to provide the data about residuals, except the data about the rodenticides that are sprayed on an overall scale.				✖					
Environmental impact⑦	1. Test on the acute oral toxicity for birds					●					
	2. Test on the acute toxicity for fishes⑧					●					

Notes:

① If the biochemical agrochemical technical (TK) which is exempted from registration is used for the processing of formulation, the (full) component analysis test report of the technical (TK) and the complete processing and quality control items and their indexes shall be submitted.

If the registration of the adopted biochemical agrochemical technical (TK) has been approved by the examining and approving organizations of medicine, food and health products, the submission of the above data will not be compulsory; however, the copy of the registration certificate and the product quality standards shall be submitted.

② The common test condition of thermal storage stability is (54±2)℃ for 2 weeks. The alternative conditions as follows: (50±2)℃ for 4 weeks; (45±2)℃ for 6 weeks; (40±2)℃ for 8 weeks; (35±2)℃ for 12 weeks; (30±2)℃ for 18 weeks. Reasons should be given if the alternative conditions are chosen.

③ Normally, the freezing and melting stability test should be cycled for four times between (-10±2)℃ and (20±2)℃. Each cycle includes 18 hours of freezing and 6 hours of melting.

④ It shall be finished in China in accordance with Article 16 of the Agrochemical Registration Management Measures.

⑤ For the products which meet one of the following conditions, the data of the test on acute inhalation toxicity shall be provided:

a. Gas or liquefied gas;

b. Fuming preparation or steaming preparation;

c. The preparation which adopts nebulization equipment for agrochemical application;

d. Steam release preparation;

e. Aerosol;

f. The preparation whose particles (with a diameter of less than 50um) account for a large proportion (weight>1%);

g. Airplane-based agrochemical application may generate inhalable preparation;

h. The preparation whose vapor pressure of active ingredient is higher than 1×10-2Pa and which may be used in confined space like warehouses or greenhouses;

i. The preparation whose particles (with a diameter of less than 50μm) or small drops which account for a large proportion (weight>1%) can be generated according to the use.

⑥ The 1-year report of the field efficacy test on the poison for the prevention and treatment of field, wood and prairie rodents in two places.

⑦ Adequate data have shown that if the possibility of contact between agrochemical and certain environmental organism is extremely low, the test can be exempted through application.

⑧ It is unnecessary to provide the rodenticides for the prevention and treatment of mice.

3 Micro-organic Rodenticide

Registration Category	1. Type D: New agrochemical formulations, including the one which have not been authorized for the first time within the 6-year protection period; 2. Type E: New dosage form; 3. Type F: New content; 4. Type G: New mixed formulation; 5. Type H: New use scope; 6. Type I: New use method; 7. Type L: Similar formulation and same use scope and use method; 8. Type M: Similar formulation but different use scope and use method. Note: "●" indicates "Necessary", and "✖" means "Unnecessary".

Data Classification	Data Item	Explanation and Description	D	E	F	G	H	I	L	M
Basic data	1. Application form	It shall be filled according to the application form issued by the Ministry of Agriculture.					●			
	2. Documents of the applicant	(1) The copies of the production license and the business license with the official seal and the standard social credit codes submitted by agrochemical producers; (2) The information about new agrochemical developers' application for agrochemical registration; (3) The identification document of overseas enterprises, the information about the registration and use in relevant countries and regions, the information about the establishment of offices or agencies in China and the business license.					●			
	3. Declaration of the applicant	The declaration for the reliability and legality of the application materials.					●			
	4. Summary report									
	4.1 Introduction to products	The brief introduction including the place of origin, chemistry, effect, toxicology, environmental impact, and overseas registration of products.					●			
	4.2 Risk evaluation report	The risk evaluation summary including the occupational health and environment of products.					●			
	4.3 Benefit analysis report	The summary including the analysis of the economic, social and environmental benefits of products.					●			
	5. Label and instruction	The samples of the label and instruction made in accordance with Regulations on the Label and Instruction of Agrochemicals.					●			
	6. Other documents related to the registration	(1) The information about the chemistry, effect, residual, toxicology and environmental impact of products or the comprehensive inquiry report in other countries or regions; (2) The basis of the naming of the active ingredients of new agrochemicals; (3) For the new dosage forms which have not be stipulated in the national standards, the applicant should submit the basis of naming and the appraisal report; (4) The information about the sources of technical.					●			
	7. Material safety data sheet						●			

	8. References	The sources of quotations shall be given.	●
Product chemistry and biological features ①	1. Identification of active ingredients, biological features and other restrictive components like safener, stabilizer and synergist	(1) The general names, internationally general names (usually Latin names) and categorical statuses (such as family, genus, species, subspecies, strain, serotype, pathovar or other naming related microorganisms) of active ingredients; (2) The general names of other restrictive components like safener, stabilizer and synergist; the names approved by the International Standard Organization (ISO) and the general names, chemical names and the accession number of American Chemical Abstracts (CAS number) in other international organizations and countries; the digital codes, development numbers, molecular formula, structural formula, isomer composition, relative molecular mass or molecular mass scope (with the issuance time of the International relative atomic mass index for the calculation) of the Collaborative International Pestricides Analytical Committee (CIPAC).	●
	2. Basic information about TK	Provide the information about the producers, registration, quality control items and indexes of the adopted TK.	●
	3. Product composition	(1) The chemical names, numbers of American Chemical Abstracts (CAS number), molecular formula, structural formula, contents and functions of the components for the processing of the formulation. For the mixed solvents and assistants represented with codes, the information about their composition, sources and safety (such as the material safety data sheet (MSDS)) shall be offered. For the assistants with special functions, including safener, stabilizer and synergist, the information about their quality specification, basic physicochemical properties, sources, safety (such as the material safety data sheet (MSDS)) and domestic and overseas use shall be offered; (2) For the separately-wrapped assistants (designated ones) added in the on-site solution preparation, their composition and the above information shall be separately offered.	●
	4.Description of the processing method		
	4.1 Process flow chart		●
	4.2 Quantity of components and the sequence of their use		●
	4.3 Main equipment and operation conditions		●
	4.4 Description of the quality control measures in the production		●
	5. Physicochemical properties	(1) Physicochemical properties include appearance (color, state and smell), density, and the corrosiveness to packing materials. For the products which require designated assistants in their use, the information about the mixture of the products and the designated assistants must be offered. (2) The measurement report on relevant physicochemical properties shall be offered according to product features and in accordance with the Guidelines of the Measurement Test on Physicochemical Properties of Agrochemicals.	●

	6. Production quality specification	The product quality specification shall meet the following requirements during the quality assurance period.	
	6.1 Appearance	The color, state and smell of products shall be clearly described.	●
	6.2 Content of active ingredient	The content of the products with other restrictive components like safener, stabilizer and synergist consists of labeled content and the scope of acceptable fluctuation, and the requirement on the scope of acceptable fluctuation is consistent with that on chemical rodenticide.	●
	6.3 Content of micro-organic pollutants and harmful impurities	The maximum content of micro-organic pollutants and harmful impurities in products shall be specified.	●
	6.4 Content of other restrictive components	The content of the products with other restrictive components like safener, stabilizer and synergist consists of labeled content and the scope of acceptable fluctuation, and the requirement on the scope of acceptable fluctuation is consistent with that on chemical rodenticide.	●
	6.5 Other control items and indexes related to dosage form	(1) Different dosage forms need the technical indexes consistent with their features; (2) The dosage forms that are not specified in this requirement can be specified according to the specification requirements by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The control items of innovative dosage forms can be defined according to the features, utilization method and safety of active ingredients. Meanwhile, the information about the appraisal test on dosage form shall be submitted.	●
	7. Test methods for the quality control items of products and method confirmation		●
	7.1 Test methods of identifying the active ingredients of products	Necessary maps, photos or sequences shall be described and provided from such aspects as morphological characteristics, physiological and biochemical response characteristics, serological reaction, and molecular biology (protein and DNA).	●
	7.2 Methods of testing active ingredients, micro-organic pollutants and harmful impurities, and other restrictive components like safener, stabilizer and synergist and method confirmation	(1) Test methods: Complete test methods shall be provided. The test methods usually include method summary, principle, information about samples, reference materials, apparatus, agents, solution preparation, operation conditions, test procedure, calculation for results, statistical methods, and allowable deviation; (2) Method confirmation: It shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●
	7.3 Test methods of other technical indexes	They shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●
	8. Information about the confirmation of quality specification of products	Make necessary explanation for the basis and rationality of technical indexes.	●
	9.Stability of storage	(1) The data of the test on the storage stability at the room temperature of at least a batch of samples shall be provided, such as one-year storage at 20-25℃ or two-year storage at 0-5℃. (2) The same products wrapped with different materials shall be tested for the storage stability at the room temperature respectively;	●

		(3) Usually, it is unnecessary to submit the data of the test on thermal storage stability.	
	10. Product quality test report and the test method demonstration report②	(1) The product quality test report shall include all the items as specified in the product quality specification; (2) The methods of testing the contents of active ingredients, mirco-organic pollutants, harmful impurities and other restrictive components like safener, stabilizer and synergist shall be demonstrated by the registration test unit which issues the product quality test report. Meanwhile, the test method demonstration report shall also be issued. The test methods of other control items can be exempted from the method demonstration. (3) The test method demonstration report includes the test conditions proposed by the consignor, the test conditions (such as chromatographic condition and sample preparation) of the registration test unit and the explanation for any change, and all the results, standard deviation and typical map (including reference materials and samples) of the parallel test. Meanwhile, the feasibility of the test methods shall be evaluated.	●
	11. Packing (material, shape, size and net content), storage and transport, safety warning, and quality assurance period		
	11.1 Packing and storage and transport	The applicant shall select appropriate packing materials, package sizes and transport tools according to the hazard category of products. The matters worthy of attention for the transport and storage shall be defined according to the state laws and regulations on safe production, storage and transport.	●
	11.2 Safety warning	The hazard degree of products is evaluated and classified according to the data about the physicochemical properties and biological features of products and the hazard classification standards of biological products and chemicals. Moreover, it is made public in the form of label and material safety data sheet (MSDS).	●
	11.3 Quality assurance period	An appropriate product quality assurance period is defined according to the data of the test on the stability at the room temperature.	●
Toxicology	1. Data of the test on acute oral toxicity		●
	2. Data of the test on acute percutaneous toxicity		●
	3. Data of the test on acute inhalation toxicity③		●
	4. Data of the test on eye irritation		●
	5. Data of the test on skin irritation		●
	6. Data of the test on skin sensitization		●

	7. Heath risk evaluation report	If TK requires supplementary toxicological data, the data shall be offered.	●	✖	●
Efficacy	1. Benefit analysis				
	1.1 The information about the target organisms to be registered	The features and harm of target organisms, their distribution in China, the rules of occurrence, and their threat to human health.	●		
	1.2 Analysis of the value and strength of products	The method and cost of using the products to be registered and the benefits the products bring to human health, safety and environment; the function and use of the products to be registered and the mutual compatibility between the products and the current measures for controlling harmful organisms; the information about the existing registered products whose functions are to be registered; the comparative analysis with existing registered products or common medicine; the role in the resistance management of existing registered products; the possibility to substitute the agrochemicals with higher risk.	●		
	2. Data of the efficacy test				
	2.1 Data of the test on indoor bioactivity	Action method, action spectrum, action mechanism or action mechanism prediction analysis.	●	✖	
	2.2 Report of the indoor efficacy test②	The report of the 1-year indoor efficacy test on the poison for the prevention and treatment of commensal rodents in two provincial administrative regions.	●		
	2.3 Report on the on-site test②	The report of the 1-year indoor efficacy test on the poison for the prevention and treatment of commensal rodents in two provincial administrative regions; the report of the 2-year indoor efficacy test on the poison for the prevention and treatment of field, wood and prairie rodents in two provincial administrative regions in China.	●	●④	●
	3. Features of utilization	Product features and the matters worthy of attention in the use.	●		
	4. Comprehensive evaluation report	Summary of all the data about efficacy.	●		
Residuals		It is unnecessary to provide the data about residuals, except the data about the rodenticides that are sprayed on an overall scale.	✖		
Environmental impact⑤	1.Data of the test on the toxicity for birds		●	●	
	2.Data of the test on the toxicity for fishes ⑥		●	●	

Notes:

① If the micro-organic TK which is exempted from registration is used for the processing of formulation, the strain appraisal report, strain code and strain description of the TK, the complete production technology, the component analysis test report and the data of the test on stability (sensitivity to temperature and pH value), quality control items and their indexes shall be submitted.

If the registration of the adopted micro-organic TK has been approved by the examining and approving organizations of medicine, food and health products, the submission of the above data will not be compulsory; however, the copy of the registration certificate and the product quality standards shall be submitted.

② It shall be finished in China in accordance with Article 16 of the Agrochemical Registration Management Measures.

③ For the products which meet one of the following conditions, the data of the test on acute inhalation toxicity shall be provided:

a. Gas or liquefied gas;

b. Fuming preparation or steaming preparation;

c. The preparation which adopts nebulization equipment for agrochemical application;

d. Steam release preparation;

e. Aerosol;

f. The preparation whose particles (with a diameter of less than 50um) account for a large proportion (weight>1%);

g. Airplane-based agrochemical application may generate inhalable preparation;

h. The preparation whose vapor pressure of active ingredient is higher than 1×10-2Pa and which may be used in confined space like warehouses or greenhouses;

i. The preparation whose particles (with a diameter of less than 50μm) or small drops which account for a large proportion (weight>1%) can be generated according to the use.

④ The 1-year report of the field efficacy test on the poison for the prevention and treatment of field, wood and prairie rodents in two places.

⑤ Adequate data have shown that if the possibility of contact between agrochemical and certain environmental organism is extremely low, the test can be exempted through application.

⑥ It is unnecessary to provide the rodenticides for the prevention and treatment of mice.

4 Botanical Rodenticide

Registration Category	1. Type D: New agrochemical formulations, including the one which have not been authorized for the first time within the 6-year protection period; 2. Type E: New dosage form; 3. Type F: New content; 4. Type G: New mixed formulation; 5. Type H: New use scope; 6. Type I: New use method; 7. Type L: Similar formulation and same use scope and use method; 8. Type M: Similar formulation but different use scope and use method. Note: "●" indicates "Necessary", and "✖" means "Unnecessary".

Data Classification	Data Item	Explanation and Description	D	E	F	G	H	I	L	M
Basic data	1. Application form	It shall be filled according to the application form issued by the Ministry of Agriculture.					●			
	2. Documents of the applicant	(1) The copies of the production license and the business license with the official seal and the standard social credit codes submitted by agrochemical producers; (2) The information about new agrochemical developers' application for agrochemical registration; (3) The identification document of overseas enterprises, the information about the registration and use in relevant countries and regions, the information about the establishment of offices or agencies in China and the business license.					●			
	3. Declaration of the applicant	The declaration for the reliability and legality of the application materials.					●			
	4. Summary report									
	4.1 Introduction to products	The brief introduction including the place of origin, chemistry, effect, toxicology, environmental impact, and overseas registration of products.					●			
	4.2 Risk evaluation report	The risk evaluation summary including the occupational health and environment of products.					●			
	4.3 Benefit analysis report	The summary including the analysis of the economic, social and environmental benefits of products.					●			
	5. Label and instruction	The samples of the label and instruction made in accordance with Regulations on the Label and Instruction of Agrochemicals.					●			

	6. Other documents related to the registration	(1) The information about the chemistry, effect, residual, toxicology and environmental impact of products or the comprehensive inquiry report in other countries or regions; (2) The basis of the naming of the active ingredients of new agrochemicals; (3) For the new dosage forms which have not be stipulated in the national standards, the applicant should submit the basis of naming and the appraisal report; (4) The information about the sources of technical.	●
	7. Material safety data sheet		●
	8. References	The sources of quotations shall be given.	●
Product chemistry ①	1.Product identification		
	1.1 Product name	For the botanical agrochemicals which are extracted from a plant, they can be named with the active ingredient or in the form “the general name of the plant used as the raw material + extract”. However, the representative active ingredient shall be marked. For those extracted from several plants, they shall be named with the representative active ingredient.	●
	1. Identification of active ingredients or representative ones and safener, stabilizer, synergist and other restrictive components	(1) The general names of active ingredients or representative ones and other restrictive components like safener, stabilizer and synergist; the names approved by the International Standard Organization (ISO) and the general names, chemical names and the accession number of American Chemical Abstracts (CAS number) in other international organizations and countries; the digital codes, development numbers, molecular formula, structural formula, isomer composition, relative molecular mass or molecular mass scope (with the issuance time of the International relative atomic mass index for the calculation) of the Collaborative International Pestricides Analytical Committee (CIPAC); (2) If the active ingredients exist in the form of certain salt, the data about the identification of corresponding derivatives shall be offered.	●
	2. Basic information about technical (TK)	Provide the information about the producers, registration, quality control items and indexes of the adopted technical (TK).	●
	3.Product composition	(1) The chemical names, numbers of American Chemical Abstracts (CAS number), molecular formula, structural formula, contents and functions of the components for the processing of the formulation. For the mixed solvents and assistants represented with codes, the information about their composition, sources and safety (such as the material safety data sheet (MSDS)) shall be offered. For the assistants with special functions, including safener, stabilizer and synergist, the information about their quality specification, basic physicochemical properties, sources, safety (such as the material safety data sheet (MSDS)) and domestic and overseas	●

		use shall be offered; (2) For the separately-wrapped assistants (designated ones) added in the on-site solution preparation, their composition and the above information shall be separately offered.	
	4.Description of the processing method		
	4.1 Process flow chart		●
	4.2 Quantity of components and the sequence of their use		●
	4.3 Main equipment and operation conditions		●
	4.4 Description of the quality control measures in the production		●
	5. Physicochemical properties	(1) Physicochemical properties include appearance (color, state and smell), density, viscosity, oxidizability/reducibility, the corrosiveness to packing materials, the compatibility with nonpolar organic solvents (applicable to the dosage form for the dilution with organic solvents), explosiveness, and combustibility. For the products which require designated assistants in their use, the information about the mixture of the products and the designated assistants must be offered. (2) The measurement report on the physicochemical properties shall be offered in accordance with the Guidelines of the Measurement Test on Physicochemical Properties of Agrochemicals. If specific parameters are not suitable for products, the explanation shall be offered.	●
	6. Production quality specification	The product quality specification shall meet the following requirements during the quality assurance period.	
	6.1 Appearance	The color, state and smell of products shall be clearly described.	●
	6.2 Content of active ingredient or representative ones	(1) The content of active ingredients or representative ones consists of labeled content and the scope of acceptable fluctuation. The acceptable fluctuation shall not exceed ±25% of the labeled content. (2) If active ingredient exists in the form of certain salt, the name and quality percentage of products will be represented with the actual existence. Meanwhile, the active parts and the content of paired counter-ions shall be labeled.	●
	6.3 Content of relevant impurities	The maximum content of the products with relevant impurities shall be specified and represented with quality percentage.	●
	6.4 Content of other restrictive components	The content of the products with other restrictive components like safener, stabilizer and synergist consists of labeled content and the scope of acceptable fluctuation, and the requirement on the scope of acceptable fluctuation is consistent with that on chemical rodenticide.	●

	6.5 Other control items and indexes related to dosage form	(1) Different dosage forms need the technical indexes consistent with their features; (2) The dosage forms that are not specified in this requirement can be specified according to the specification requirements by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The control items of innovative dosage forms can be defined according to the features, utilization method and safety of active ingredients. Meanwhile, the information about the appraisal test on dosage form shall be submitted.	●
	7. Test methods for the quality control items of products and method confirmation		
	7.1 Test methods of identifying the active ingredients of products	(1) At least one test method shall be adopted to identify the active ingredients of technical for the processing of formulation. If the chemical method is used for the identification, at least two identification test methods shall be offered. (2) If TK is used for the processing of formulation, the characteristic peak and retention time in the “chemical fingerprint” map of the formulation shall be adopted for the identification of products.	●
	7.2 Methods of testing active ingredients or representative ones, relevant impurities, and other restrictive components like safener, stabilizer and synergist and method confirmation	(1) Test methods: Complete test methods shall be provided. The test methods usually include method summary, principle, information about samples, reference materials, apparatus, agents, solution preparation, operation conditions, test procedure, calculation for results, statistical methods, and allowable deviation; (2) Method confirmation: It shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●
	7.3 Test methods of other technical indexes	They shall be conducted in accordance with the Guidelines on the Confirmation of the Product Quality Analysis Methods for Agrochemicals.	●
	8. Information about the confirmation of quality specification of products	Make necessary explanation for the basis and rationality of technical indexes.	●
	9. Data of the test on the stability of storage at the room temperature	(1) The data of the test on the storage stability at the room temperature of at least a batch of samples shall be provided. (2) The same products wrapped with different materials shall be tested for the storage stability at the room temperature respectively; (3) Usually, samples are stored under specific conditions for two years in the test on the stability at the room temperature.	●

	10. Product quality test report and the test method demonstration report②	(1) The product quality test report shall include all the items as specified in the product quality specification; (2) The methods of testing the contents of active ingredients or representative ones, relevant impurities and other restrictive components like safener, stabilizer and synergist shall be demonstrated by the registration test unit which issues the product quality test report. Meanwhile, the test method demonstration report shall also be issued. The test methods of other control items can be exempted from the method demonstration. (3) The test method demonstration report includes the test conditions proposed by the consignor, the test conditions (such as chromatographic condition and sample preparation) of the registration test unit and the explanation for any change, and all the results, standard deviation and typical map (including reference materials and samples) of the parallel test. Meanwhile, the feasibility of the test methods shall be evaluated.	●		
	11. Packing (material, shape, size and net content), storage and transport, safety warning, and quality assurance period				
	11.1 Packing and storage and transport	The applicant shall select appropriate packing materials, package sizes and transport tools according to the hazard category of products. The matters worthy of attention for the transport and storage shall be defined according to the state laws and regulations on safe production, storage and transport.	●		
	11.2 Safety warning	The hazard degree of products is evaluated and classified according to the data about the physicochemical properties of products and the hazard classification standards of chemicals. Moreover, it is made public in the form of label and material safety data sheet (MSDS).	●		
	11.3 Quality assurance period	An appropriate product quality assurance period is defined according to the data of the test on the stability at the room temperature.	●		
Toxicology	1. Data of the test on acute oral toxicity		●		
	2. Data of the test on acute percutaneous toxicity		●		
	3. Data of the test on acute inhalation toxicity③		●		
	4. Data of the test on eye irritation		●		
	5. Data of the test on skin irritation		●		
	6. Data of the test on skin sensitization		●		
	7. Heath risk evaluation report	If TK requires a whole set of toxicological data, the data shall be offered.	●	✖	●

Efficacy	1. Benefit analysis				
	1.1 The information about the target organisms to be registered	The features and harm of target organisms, their distribution in China, the rules of occurrence, and their threat to human health.	●		
	1.2 Analysis of the value and strength of products	The method and cost of using the products to be registered and the benefits the products bring to human health, safety and environment; the function and use of the products to be registered and the mutual compatibility between the products and the current measures for controlling harmful organisms; the information about the existing registered products whose functions are to be registered; the comparative analysis with existing registered products or common medicine; the role in the resistance management of existing registered products; the possibility to substitute the agrochemicals with higher risk.	●		
	2. Data of the efficacy test				
	2.1 Data of the test on indoor bioactivity	Action method, action spectrum, action mechanism or action mechanism prediction analysis.	●	×	
	2.2 Report of the indoor efficacy test②	The report of the 1-year indoor efficacy test on the poison for the prevention and treatment of commensal rodents in two provincial administrative regions.	●		
	2.3 Report on the on-site test②	The report of the 1-year indoor efficacy test on the poison for the prevention and treatment of commensal rodents in two provincial administrative regions; the report of the 2-year indoor efficacy test on the poison for the prevention and treatment of field, wood and prairie rodents in two provincial administrative regions in China.	●	●④	●
	3. Features of utilization	Product features and the matters worthy of attention in the use.	●		
	4. Comprehensive evaluation report	Summary of all the data about efficacy.	●		
Residuals		It is unnecessary to provide the data about residuals, except the data about the rodenticides that are sprayed on an overall scale.	×		
Environmental impact⑤	1.Summary of the environmental data about TK (technical)		●		
	2.Data of the test on the acute oral toxicity for birds	The birds in the test shall be the ones which are sensitive in the technical test on the acute oral toxicity for birds.	●		
	3.Data of the test on the acute toxicity of fishes⑥	The fishes in the test shall be the one which are sensitive in the technical test on the acute oral toxicity for fishes.	●		

Notes:

① If the TK of botanical agrochemicals, which is exempted from registration, is used for the processing of formulation, the complete production technology, the component analysis test report, quality control items and their indexes shall be submitted.

If the registration of the adopted TK of botanical agrochemicals has been approved by the examining and approving organizations of medicine, food and health products, the submission of the above data will not be compulsory; however, the copy of the registration certificate and the product quality standards shall be submitted.

② It shall be finished in China in accordance with Article 16 of the Agrochemical Registration Management Measures.

③ For the products which meet one of the following conditions, the data of the test on acute inhalation toxicity shall be provided:

a. Gas or liquefied gas;

b. Fuming preparation or steaming preparation;

c. The preparation which adopts nebulization equipment for agrochemical application;

d. Steam release preparation;

e. Aerosol;

f. The preparation whose particles (with a diameter of less than 50um) account for a large proportion (weight>1%);

g. Airplane-based agrochemical application may generate inhalable preparation;

h. The preparation whose vapor pressure of active ingredient is higher than 1×10-2Pa and which may be used in confined space like warehouses or greenhouses;

i. The preparation whose particles (with a diameter of less than 50μm) or small drops which account for a large proportion (weight>1%) can be generated according to the use.

④ The 1-year report of the field efficacy test on the poison for the prevention and treatment of field, wood and prairie rodents in two places.

⑤ Adequate data have shown that if the possibility of contact between agrochemical and certain environmental organism is extremely low, the test can be exempted through application.

⑥ It is unnecessary to provide the rodenticides for the prevention and treatment of mice.

Attachment 5

Interpretation and Specification of the Data Requirements for Change of Registration

1 Expand application scope

Data Category	Data Item	Explanation and Description
General data	1. Application form	
	2. Applicant statement	Applicant statement on the authenticity and legality of application materials.
	3. Photocopy of the registration certificate	
	4. Description and cause of the change	
	5. Labels and manuals	(1) Specimens of labels and manuals prepared according to the Measures for the Administration of Pesticide Labels and Manuals; (2) Registration approval label.
	6. Other documents related to registration change	Provide related documents according to need.
Toxicology	1. Data of advanced tests that health risk assessment needs	If the primary health risk assessment indicates that the health risk of pesticides to human body is unacceptable, the data of advanced tests (including, but not limited to: pesticide user field exposure level test and resident exposure level simulation test) may be provided.
	2. Health risk assessment report	Submit a pesticide user health risk assessment report or a resident health risk assessment report.
Efficacy ①②③	1. Data of efficacy trial	
	1.1 Data of laboratory bioactivity test	Laboratory activity test report (for products involving new target objects).
	1.2 Data of laboratory crop safety test	Laboratory crop safety test report (for products involving new crops).
	1.3 Data of plot efficacy trial④	(1) For insecticides and fungicides, a report of plot efficacy trial conducted in four provincial-level administrative regions in China for two years should be provided; for herbicides and plant growth regulators, a report of plot efficacy trial conducted in five provincial-level administrative regions in China for two years should be provided; for herbicide with a long residual effect, a report of safety trial of main aftercrops should also be provided; (2) For crops planted in localized regions, or diseases, insects and weeds limited to localized regions, a report of field efficacy trial conducted in three provincial-level administrative regions in China for two years may be provided; (3) For sterilant herbicide or forest pesticide, a report of field efficacy trial conducted in three provincial-level administrative regions in China for two years should be provided; (4) For pesticide used in relevantly stable environmental conditions, such as for storage, antiseptic, and preservation purpose, a report of efficacy trial conducted over two periods in two provincial-level administrative regions in China or over one period in four provincial-level administrative regions in China may be provided. (5) For a product not involving new application scope or new application method, a one-year field efficacy trial report may be provided instead.

	2. Data of resistance risk assessment	For a product involving new target objects, data for resistance research should be provided, including target organism sensitivity test, drug resistance monitoring method, drug resistance risk assessment, etc.
	3. Other data	Description of site selection of plot test (needed if not included in the Guidelines for Field Efficacy Trial Areas for Pesticide Registration); influence on major predators and parasites in the field; influence on neighboring crops; registration and application status of this crop or target objects at abroad (for products of unregistered application scope); product features and application precautions; other data relevant with this pesticide variety and application scope.
	4. Comprehensive assessment report	Recapitulative summary of all efficacy data.
Residue ⑤	1. Data of pesticide residue storage stability test ⑥	It is provided only when the application scope in crops is expanded.
	2. Data of residue analysis method	It is provided only when the application scope in crops is expanded.
	3. Data of pesticide residue test in crops ④	When the application scope in crops is expanded, this data should be provided; for expansion of target objects (i.e. the crops are not changed), if it might result in the rise of residue risk, judging from the application period, application frequency, dosage and application interval, data of the residue test conducted at a halved number of locations should be submitted, but the minimum number of locations is two.
	4. Data of pesticide residue test in processed agricultural products ⑥	It is provided only when the application scope in crops is expanded.
	5. Dietary risk assessment report	It is provided depending on the provision condition of the data of residue test.
Environmental impact	1. Supplementary data of environmental impact	The data of environmental impact should be supplemented according to the expanded application scope and the present Requirements. No more data is needed if the submitted data of environmental impact meets the requirements.
	2. Environmental risk assessment report	Decide on whether to submit a risk assessment report or not according to the requirements of the risk assessment report in the present Requirements and the registration category of the product.

Note:

① If a biochemical pesticide, microbial pesticide or botanical pesticide formulation involves a product of unregistered application scope, data should be provided in reference to category H (products of unregistered application scope) of biochemical pesticide, microbial pesticide and botanical pesticide formulations in the data requirements for pesticide registration respectively; if it does not involve a product of unregistered application scope, a report of field efficacy trial conducted in three regions for one year (forest pesticides, crops planted in localized regions, and diseases, insects and weeds limited to localized regions) or in four regions for one year (insecticides and fungicides) or in five regions for one year (herbicides and plant growth regulators) may be provided.

② For a public health pesticide formulation, data should be provided in reference to category H (products of unregistered application scope) in the data requirements for public health pesticide registration.

③ For a rodenticide formulation, data should be provided in reference to category H (products of unregistered application scope) in the data requirements for rodenticide pesticide registration.

④ According to Article 16 of the Measures for the Administration of Pesticide Registration, it should be completed in China.

⑤ For non-food crops, non-feed crops, insecticides and rodenticides, it is not required.

⑥ If it has been submitted during registration of a new pesticide, there is no need to submit it again. If there is queried data, the data source should be indicated.

2 Change application method

Data Category	Data Item	Explanation and Description
General data	1. Application form	
	2. Applicant statement	Applicant statement on the authenticity and legality of application materials.
	3. Photocopy of the registration certificate	
	4. Description and cause of the change	
	5. Labels and manuals	(1) Specimens of labels and manuals prepared according to the Measures for the Administration of Pesticide Labels and Manuals; (2) Registration approval label.
	6. Other documents related to registration change	Provide related documents according to need.
Toxicology	1. Data of advanced tests that health risk assessment needs	If the primary health risk assessment indicates that the health risk of pesticides to human body is unacceptable, the data of advanced tests (including, but not limited to: pesticide user field exposure level test and resident exposure level simulation test) may be provided.
	2. Health risk assessment report	Submit a pesticide user health risk assessment report or a resident health risk assessment report.
Efficacy ①②③	1. Plot efficacy trial report ④	(1) For insecticides and fungicides, a report of plot efficacy trial conducted in four provincial-level administrative regions in China for two years should be provided; for herbicides and plant growth regulators, a report of plot efficacy trial conducted in five provincial-level administrative regions in China for two years should be provided; for herbicide with a long residual effect, a report of safety trial of main aftercrops should also be provided; (2) For crops planted in localized regions, or diseases, insects and weeds limited to localized regions, a report of field efficacy trial conducted in three provincial-level administrative regions in China for two years may be provided; (3) For sterilant herbicide or forest pesticide, a report of field efficacy trial conducted in three provincial-level administrative regions in China for two years should be provided; (4) For pesticide used in relevantly stable environmental conditions, such as for storage, antiseptic, and preservation purpose, a report of efficacy trial conducted over two periods in two provincial-level administrative regions in China or over one period in four provincial-level administrative regions in China may be provided. (5) For a product not involving new application method, a one-year field efficacy trial report may be provided
	2. Other data	Description of site selection of plot test (needed if not included in the Guidelines for Field Efficacy Trial Areas for Pesticide Registration); influence on major predators and parasites in the field; influence on neighboring crops; registration and application status of this crop or target objects at abroad (for products of unregistered application scope); product features and application precautions; other data relevant with this pesticide variety and application scope.
	3. Comprehensive assessment report	Recapitulative summary of efficacy data.
Residue ⑤	1. Data of pesticide residue test in crops ④	It should be provided when the change of application method might result in increase of final residue quantity.

	2. Data of residue analysis method	
	3. Dietary risk assessment report	It is provided depending on the provision condition of the data of residue test.
Environmental impact	1. Supplementary data of environmental impact	The data of environmental impact should be supplemented according to the changed application method and the present Requirements. No more data is needed if the submitted data of environmental impact meets the requirements.
	2. Environmental risk assessment report	It should be provided when the change of application method might result in the rise of environmental risk.

Note:

① If a biochemical pesticide, microbial pesticide or botanical pesticide formulation involves a product of unregistered application method, data should be provided in reference to category I (products of unregistered application method) of biochemical pesticide, microbial pesticide and botanical pesticide formulations in the data requirements for pesticide registration respectively; if it does not involve a product of unregistered application method, a report of field efficacy trial conducted in three regions for one year (forest pesticides, crops planted in localized regions, and diseases, insects and weeds limited to localized regions) or in four regions for one year (insecticides and fungicides) or in five regions for one year (herbicides and plant growth regulators) may be provided.

② For a public health pesticide formulation, data should be provided in reference to category I (products of unregistered application method) in the data requirements for public health pesticide registration.

③ For a rodenticide formulation, data should be provided in reference to category I (products of unregistered application method) in the data requirements for rodenticide pesticide registration.

④ According to Article 16 of the Measures for the Administration of Pesticide Registration, it should be completed in China.

⑤ For non-food crops, non-feed crops, insecticides and rodenticides, it is not required.

3 Increase application dosage

Data Category	Data Item	Explanation and Description
General data	1. Application form	
	2. Applicant statement	Applicant statement on the authenticity and legality of application materials.
	3. Photocopy of the registration certificate	
	4. Description and cause of the change	
	5. Labels and manuals	(1) Specimens of labels and manuals prepared according to the Measures for the Administration of Pesticide Labels and Manuals; (2) Registration approval label.
	6. Other documents related to registration change	Provide related documents according to need.
Toxicology	1. Data of advanced tests that health risk assessment needs	If the primary health risk assessment indicates that the health risk of pesticides to human body is unacceptable, the data of advanced tests (including, but not limited to: pesticide user field exposure level test and resident exposure level simulation test) may be provided.
	2. Health risk assessment report	Submit a pesticide user health risk assessment report or a resident health risk assessment report.
Efficacy ①②	1. Plot efficacy trial report ③	(1) For insecticides and fungicides, a report of plot efficacy trial conducted in four provincial-level administrative regions in China for one year should be provided; for herbicides and plant growth regulators, a report of plot efficacy trial conducted in five provincial-level administrative regions in China for one year should be provided; for herbicide with a long residual effect, a report of safety trial of main aftercrops should also be provided; (2) For crops planted in localized regions, or diseases, insects and weeds limited to localized regions, a report of field efficacy trial conducted in three provincial-level administrative regions in China for one year may be provided; (3) For sterilant herbicide or forest pesticide, a report of field efficacy trial conducted in three provincial-level administrative regions in China for one year should be provided; (4) For pesticide used in relevantly stable environmental conditions, such as for storage, antiseptic, and preservation purpose, a report of efficacy trial conducted over one period in two provincial-level administrative regions in China may be provided.
	2. Comprehensive assessment report	Recapitulative summary of efficacy data.
Residue ④	1. Data of pesticide residue test in crops ③	Data of supervised residue test conducted at a halved number of locations should be submitted, but the number of locations may not less than two.
	2. Data of residue analysis method	
	3. Dietary risk assessment report	
Environmental impact	Environmental risk assessment report	

Note:

① For a public health pesticide formulation, a report of simulated site test or site test conducted in two regions for one year should be provided.

② For a rodenticide formulation, a report of site or field efficacy trial conducted in two regions for one year should be provided.

③ According to Article 16 of the Measures for the Administration of Pesticide Registration, it should be completed in China.

④ For non-food crops, non-feed crops, insecticides and rodenticides, it is not required.

4 Reduce application dosage

Data Category	Data Item	Explanation and Description
General data	1. Application form	
	2. Applicant statement	Applicant statement on the authenticity and legality of application materials.
	3. Photocopy of the registration certificate	
	4. Description and cause of the change	
	5. Labels and manuals	(1) Specimens of labels and manuals prepared according to the Measures for the Administration of Pesticide Labels and Manuals; (2) Registration approval label.
	6. Other documents related to registration change	Provide related documents according to need.
Efficacy ①②	1. Plot efficacy trial report ③	(1) For insecticides and fungicides, a report of plot efficacy trial conducted in four provincial-level administrative regions in China for one year should be provided; for herbicides and plant growth regulators, a report of plot efficacy trial conducted in five provincial-level administrative regions in China for one year should be provided; (2) For crops planted in localized regions, or diseases, insects and weeds limited to localized regions, a report of field efficacy trial conducted in three provincial-level administrative regions in China for one year may be provided; (3) For sterilant herbicide or forest pesticide, a report of field efficacy trial conducted in three provincial-level administrative regions in China for one year should be provided; (4) For pesticide used in relevantly stable environmental conditions, such as for storage, antiseptic, and preservation purpose, a report of efficacy trial conducted over one period in two provincial-level administrative regions in China may be provided.
	2. Comprehensive assessment report	Recapitulative summary of efficacy data.

Note:

① For a public health pesticide formulation, a report of simulated site test or site test conducted in two regions for one year should be provided.

② For a rodenticide formulation, a report of site or field efficacy trial conducted in two regions for one year should be provided.

③ According to Article 16 of the Measures for the Administration of Pesticide Registration, it should be completed in China.

5 Change TC (TK) quality specification or composition

Data Category	Data Item	Explanation and Description
General data	1. Application form	
	2. Applicant statement	Applicant statement on the authenticity and legality of application materials.
	3. Photocopy of the registration certificate	
	4. Description and cause of the change	
	5. Labels and manuals	(1) Specimens of labels and manuals prepared according to the Measures for the Administration of Pesticide Labels and Manuals; (2) Registration approval label.
	6. Other documents related to registration change	Provide related documents according to need.
Product chemistry	1. Physic-chemical properties of TC (TK)	The requirements are shown in the data requirements for registration of pesticide TC (TK) under the corresponding category (chemical pesticides, biochemical pesticides, microbial pesticides, botanical pesticides, public health pesticides and rodenticide pesticides).
	2. (Complete) composition analysis	The requirements are shown in the data requirements for registration of pesticide TC (TK) under the corresponding category (chemical pesticides, biochemical pesticides, microbial pesticides, botanical pesticides, public health pesticides and rodenticide pesticides).
	3. Product quality test report ①	The product quality test report should include all the items specified in the product quality specification.
	4. Product quality specification	The requirements are shown in the data requirements for registration of pesticide TC (TK) under the corresponding category (chemical pesticides, biochemical pesticides, microbial pesticides, botanical pesticides, public health pesticides and rodenticide pesticides)。
Other test data and description	Data and description of toxicological and environmental impact tests are submitted according to the content of applied change.	

Note:

① According to Article 16 of the Measures for the Administration of Pesticide Registration, it should be completed in China.

6 Change formulation quality specification or composition

Data Category	Data Item	Explanation and Description
General data	1. Application form	
	2. Applicant statement	Applicant statement on the authenticity and legality of application materials.
	3. Photocopy of the registration certificate	
	4. Description and cause of the change	
	5. Labels and manuals	(1) Specimens of labels and manuals prepared according to the Measures for the Administration of Pesticide Labels and Manuals; (2) Registration approval label.
	6. Other documents related to registration change	Provide related documents according to need.
Product chemistry ①	1. Product composition	The requirements are shown in the data requirements for registration of pesticide formulations under the corresponding category (chemical pesticides, biochemical pesticides, microbial pesticides, botanical pesticides, public health pesticides and rodenticide pesticides).
	2. Physic-chemical properties	The requirements are shown in the data requirements for registration of pesticide formulations under the corresponding category (chemical pesticides, biochemical pesticides, microbial pesticides, botanical pesticides, public health pesticides and rodenticide pesticides).
	3. Product quality specification	The requirements are shown in the data requirements for registration of pesticide formulations under the corresponding category (chemical pesticides, biochemical pesticides, microbial pesticides, botanical pesticides, public health pesticides and rodenticide pesticides).
	4. Product quality test report ②	The product quality test report should include all the items specified in the product quality specification.
	5. Data of storage stability test ③	Data of thermal storage stability, low-temperature stability (if necessary) and freezing-thawing stability (if necessary) tests for at least three batches of samples should be provided.
Other test data and description	Data and description of toxicological and environmental impact tests are submitted according to the content of applied change of registration.	

Note:

① If the content of essence in a household insecticide is not greater than 1%, the application for change of registration is not required when the type of essence is changed.

② According to Article 16 of the Measures for the Administration of Pesticide Registration, it should be completed in China.

② For a microbial pesticide, the data of storage stability test at specific temperature should be submitted.

7 Change toxicity level

Data Category	Data Item	Explanation and Description
General data	1. Application form	
	2. Applicant statement	Applicant statement on the authenticity and legality of application materials.
	3. Photocopy of the registration certificate	
	4. Description and cause of the change	
	5. Labels and manuals	(1) Specimens of labels and manuals prepared according to the Measures for the Administration of Pesticide Labels and Manuals; (2) Registration approval label.
	6. MSDS	
	7. Other documents related to registration change	Provide related documents according to need.
Other test data and description	A toxicological test report or description should be submitted based on the content of change.	

Annex 6

Data Requirements for Registration of Pesticides Used in Characteristic Minor Crops

1 Scope of Application

The Requirements are applicable to the registration of expansion of application scope of the products that have completed pesticide registration. Joint test is encouraged.

2 Test Requirements

2.1 Number of locations

2.1.1 A field efficacy trial shall be done at least at three locations;

2.1.2 A residue test shall be done at least at four locations;

2.1.3 If the crop is planted in multiple provinces (regions or municipalities directly under the central government), the test shall be conducted in the provinces (regions or municipalities directly under the central government) with different ecological types; If the crop is locally planted in only 1-2 provinces (regions or municipalities directly under the central government), the test may be conducted in different areas of a same province (region or municipality directly under the central government).

2.2 Number of years

The efficacy trial for registration of a pesticide used in characteristic minor crops may be completed in one year.

3 Data Requirements

3.1 Summary

3.2 Photocopy of registration certificate

3.3 Approval label and the specimens of label and manual

3.4 Efficacy

3.4.1 Benefit analysis

3.4.1.1 Overview of the crops applying for registration and target organisms

3.4.1.2 Analysis of social and economic benefits

3.4.1.3 Substitutability analysis of registered products

3.4.2 Data of efficacy trial

3.4.2.1 Data of laboratory bioactivity (only for the products involving new target objects)

3.4.2.2 Laboratory crop safety report (only for the products involving new crops)

3.4.2.3 Plot efficacy trial report

3.4.3 Others

A field efficacy trial report may be a trial report in applied crops and target objects, or a trial report in the representative crops and target objects of a same group according to the requirements for grouped management of the efficacy trials for registration of pesticides used in characteristic minor crops.

3.4.4 Comprehensive assessment report

3.5 Residue

3.5.1 Data of pesticide residue storage stability

3.5.2 Data of residue analysis method

3.5.3 Data of pesticide residue test in crops

The data of pesticide residue test in the corresponding crops may be submitted according to the *Requirements on Number of Locations of Residue Test for Pesticide Registration*. Alternatively, the data of pesticide residue test in representative crops of a group may be submitted according to the requirements for grouped management of residue tests for registration of pesticides used in characteristic minor crops.

3.5.4 Dietary risk assessment report

3.6 Others

Environmental data or description is provided based on the applied pesticides, crops and targets if needed.

Annex 7

Guidelines for Regions of Field Efficacy Trials for Pesticide Registration

The Guidelines are formulated according to the layout of the planting regions of main crops and the rules of occurrence of diseases, pests and weeds in China. For the crops, diseases, pests, weeds and some special chemicals not covered by the Guidelines, representative locations in China may be selected based on crop planting regions to conduct efficacy trials.

If the efficacy trial cannot be conducted in the regions recommended in the Guidelines owing to the occurrence condition of diseases, pests and weeds, natural disasters, etc., the applicant may make adjustment according to the actual condition and explain it during application for registration.

1 Grain Crops

1.1 Paddy rice

Diseases, pests and weeds	Yangtze River Middle Reaches paddy region	Yangtze River Lower Reaches paddy region	South China paddy region	Southwest paddy region	Huanghuai paddy region	North China paddy region
	Hunan, Jiangxi, Hubei and Henan	Jiangsu, Zhejiang, Anhui and Shanghai	Guangdong, Guangxi, Fujian and Hainan	Sichuan, Yunnan, Guizhou, Chongqing and Shaanxi	Hebei, Tianjin, Shandong and Ningxia	Heilongjiang, Liaoning, Jilin and Inner Mongolia
Sheath blight	1	1	1	1		
Rice false smut	1	1		1		1
Rice blast	1	1	1			1
Bakanae disease	1	1		1		1
Rice planthopper, rice leaf roller, leaf hopper and thrips	1	1	1	1		
Rice stem borer	1	1		1	1	
Yellow rice	1	1	1	1		

borer						
Weed in rice transplanting field and weed in seedling field	1	1	1	1		1
Weed in direct seeding field	1	1	1	2 (different regions)		
Weed in seedling-throwing field	5 (at least one location in each region)					

Note: The numbers in the table stand for the number of test locations, the same below.

1.2 Wheat

Diseases, pests and weeds	Huanghuai winter wheat region	Yangtze River Middle and Lower Reaches winter wheat region	North China winter wheat region	Southwest winter wheat region	Northwest winter wheat region	Spring wheat region
	Shandong, Henan, Shanxi and Shaanxi	Hubei, Jiangsu, Anhui, Shanghai and Zhejiang	Hebei, Beijing and Tianjin	Guizhou, Sichuan, Chongqing and Yunnan	Gansu, Qinghai and Xinjiang	Inner Mongolia, Gansu, Qinghai, Heilongjiang, Liaoning, Ningxia and Xinjiang
Powdery mildew	1	1	1	1		
Gibberellic disease	4					
Rust disease	1	1		1	1	
Sheath blight	1	1	1	1		
Cereal cyst nematode	1	1	1		1	

Aphid	1	1	1	1		
Wheat midge	2		1		1	
Wheat mite	1	1	1		1	
Underground pest (wireworm, mole cricket, grub and cut worm)	1	1	1		1	
Weed in wheat field	1	2 (different regions)				2
Weed in winter wheat field	1	1	1	1		
Weed in spring wheat field						3

1.3 Maize

Diseases, pests and weeds	Northeast China maize region	Huang-Huai-Hai maize region	Southwest maize region	Northwest maize region
	Heilongjiang, Jilin, Liaoning and Inner Mongolia	Henan, Shandong, Hebei, Shanxi, Jiangsu, Anhui and Tianjin	Yunnan, Sichuan, Guizhou, Hubei, Guangxi, Chongqing and Hunan	Shaanxi, Xinjiang, Gansu and Ningxia
Leaf blight, leaf spot, rust disease, head smut and stalk rot	1	1	1	1
Brown spot	2	2		
Corn borer, underground pest (wireworm, mole cricket, grub and cut worm), armyworm, aphid and tetranychid mite	1	1	1	1
Athetis lepigone		4		
Weed in corn field	2	2	1	

Weed in spring corn field	3			
Weed in summer corn weed		2	1	1

1.4 Potato

Diseases, pests and weeds	Southwest and Wuling Mountain planting region	Northwest planting region	North China planting region	East China and South China planting region	Northeast China planting region
	Sichuan, Guizhou, Yunnan, Chongqing and Hubei	Gansu, Shaanxi, Ningxia, Qinghai and Xinjiang	Inner Mongolia, Hebei, Shanxi, Beijing and Tianjin	Shandong, Anhui, Guangdong, Guangxi, Jiangxi, Jiangsu, Zhejiang and Fujian	Heilongjiang, Liaoning and Jilin
Late blight, early blight and tar spot	1	1	1		1
Bacterial wilt, ring rot and scab (bacteriosis)	4 (different regions)				
Aphid, underground pest (wireworm, mole cricket, grub and cut worm) and Epilachna niponica Lewia	1	1	1		1
Weed	1	1	1	1	1

2 Cash Crops

2.1 Cotton

Diseases, pests and weeds	Northwestern Inland cotton region	Yellow River Basin cotton region	Yangtze River Basin cotton region

	Xinjiang and Gansu	Shandong, Henan, Hebei, Tianjin, Shanxi and Shaanxi	Anhui, Jiangsu, Hubei, Hunan, Jiangxi and Sichuan
Damping off, blight and verticillium wilt	4 (1 or 2 locations are selected in each region; 2 locations may be selected in Xinjiang)		
Cotton bollworm, aphid, red mite, leaf bug, thrips tabaci and bemisia tabaci			
Pink bollworm			2
Weed	5 (1 or 2 locations are selected in each region; 2 locations may be selected in Xinjiang)		

2.2 Tobacco

Diseases, pests and weeds	Southwest tobacco region	North China tobacco region	Southeast tobacco region	Yangtze River Upper and Middle Reaches tobacco region	Huanghuai tobacco region
	Yunnan, Guizhou, Sichuan and Guangxi	Liaoning, Heilongjiang, Inner Mongolia, Gansu and Jilin	Guangdong, Hunan, Anhui, Jiangxi and Fujian	Hubei and Chongqing	Shandong, Henan and Shaanxi
Black shank disease, brown spot, bacterial wilt and virus disease	2		1		1
Oriental tobacco budworm and aphid	2		1		1
Weed	2	1		1	1

2.3 Sugar Cane

Pests and weeds	Southwest sugar cane region	Southeast sugar cane region	Yangtze River Middle Reaches sugar cane region

	Guangxi, Yunnan, Sichuan and Guizhou	Guangdong, Hainan and Fujian	Hubei, Hunan and Jiangxi
Sugar cane borer	2	1	
Weed	2	1	

2.4 Tea Tree

Pests	South China tea region	South of the Yangtze River tea region	Southwest tea region	North of the Yangtze River tea region
	Fujian, Hainan, Guangdong and Guangxi	Hunan, Jiangxi, Zhejiang, Hubei, Anhui and Jiangsu	Sichuan, Guizhou, Chongqing and Yunnan	Henan, Shaanxi, Shandong and Gansu
Tea lesser leafhopper, tea geometrid and tea tussock moth	1	2	1	

3 Oil-Bearing Crops

3.1 Soybean

Diseases, pests and weeds	Huang-Huai-Hai River Basin soybean region	Yangtze River Basin soybean region	Northwest soybean region	Yunnan-Guizhou Plateau soybean region	South China soybean region	Northeast China soybean region
	Hebei, Shandong, Shanxi, Henan and Tianjin	Anhui, Hubei, Jiangsu and Zhejiang	Shaanxi, Gansu, Ningxia and Xinjiang	Yunnan, Guizhou, Hunan and Sichuan	Guangdong, Guangxi and Fujian	Heilongjiang, Jilin, Liaoning and Inner Mongolia
Cereal cyst nematode	1	1	1			1
Aphid and budworm	1	1		1		1
Cotton bollworm	1	1	1		1	

Underground pest	1 (or 1 location is selected in the Yunnan-Guizhou Plateau region)	1				2
Weed in soybean field	2	1				2
Weed in spring soybean field						3
Weed in summer soybean field	2	1	1			

3.2 Peanut

Diseases, pests and weeds	Yellow River Basin peanut region	Yangtze River Basin peanut region	Yunnan-Guizhou Plateau peanut region	Northeast China peanut region	Southeast Coast peanut region	Northwest peanut region
	Shandong, Hebei, Henan, Tianjin and Beijing	Hubei, Zhejiang, Hunan, Jiangxi, Anhui, Jiangsu and Shanghai	Sichuan, Guizhou and Yunnan	Liaoning, Jilin, Heilongjiang and Inner Mongolia	Guangdong, Guangxi and Fujian	Shaanxi, Xinjiang, Gansu, Shanxi and Ningxia
Root rot and fruit rot	2	1			1	
Rust disease	2	2				
Leaf spot, stem rot (fallen vine disease) and brown spot	2	1		1		
Underground pest	4 (different regions)					

Aphid	1 or 2	1 or 2			1 or 2	
Weed	2	1	1	1		

3.3 Rape

Diseases, pests and weeds	Yangtze River Middle Reaches rape region	Yangtze River Upper Reaches rape region	Yangtze River Lower Reaches rape region	Northwest Plateau rape region	Northeast China rape region
	Hubei, Hunan, Jiangxi, Anhui and Henan	Sichuan, Chongqing, Yunnan and Guizhou	Jiangsu, Zhejiang and Shanghai	Qinghai, Xinjiang, Gansu, Inner Mongolia and Shaanxi	Heilongjiang, Jilin and Liaoning
Sclerotinia and downy mildew	1	1	1	1	
Aphid	1	1	1	1	
Weed in rape field	2	1		2	
Weed in winter rape field	2	1	1		
Weed in spring rape field				3 (different regions)	

4 Vegetable

Vegetable category	Southern vegetable region	Central vegetable region	Northern vegetable region	Western vegetable region
	Guangdong, Guangxi, Hainan, Chongqing, Sichuan, Guizhou, Yunnan and Fujian	Shanghai, Jiangsu, Zhejiang, Anhui, Jiangxi, Henan, Hubei and Hunan	Shandong, Hebei, Liaoning, Jilin, Heilongjiang, Beijing, Tianjin and Inner Mongolia	Shaanxi, Gansu, Qinghai, Shanxi, Ningxia, Xinjiang and Tibet

Brassicaceous vegetable	Downy mildew and soft rot
	Cabbage caterpillar, diamond back moth, aphid, asparagus caterpillar and Spodoptera litura
Cucumber	Downy mildew, powdery mildew, anthracnosis, Pseudomonas lachrymans and blast
	Aphid and Liriomyza sativae
Tomato	Early blight, gray mold, virus disease, leaf mold and late blight
	Trialeurodes vaporariorum
Chili	Anthracnosis , epidemic and gray mold
	Bemisia tabaci
Watermelon	Anthracnosis, blast and Trialeurodes vaporariorum
Note: One location is selected in each vegetable region to do the test.	

5 Fruit Trees

5.1 Apple

Diseases and pests	Western region	Bohai Bay Rim region
	Shaanxi, Henan, Shanxi, Gansu, Xinjiang, Ningxia, Sichuan, Yunnan and Guizhou	Shandong, Liaoning, Hebei, Beijing, Tianjin and Jiangsu
Alternaria leaf spot, ring spot, anthracnosis, canker disease and brown spot	2	2
Red mite, peach fruit borer and leaf roller	2	2

5.2 Citrus

Diseases and pests	Southwest region	South China region	Yangtze River Middle and Lower Reaches regions
	Guangxi, Sichuan,	Guangdong,	Jiangxi, Hubei,

	Chongqing, Yunnan, Guizhou and Shaanxi (southern part)	Fujian and Hainan	Hunan, Anhui and Zhejiang
Scab, anthracnosis and canker	2	1	1
Aphid, leafminer, red mite, scale insect, Phyllocoptruta oleivora Ashmead, phylloxera and whitefly	2	1	1

5.3 Pear Trees

Diseases and pests	Northern region near the coast	Southwestern region	Yellow River Middle Reaches region	Yangtze River Middle and Lower Reaches region	Northeast China region	Northwest region
	Beijing, Hebei and Shandong	Yunnan, Guizhou, Sichuan, Chongqing and Guangxi	Shanxi, Shaanxi and Henan	Hunan, Hubei, Jiangxi, Anhui, Jiangsu and Zhejiang	Liaoning, Jilin, Heilongjiang and Inner Mongolia (Northeast China)	Gansu and Xinjiang
Black spot and rust disease	1	1	1	1		
Psylla and oriental fruit moth	1	1	1	1		

5.4 Grape

Diseases	Northeast China Region	Northern region near the coast	Yellow River Middle Reaches region	Eastern coast region	Southwestern region	Yangtze River Middle Reaches region	Northwestern region

	Liaoning, Jilin, Heilongjiang and Inner Mongolia (Northeast China)	Beijing, Tianjin, Hebei and Shandong	Shanxi, Shaanxi, Henan and Inner Mongolia (central and western parts)	Shanghai, Jiangsu, Zhejiang and Fujian	Yunnan, Guizhou, Sichuan, Chongqing and Guangxi	Hunan, Hubei, Jiangxi and Anhui	Gansu, Ningxia and Xinjiang
Downy mildew, gray mold, white rot and powdery mildew	1		1		1		1
Anthracnosis and spot anthracnose		1	1	1		1	

Annex 8

Crop Classification of Residue Test for Pesticide Registration

1 Cereals

1.1 Rice: paddy rice, upland rice, etc.

Representative crop: paddy rice

1.2 Wheat: wheat, barley, oat, rye, buckwheat, etc.

Representative crop: wheat

1.3 Upland crops: maize, sorghum, millet, coix seed, etc.

Representative crop: maize

1.4 Coarse cereals: mung bean, lentils, chick pea, red bean, etc.

Representative crop: mung bean

2 Vegetables

2.1 Bulbs

2.1.1 Bulb onions: garlic, onion, allium sinensis G. don., etc.

Representative crop: garlic

2.1.2 Green onions: chives, shallot, garlic sprouts, young garlic shoot, leek, etc.

Representative crop: chives

2.1.3 Lily

2.2 Brassicas

2.2.1 Head brassicas: head cabbage, kohlrabi, brussels sprouts, etc.

Representative crop: head cabbage

2.2.2 Flowerhead brassicas: cauliflower, broccoli, etc.

Representative crop: cauliflower

2.2.3 Steam brassicas: cabbage mustard, brassica campestris, stem mustard, potherb mustard, etc.

Representative crop: cabbage mustard

2.2.4 Chinese cabbage

2.3 Leafy vegetables

2.3.1 Green leafy vegetables: spinach, common Chinese cabbage (edible rape, pakchoi), lactuca sativa, water spinach, edible amaranth, radish leaf, beet leaf, crowndaisy chrysanthemum, leaf mustard, lamb's-lettuce, chicory, leaf lettuce, etc.

Representative crop: spinach and common Chinese cabbage

2.3.2 Leafy petioles: celery, fennel, etc.

Representative crop: celery

2.4 Solanaceous vegetables: tomato, chili, eggplant, pimento, gumbo, wintercherry, etc.

Representative crop: tomato and chili

2.5 Melons

2.5.1 Cucumber

2.5.2 Small melons: cucurbita pepo, bitter gourd, luffa cylindrica, luffa acutangula, calabash gourd, zucchini, etc.

Representative crop: cucurbita pepo

2.5.3 Large melons: wax gourd, pumpkin, cucurbita maxima, etc.

Representative crop: wax gourd

2.6 Legume vegetables

2.6.1 Pods edible: cowpea, phaseolus vulgaris, pea, asparagus pea, hyacinth bean, sword bean, etc.

Representative crop: cowpea

2.6.2 Pods inedible: petits pois, vicia faba, lima bean, etc.

Representative crop: petits pois

2.7 Stalks and stems: asparagus, stem lettuce, artichoke, rheum officinale, etc.

Representative crop: asparagus and stem lettuce

2.8 Root and tuber vegetables

2.8.1 Root vegetables: radish, carrot, beetroot, celeriac, root mustard, horse-radish, turnip, ginger, etc.

Representative crop: radish

2.8.2 Tubers and bulbs

2.8.2.1 Potato

2.8.2.2 Others: sweet potato, Chinese yam, great burdock, cassava, etc.

Representative crop: sweet potato

2.9 Aquatic vegetables

2.9.1 Stem leaves: cress, nasturtium officinale, zizania aquatica, cattail, etc.

Representative crop: cress and nasturtium officinale

2.9.2 Fruits: water chestnut, gorgon fruit, etc.

Representative crop: water chestnut

2.9.3 Roots: lotus root, chufa, arrowhead, etc.

Representative crop: lotus root

2.10 Others

Bamboo shoots, day lily, etc.

3 Fruits

3.1 Citrus fruits: tangerine, citrus sinensis, citrus reticulata, lemon, pomelo, , bergamot, kumquat, etc.

Representative crop: tangerine and citrus sinensis

3.2 Pip fruits: apple, pear, quince, persimmon, hawthorn, etc.

Representative crop: apple or pear

3.3 Stone fruits: peach, jujube, nectarine, apricot, loquat, plum, cherry, etc.

Representative crop: peach and jujube

3.4 Berries and other small fruits

3.4.1 Cane and shrub

3.4.1.1 Matrimony vine

3.4.1.2 Others: blueberry, mulberry, blackberry, raspberry, gooseberry, cranberry, shadberry, etc.

Representative crop: blueberry

3.4.2 Small fruit vine climbing

3.4.2.1 Edible peel: grape, schisandra chinensis, etc.

Representative crop: grape

3.4.2.2 Inedible peel: kiwi fruit, passionflower, etc.

Representative crop: kiwi fruit

3.4.3 Strawberry

3.5 Assorted tropical and sub-tropical fruits

3.5.1 Edible peel: carambola, waxberry, guava, olive, fig, etc.

Representative crop: carambola and waxberry

3.5.2 Inedible peel

3.5.2.1 Small fruits: litchi, longan, clausena lansium, rambutan, etc.

Representative crop: litchi

3.5.2.2 Medium fruits: mango, avocado, pomegranate, sugar apple, durian, mangosteen, etc.

Representative crop: mango and avocado

3.5.2.3 Large fruits: banana, pawpaw, coconut, etc.

Representative crop: banana

3.5.2.4 Spiny fruit: pineapple, jackfruit, durian, dragon fruit, etc.

Representative crop: pineapple

3.6 Melon fruits

3.6.1 Watermelone

3.6.2 Other melon fruits: muskmelon, Hami melon, honey dew melon, etc.

Representative crop: muskmelon

4 Nuts

4.1 Small nuts: almond, hazelnut, cashew nut, pine nut, pistachio, ginkgo, etc.

Representative crop: almond

4.2 Large nuts: walnut, chestnut, hickory nut, etc.

Representative crop: walnut

5 Sugar-Yielding Crops

5.1 Sugar cane

5.2 Beet

6 Oil-Bearing Crops

6.1 Small rapeseed: rapeseed, sesame, linseed, mustard seed, etc.

Representative crop: rapeseed

6.2 Others

6.2.1 Soybean

6.2.2 Peanut

6.2.3 Cotton seeds

6.2.4 Sunflower seeds

6.2.5 Tea seed

7 Beverage Crops

7.1 Tea

7.2 Coffee bean and cocoa bean

7.3 Hop

7.4 Chrysanthemum, rose, etc.

8 Edible Fungi

8.1 Mushrooms: cap fungus, lentinus edodes, flammulina velutiper, agrocybe cylindracea, dictyophora indusiata, volvaria volvacea, morchella, boletus, tricholoma, tricholoma matsutake, agaricus bisporus, hedgehog hydnum, pleurotus nebrodensis, pleurotus eryngii, etc.

Representative crop: pleurotus ostreatus, lentinula edodes and flammulina velutipes

8.2 Agaric: agaric, tremella, tremella aurantialba, auricularia polytricha, umbilicaria, etc.

Representative crop: agaric

9 Seasoners

9.1 Leaves: coriander, peppermint, sweet basil, purple perilla, etc.

Representative crop: coriander

9.2 Fruits: Chinese prickly ash, black pepper, amomum kravanh, etc.

9.3 Seeds: mustard, star anise, etc.

9.4 Tubers: cassia bark, horseradish, etc.

10 Feed Crops

Medicago, ryegrass, etc.

11 Medicinal Plants

11.1 Tubers: ginseng, pseudo-ginseng, rhizoma gastrodiae, liquorice, pinellia ternata, bighead atractylodes rhizome, ophiopogon japonicus, etc.

11.2 Leaves and stalks: plantago asiatica, cordate houttuynia, Chinese mugwort, wormwood, etc.

11.3 Flowers and fruits: honeysuckle, etc.

12 Others

Tobacco, etc.

Note: According to this crop classification, 1-2 more non-representative crop categories may be selected and tested on the basis of residue test of representative crops before application for registration in this crop.

Annex 9

Requirements for the Number of Locations of Residue Test for Pesticide Registration

No.	Crops	No. of locations
1	Paddy rice, wheat, maize, potato, cucumber, tomato, chili, head cabbage, tangerine (citrus sinensis), apple (pear), etc.	≥12
2	Winter wheat, summer maize, Chinese cabbage, common Chinese cabbage, phaseolus vulgaris, grape, watermelon, soybean (including petits pois), peanut, rapeseed, tea, etc.	≥10
3	Chives, cauliflower, spinach, celery, eggplant, cucurbita pepo, wax gourd, cowpea, stem lettuce, radish (including radish leaf), carrot, sweet potato, peach, jujube, strawberry, kiwi fruit, cottonseed, etc.	≥8
4	Spring wheat, spring maize, mung bean, garlic, asparagus, cabbage mustard, Chinese yam, zucchini, cress, lotus root, zizania aquatica, bamboo shoots, muskmelon, persimmon, loquat, litchi, mango, banana, pomegranate, waxberry, pawpaw, pineapple, sugar cane, beet, sunflower seeds, lentinus edodes, flammulina velutiper, cap fungus, agaric, etc.	≥6
5	Lily, water chestnut, gorgon fruit, day lily, nasturtium officinale, fennel, horse-radish, almond, matrimony vine, blueberry, mulberry, olive, coconut, durian, walnut, gingko, tea seed, coffee bean, cocoa bean, hop, chrysanthemum, rose, seasoners, medicinal plants, etc.	≥4
6	For pesticides used in relevantly stable environmental conditions, such as for storage, antiseptic, and preservation purpose	≥4

Notes:

1. Priority shall be given to arranging test locations in main producing areas of the crop.

2. The test layout should give comprehensive consideration to the influence of crop planting areas, varieties, farming methods, main producing areas and climate zone difference on pesticide residue.

3. Except the characteristic minor crops planted relatively in a concentrated manner, the distance between test locations under a same farming method should not be less than 200 km.

Annex 10

Specification for Identification of Me-too Pesticides

1 General Principles

1.1 If registration of me-too TCs or me-too formulations is applied for, identification of me-too pesticides should be conducted.

1.2 The identification of me-too pesticides should be jointly reviewed by the experts in the fields of product chemistry, toxicology and environmental impact.

1.3 The identification of me-too pesticides is conducted in two stages. The first stage is identification of data of product chemistry, and the second stage is identification of toxicological data and environmental impact data.

2 Identification of me-too TCs

2.1 Procedure and standard

2.1.1 Identification of data of product chemistry

2.1.1.1 Compared with the control product (M1, the same below), when the product (M2, the same below) applying for identification meets all of the following requirements, it may be identified that M2 and M1 are me-too TCs.

2.1.1.1.1 The content of active ingredients in M2 is not lower than that in M1;

2.1.1.1.2 The limit of relevant impurities in M2 is not higher than that in M1;

2.1.1.1.3 The control indexes of other items of M2 are not lower than those of M1;

2.1.1.1.4 Compared with M1, M2 does not have new relevant impurities;

2.1.1.1.5 Compared with M1, the relative value of the limit of irrelevant impurities in M2 is increased by not more than 50% or the absolute value is increased by not more than 0.3%, whichever is the bigger;

2.1.1.1.6 Compared with M1, M2 does not have new irrelevant impurities;

2.1.1.1.7 The result of Salmonella typhimurium/reverse mutation test of M2 is equal to or better than that of M1.

2.1.1.2 When the requirements in any of 2.1.1.1.1, 2.1.1.1.3 and 2.1.1.1.7 are not met, it is identified that M2 is not a me-too TC.

2.1.1.3 When the requirements in 2.1.1.1.1, 2.1.1.1.3 and 2.1.1.1.7 are all met at the same time, but the requirements in any of 2.1.1.1.2, 2.1.1.1.4, 2.1.1.1.5 and 2.1.1.1.6 are not met, the identification in the second stage needs to be conducted.

2.1.2 Identification of toxicological and environmental impact data

2.1.2.1 Identification of toxicological data

2.1.2.1.1 The result of toxicological test of M2 is compared with the test results of corresponding items of M1. If the coefficient of the acute toxicity test result is not greater than 2 (or although it is greater than 2, it does not exceed the reasonable test dose growth coefficient) and the evaluation

conclusions of appeared positive and negative results are consistent, it will be identified that they are identical in terms of toxicological data.

2.1.2.1.2 If the result of actual toxicity test cannot identify that the toxicological data of M2 and M1 is identical, the results of repeated administration test (subacute to chronic toxicity test) and reproductive toxicity, mutagenicity and carcinogenicity test results should also be evaluated and identification should be conducted according to the principle given in 2.1.2.1.1. If the organs with a toxic effect are same, and the change in NOELs and NOAELs does not exceed the change in dosage level, it will be identified that their toxicological data is identical.

2.1.2.2 Identification of environmental impact data

Under the preconditions that the test organisms are same, the results of bird acute oral toxicity test, fish acute toxicity test, Daphnia magna acute immobilisation test, honeybee acute contact toxicity test and silkworm acute toxicity test of M1 are taken as reference. If the coefficient of M2 is not greater than 5 (or although it is greater than 5, it does not exceed the reasonable test dose growth coefficient), compared with the test results of corresponding items of M1, it may be identified that the environmental impact data of M2 and M1 are identical.

2.2 Data requirements

2.2.1 The producer name and registration certificate number of M1

2.2.2 Production process, complete composition analysis report, physic-chemical properties, product quality specification and Salmonella typhimurium/reverse mutation test data of M2.

2.2.3 The toxicological and environmental impact data of M2 are provided according to need

2.2.3.1 The toxicological data includes: acute oral, dermal and inhalation toxicity test, eye irritation test, skin irritation test, skin sensitization test, subchronic (acute) toxicity test (90D rat feeding test is required. According to product features, 28D dermal or 28D inhalation toxicity test should be done, too), mutagenicity test, in vitro mammal cell gene mutation test, in vitro mammal cell chromosomal aberration test and in vivo mammal marrow cell micronucleus test.

2.2.3.2 The environmental impact data includes: bird acute oral toxicity test, fish acute toxicity test, Daphnia magna acute immobilisation test, honeybee acute contact toxicity test and silkworm acute toxicity test.

2.2.4 If authorization is obtained from the holder of the M1 registration certificate, an original copy of the power of attorney bearing the signature of the legal representative of the authorizing party and an official seal should be provided.

3 Identification of Me-too Formulations

3.1 Procedure and standard

3.1.1 If authorization is obtained from the holder of the M1 registration certificate, the sources of TCs are same or the TCs used are identified as me-too TCs, it may be identified that they are me-too formulations.

3.1.2 If authorization is not obtained from the holder of the M1 registration certificate, identification should be conducted according to the identification procedures in two stages. When all the requirements in the first and second stages are met at the same time, it may be identified that M2 and M1 are me-too formulations.

3.1.2.1 Identification of date of product chemistry

3.1.2.1.1 The TCs used by M2 and M1 are me-too TCs;

3.1.2.1.2 M2 and M1 are same in terms of the content of active ingredients and formulation type;

3.1.2.1.3 The safeners, stabilizers, synergists and other restrictive components in M2 and M1 are same in terms of type and content;

3.1.2.1.4 The control indexes of other main items of M2 are not lower than those of M1;

3.1.2.1.5 M2 shall not contain any adjuvant prohibited by the State. The type and limit of the adjuvant restricted by the State shall meet the requirements.

3.1.2.2 Identification of toxicological and environmental impact data

3.1.2.2.1 Identification of toxicological data

The result of toxicological test of M2 is compared with the test results of corresponding items of M1. If the coefficient of the acute toxicity test result is not greater than 2 (or although it is greater than 2, it does not exceed the reasonable test dose growth coefficient) and the evaluation conclusions of appeared positive and negative results are consistent, it will be identified that they are identical in terms of toxicological data.

3.1.2.2.2 Identification of environmental impact data

Under the preconditions that the test organisms are same, the results of bird acute oral toxicity test, fish acute toxicity test, Daphnia magna acute immobilisation test, honeybee acute contact toxicity test and silkworm acute toxicity test of M1 are taken as reference. If the coefficient of M2 is not greater than 5 (or although it is greater than 5, it does not exceed the reasonable test dose growth coefficient), compared with the test results of corresponding items of M1, it may be identified that the environmental impact data of M2 and M1 are identical.

3.2 Data requirements

3.2.1 If authorization is obtained from the holder of the M1 registration certificate, an original copy of the power of attorney bearing the signature of the legal representative of the authorizing party and an official seal and the registration certificate number of the TC used in M1 should be provided

3.2.2 If authorization is not obtained from the holder of the M1 registration certificate, the following data should be provided.

3.2.2.1 The producer name and registration certificate number of M1.

3.2.2.2 Registration certificate number of the TC used in M2, product composition, description of processing method, physic-chemical properties and product quality specification.

3.2.2.3 The toxicological data of M2 includes: acute oral, dermal and inhalation toxicity test, eye irritation test, skin irritation test and skin sensitization test.

3.2.2.4 The environmental impact data of M2 includes: bird acute oral toxicity test, fish acute toxicity test, Daphnia magna acute immobilisation test, honeybee acute contact toxicity test and silkworm acute toxicity test.

Annex 11

Principles of Nomenclature for Pesticides

In order to regulate the names of pesticides and protect the lawful rights and interests of pesticide producers and users, the naming of pesticides is specified as follows in accordance with relevant provisions of the *Regulations on Pesticide Management* and the *Measures for the Administration of Pesticide Registration*:

1. The name of TC (TK) is expressed with "Chinese common names or simplified common names of active ingredients".

2. The name of a formulation with single active ingredient is expressed with "Chinese common name of the active ingredient".

3. The name of a ready-mixture is expressed with "Chinese common names or simplified common names of active ingredients". If a Chinese common name consists of more than three characters, a simplified common name may be used. In principle, the name of a ready-mixture consists of not more than nine characters. If there are more than nine characters, simplified common names should be adopted; if there are not more than nine characters, no simplified common names should be used. A separation dot (expressed with round dot "·", medium solid point, half-angle) should be inserted between Chinese common names or simplified common names of active ingredients, which are arranged according to the sequence of pinyin of Chinese common names.

4. Simplified common names should be selected from Chinese common names of active ingredients on the principle of being concise, understandable and convenient for memory and not causing ambiguity. In principle, a simplified common name does not exceed three characters. Each active ingredient can have only one simplified common name. The salts of a same ingredient in different forms or different isomers with a same chemical structure may use a same simplified common name, while the differences are stated in the remark column of the registration certificate and the active ingredients column of the label.

5. Simplified common names shall not be confused with the names of pharmaceuticals, veterinary drugs, cosmetics, detergents, food, food additives, beverage and health products; or with the common names or popular names of other active ingredients of pesticides or the names of formulation types.

6. The name of a directly used public health pesticide is expressed with the terms of function description plus formulation type. If it is used after dilution, the pesticide name should be used pursuant to the provisions of clauses 2 and 3.

7. The name of a botanical pesticide may be expressed with "plant name + extract".

8. Simplified common names are determined by the National Pesticide Registration Review Committee and may be used upon approval of the Ministry of Agriculture.

9. The pesticide names approved and registered before release of this regulation may remain unchanged.

Annex 12

Principles for Setting the Content of Active Ingredients of Pesticides

In order to provide scientific and reasonable guidance on the development of pesticide products and the registration of pesticides and regulate the order of the pesticide market, the principle for setting the content of active ingredients of pesticides is specified as follows in accordance with relevant provisions of the *Regulations on Pesticide Management* and the *Measures for the Administration of Pesticide Registration*:

1. If a national standard or industrial standard has specific provisions on the content of active ingredients, the content of active ingredients shall meet the requirements of the standard.

2. If no standard or industrial standard is formulated, or the existing national standards or industrial standards don't have specific provisions on the content of active ingredients, the content of active ingredients in the formulation (the total content of active ingredients in the ready-mixture with the same proportioning) shall be set according to the following requirements:

   2.1 For a product with same active ingredients and formulation type, if the content of active ingredients is ≥10% (or 100 g/L), the interval of its content change may not be smaller than 5% (or 50 g/L); if the content of active ingredients is <10% (or 100 g/L), the interval of its content change may not be smaller than 50% of the content of active ingredients.

   2.2 If the content of active ingredients is "≥10% or 100 g/L", the content may have at most three significant digits; if the content of active ingredients is "<10% or 100 g/L", the content may have at most two significant digits.

3. For an emulsifiable concentration (EC), micro emulsion formulation (ME) or wettable powder (WP) product, the content of its active ingredients may not be lower than the content of active ingredients of the approved and registered products (including ready-mixtures with the same proportioning).

4. The content of active ingredients in a liquid formulation may be expressed with mass fraction (%) or mass concentration (g/L); when it is expressed with mass concentration, the product quality standard should specify mass fraction, too.

5. For a pesticide product containing penetrants or synergists, the content of its active ingredients should be set according to the requirements for setting of the content of active ingredients in like products not containing penetrants or synergists.

6. If the content of active ingredients in a pesticide applying for registration does not conform to the above provisions, the content of active ingredients may be changed according to the principle of similarity and the following data should be submitted:

   6.1 Description of change in the content of active ingredients;

   6.2 Data of product chemistry after change of content; the data of normal-temperature storage stability test or microbial pesticide storage stability test may be the test data before change of content;

   6.3 If the content of active ingredients is increased, data of acute toxicity test should be submitted.

7. Under special circumstances, the applicant should submit description of scientificalness, reasonableness and validity and relevant proof documents. The application will be examined and approved by the National Pesticide Registration Review Committee.

Annex 13

Product Quality Specification and Physic-Chemical Property Items of Pesticide Formulations in Different Formulation Types

1 Solid Formulations

1.1 Dust Formulations (DP)

1.1.1 DP product quality specification should include:

1.1.1.1 Appearance;

1.1.1.2 Content of active ingredients;

1.1.1.3 Content of relevant impurities;

1.1.1.4 Content of other restrictive components;

1.1.1.5 Water;

1.1.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

1.1.1.7 Dry sieve test;

1.1.1.8 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, dry sieve test, etc. shall meet the requirements of the product quality specification.

1.1.2 The physic-chemical property items of a DP product should include:

1.1.2.1 Appearance (color, physical state and odor);

1.1.2.2 Density;

1.1.2.3 Oxidation/reduction properties;

1.1.2.4 Corrosiveness to packing material;

1.1.2.5 Explosibility;

1.1.2.6 Solid combustibility.

1.2 Water Dispersible Tablet (WT)

1.2.1 WT product quality specification should include:

1.2.1.1 Appearance;

1.2.1.2 Content of active ingredients;

1.2.1.3 Content of relevant impurities;

1.2.1.4 Content of other restrictive components;

1.2.1.5 Water;

1.2.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

1.2.1.7 Disintegration time (applicable to effervescent tablets only);

1.2.1.8 Suspensibility;

1.2.1.9 Wet sieve test;

1.2.1.10 Persistent foaming;

1.2.1.11 Tablet integrity;

1.2.1.12 Wear rate;

1.2.1.13 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, disintegration time, suspensibility, wet sieve test, wear rate, etc. shall meet the requirements of the product quality specification.

1.2.2 The physic-chemical property items of a WT product should include:

1.2.2.1 Appearance (color, physical state and odor);

1.2.2.1 Density;

1.2.2.3 Oxidation/reduction properties;

1.2.2.4 Corrosiveness to packing material;

1.2.2.5 Explosibility;

1.2.2.6 Solid combustibility.

1.3 Granule (GR)

1.3.1 GR product quality specification should include:

1.3.1.1 Appearance;

1.3.1.2 Content of active ingredients;

1.3.1.3 Content of relevant impurities;

1.3.1.4 Content of other restrictive components;

1.3.1.5 Water;

1.3.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

1.3.1.7 Bulk density;

1.3.1.8 Nominal size range;

1.3.1.9 Dust;

1.3.1.10 Abrasive resistance (expulsion rate or breakage rate);

1.3.1.11 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, nominal size range, dust, abrasive resistance, etc. shall meet the requirements of the product quality specification.

1.3.2 The physic-chemical property items of a GR product should include:

1.3.2.1 Appearance (color, physical state and odor);

1.3.2.2 Density;

1.3.2.3 Oxidation/reduction properties;

1.3.2.4 Corrosiveness to packing material;

1.3.2.5 Explosibility;

1.3.2.6 Solid combustibility.

1.4 Water Soluble Powder (SP)

1.4.1 SP product quality specification should include:

1.4.1.1 Appearance;

1.4.1.2 Content of active ingredients;

1.4.1.3 Content of relevant impurities;

1.4.1.4 Content of other restrictive components;

1.4.1.5 Water;

1.4.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

1.4.1.7 Wetting time;

1.4.1.8 Solubility and solution stability (for a product in a water soluble packing bag, the test samples should be the mixture of the pesticide product and the packing bag, and the mass ratio of the sample should be same as the ratio between the content and the packing bag in actual use);

1.4.1.9 Persistent foaming (for a product in a water soluble packing bag, the test samples should be the mixture of the pesticide product and the packing bag, and the mass ratio of the sample should be same as the ratio between the content and the packing bag in actual use);

1.4.1.10 Solubility of packing bags (applicable only when water soluble packing bags are adopted);

1.4.1.11 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, wetting time, solubility and solution stability, etc. shall meet the requirements of the product quality specification.

Note: When water soluble packing bags are adopted, then after storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, wetting time, solubility and solution stability, solubility of packing bags, etc. shall meet the requirements of the product quality specification.

1.4.2 The physic-chemical property items of an SP product should include:

1.4.2.1 Appearance (color, physical state and odor);

1.4.2.2 Density;

1.4.2.3 Oxidation/reduction properties;

1.4.2.4 Corrosiveness to packing material;

1.4.2.5 Explosibility;

1.4.2.6 Solid combustibility.

1.5 Water Soluble Granules (SG)

1.5.1 SG product quality specification should include:

1.5.1.1 Appearance;

1.5.1.2 Content of active ingredients;

1.5.1.3 Content of relevant impurities;

1.5.1.4 Content of other restrictive components;

1.5.1.5 Water;

1.5.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

1.5.1.7 Solubility and solution stability (for a product in a water soluble packing bag, the test samples should be the mixture of the pesticide product and the packing bag, and the mass ratio of the sample should be same as the ratio between the content and the packing bag in actual use);

1.5.1.8 Persistent foaming (for a product in a water soluble packing bag, the test samples should be the mixture of the pesticide product and the packing bag, and the mass ratio of the sample should be same as the ratio between the content and the packing bag in actual use);

1.5.1.9 Dust;

1.5.1.10 Abrasive resistance;

1.5.1.11 Solubility of packing bags (applicable only when water soluble packing bags are adopted);

1.5.1.12 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, solubility and solution stability, abrasive resistance, etc. shall meet the requirements of the product quality specification.

Note: When water soluble packing bags are adopted, then after storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, solubility and solution stability, solubility of packing bags, etc. shall meet the requirements of the product quality specification.

1.5.2 The physic-chemical property items of an SG product should include:

1.5.2.1 Appearance (color, physical state and odor);

1.5.2.2 Density;

1.5.2.3 Oxidation/reduction properties;

1.5.2.4 Corrosiveness to packing material;

1.5.2.5 Explosibility;

1**.5.2.6** Solid combustibility.

1.6 Water Soluble Tablets (ST)

1.6.1 ST product quality specification should include:

1.6.1.1 Appearance;

1.6.1.2 Content of active ingredients;

1.6.1.3 Content of relevant impurities;

1.6.1.4 Content of other restrictive components;

1.6.1.5 Water;

1.6.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

1.6.1.7 Disintegration time (applicable to effervescent tablets only);

1.6.1.8 Solubility and solution stability;

1.6.1.9 Persistent foaming;

1.6.1.10 Tablet integrity;

1.6.1.11 Wear rate;

1.6.1.12 Wet sieve test;

1.6.1.13 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, disintegration time (applicable to effervescent tablets only) , Solubility and solution stability, wear rate, wet sieve test, etc. shall meet the requirements of the product quality specification.

1.6.2 The physic-chemical property items of an ST product should include:

1.6.2.1 Appearance (color, physical state and odor);

1.6.2.2 Density;

1.6.2.3 Oxidation/reduction properties;

1.6.2.4 Corrosiveness to packing material;

1.6.2.5 Explosibility;

1.6.2.6 Solid combustibility.

1.7 Wettable Powder (WP)

1.7.1 WP product quality specification should include:

1.7.1.1 Appearance;

1.7.1.2 Content of active ingredients;

1.7.1.3 Content of relevant impurities;

1.7.1.4 Content of other restrictive components;

1.7.1.5 Water;

1.7.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

1.7.1.7 Wet sieve test;

1.7.1.8 Suspensibility (for a product in a water soluble packing bag, the test samples should be the mixture of the pesticide product and the packing bag, and the mass ratio of the sample should be same as the ratio between the content and the packing bag in actual use);

1.7.1.9 Persistent foaming (for a product in a water soluble packing bag, the test samples should be the mixture of the pesticide product and the packing bag, and the mass ratio of the sample should be same as the ratio between the content and the packing bag in actual use);

1.7.1.10 Wetting time;

1.7.1.11 Solubility of packing bags (applicable only when water soluble packing bags are adopted);

1.7.1.12 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, wet sieve test, suspensibility, wetting time, etc. shall meet the requirements of the product quality specification.

Note: When water soluble packing bags are adopted, then after storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, suspensibility, wet sieve test and solubility of packing bags shall meet the requirements of the product quality specification.

1.7.2 The physic-chemical property items of a WP product should include:

1.7.2.1 Appearance (color, physical state and odor);

1.7.2.2 Density;

1.7.2.3 Oxidation/reduction properties;

1.7.2.4 Corrosiveness to packing material;

1.7.2.5 Explosibility;

1.7.2.6 Solid combustibility.

1.8 Tablets (TB)

1.8.1 TB product quality specification should include:

1.8.1.1 Appearance;

1.8.1.2 Content of active ingredients;

1.8.1.3 Content of relevant impurities;

1.8.1.4 Content of other restrictive components;

1.8.1.5 Water;

1.8.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

1.8.1.7 Tablet integrity;

1.8.1.8 Wear rate;

1.8.1.9 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, tablet integrity, wear rate, etc. shall meet the requirements of the product quality specification.

1.8.2 The physic-chemical property items of a TB product should include:

1.8.2.1 Appearance (color, physical state and odor);

1.8.2.2 Density;

1.8.2.3 Oxidation/reduction properties;

1.8.2.4 Corrosiveness to packing material;

1.8.2.5 Explosibility;

1.8.2.6 Solid combustibility.

1.9 Emulsifiable Powder (EP)

1.9.1 EP product quality specification should include:

1.9.1.1 Appearance;

1.9.1.2 Content of active ingredients;

1.9.1.3 Content of relevant impurities;

1.9.1.4 Content of other restrictive components;

1.9.1.5 Water;

1.9.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

1.9.1.7 Wetting time;

1.9.1.8 Wet sieve test;

1.9.1.9 Dispersion stability;

1.9.1.10 Persistent foaming;

1.9.1.11 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, wetting time, wet sieve test, dispersion stability, etc. shall meet the requirements of the product quality specification.

1.9.2 The physic-chemical property items of an EP product should include:

1.9.2.1 Appearance (color, physical state and odor);

1.9.2.2 Density;

1.9.2.3 Oxidation/reduction properties;

1.9.2.4 Corrosiveness to packing material;

1.9.2.5 Explosibility;

1.9.2.6 Solid combustibility.

1.10 Emulsifiable Granules (EG)

1.10.1 EG product quality specification should include:

1.10.1.1 Appearance;

1.10.1.2 Content of active ingredients;

1.10.1.3 Content of relevant impurities;

1.10.1.4 Content of other restrictive components;

1.10.1.5 Water;

1.10.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

1.10.1.7 Wetting time;

1.10.1.8 Wet sieve test;

1.10.1.9 Dispersion stability;

1.10.1.10 Persistent foaming;

1.10.1.11 Dust;

1.10.1.12 Abrasive resistance;

1.10.1.13 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, wetting time, wet sieve test, dispersion stability, dust, abrasive resistance, etc. shall meet the requirements of the product quality specification.

1.10.2 The physic-chemical property items of an EG product should include:

1.10.2.1 Appearance (color, physical state and odor);

1.10.2.2 Density;

1.10.2.3 Oxidation/reduction properties;

1.10.2.4 Corrosiveness to packing material;

1.10.2.5 Explosibility;

1.10.2.6 Solid combustibility.

1.11 Water Dispersible Granules (WG)

1.11.1 WG product quality specification should include:

1.11.1.1 Appearance;

1.11.1.2 Content of active ingredients;

1.11.1.3 Content of relevant impurities;

1.11.1.4 Content of other restrictive components;

1.11.1.5 Water;

1.11.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

1.11.1.7 Suspensibility (for a product in a water soluble packing bag, the test samples should be the mixture of the pesticide product and the packing bag, and the mass ratio of the sample should be same as the ratio between the content and the packing bag in actual use);

1.11.1.8 Wet sieve test;

1.11.1.9 Dispersity;

1.11.1.10 Wetting time;

1.11.1.11 Persistent foaming (for a product in a water soluble packing bag, the test samples should be the mixture of the pesticide product and the packing bag, and the mass ratio of the sample should be same as the ratio between the content and the packing bag in actual use);

1.11.1.12 Dust;

1.11.1.13 Abrasive resistance;

1.11.1.14 Solubility of packing bags (applicable only when water soluble packing bags are adopted);

1.11.1.15 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, suspensibility, wet sieve test, dispersity, dust and abrasive resistance shall meet the requirements of the product quality specification.

Note: When water soluble packing bags are adopted, thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components,

acidity/basicity or pH value, suspensibility, dispersity and solubility of packing bags shall meet the requirements of the product quality specification.

1.11.2 The physic-chemical property items of a WG product should include:

1.11.2.1 Appearance (color, physical state and odor);

1.11.2.2 Density;

1.11.2.3 Oxidation/reduction properties;

1.11.2.4 Corrosiveness to packing material;

1.11.2.5 Explosibility;

1.11.2.6 Solid combustibility test.

2 Liquid Formulations

2.1 Ultra Low Volume Concentrate (UL)

2.1.1 UL product quality specification should include:

2.1.1.1 Appearance;

2.1.1.2 Content of active ingredients;

2.1.1.3 Content of relevant impurities;

2.1.1.4 Content of other restrictive components;

2.1.1.5 Water;

2.1.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.1.1.7 Viscosity;

2.1.1.8 Low-temperature stability: After storage, the volume of the separations at the bottom of the centrifuge tube is not greater than 0.3mL;

2.1.1.9 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, etc. shall meet the requirements of the product quality specification.

2.1.2 The physic-chemical property items of a UL product should include:

2.1.2.1 Appearance (color, physical state and odor);

2.1.2.2 Density;

2.1.2.3 Viscosity;

2.1.2.4 Oxidation/reduction properties;

2.1.2.5 Corrosiveness to packing material;

2.1.2.6 Explosibility;

2.1.2.7 Flash point.

2.2 Dispersible Concentrate (DC)

2.2.1 DC product quality specification should include:

2.2.1.1 Appearance;

2.2.1.2 Content of active ingredients;

2.2.1.3 Content of relevant impurities;

2.2.1.4 Content of other restrictive components;

2.2.1.5 Water;

2.2.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.2.1.7 Dispersion stability;

2.2.1.8 Wet sieve test;

2.2.1.9 Persistent foaming;

2.2.1.10 Low-temperature stability: After storage, the volume of the separations at the bottom of the centrifuge tube is not greater than 0.3mL;

2.2.1.11 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, dispersion stability, etc. shall meet the requirements of the product quality specification.

2.2.1 The physic-chemical property items of a DC product should include:

2.2.1.1 Appearance (color, physical state and odor);

2.2.1.2 Density;

2.2.1.3 Viscosity;

2.2.1.4 Oxidation/reduction properties;

2.2.1.5 Corrosiveness to packing material;

2.2.1.6 Explosibility;

2.2.1.7 Flash point.

2.3 Oil Dispersion (OD)

2.3.1 OD product quality specification should include:

2.3.1.1 Appearance;

2.3.1.2 Content of active ingredients;

2.3.1.3 Content of relevant impurities;

2.3.1.4 Content of other restrictive components;

2.3.1.5 Water;

2.3.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.3.1.7 Dispersion stability;

2.3.1.8 Pourability;

2.3.1.9 Persistent foaming;

2.3.1.10 Wet sieve test;

2.3.1.11 Low-temperature stability: After storage, dispersion stability, wet sieve test, etc. shall meet the requirements of the product quality specification;

2.3.1.12 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, dispersion stability, pourability, wet sieve test, etc. shall meet the requirements of the product quality specification.

2.3.2 The physic-chemical property items of an OD product should include:

2.3.2.1 Appearance (color, physical state and odor);

2.3.2.2 Density;

2.3.2.3 Viscosity;

2.3.2.4 Oxidation/reduction properties;

2.3.2.5 Corrosiveness to packing material;

2.3.2.6 Explosibility;

2.3.2.7 Flash point.

2.4 Water Soluble Gel (GW)

2.4.1 GW product quality specification should include:

2.4.1.1 Appearance;

2.4.1.2 Content of active ingredients;

2.4.1.3 Content of relevant impurities;

2.4.1.4 Content of other restrictive components;

2.4.1.5 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.4.1.6 Persistent foaming;

2.4.1.7 Dilution stability;

2.4.1.8 Low-temperature stability: Appearance, dilution stability, etc. shall meet the requirements of the product quality specification.

2.4.1.9 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, dilution stability, etc. shall meet the requirements of the product quality specification.

2.4.2 The physic-chemical property items of a GW product should include:

2.4.2.1 Appearance (color, physical state and odor);

2.4.2.2 Density;

2.4.2.3 Viscosity;

2.4.2.4 Oxidation/reduction properties;

2.4.2.5 Corrosiveness to packing material;

2.4.2.6 Explosibility;

2.4.2.7 Flash point.

2.5 Soluble Concentrate (SL)

2.5.1 SL product quality specification should include:

2.5.1.1 Appearance;

2.5.1.2 Content of active ingredients;

2.5.1.3 Content of relevant impurities;

2.5.1.4 Content of other restrictive components;

2.5.1.5 Water (not applicable to water-based formulations);

2.5.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.5.1.7 Dilution stability;

2.5.1.8 Persistent foaming;

2.5.1.9 Low-temperature stability: After storage, the volume of the separations at the bottom of the centrifuge tube is not greater than 0.3mL;

2.5.1.10 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, dilution stability, etc. shall meet the requirements of the product quality specification.

2.5.2 The physic-chemical property items of an SL product should include:

2.5.2.1 Appearance (color, physical state and odor);

2.5.2.2 Density;

2.5.2.3 Viscosity;

2.5.2.4 Oxidation/reduction properties;

2.5.2.5 Corrosiveness to packing material;

2.5.2.6 Explosibility;

2.5.2.7 Flash point.

2.6 Emulsifiable Concentrate (EC)

2.6.1 EC product quality specification should include:

2.6.1.1 Appearance;

2.6.1.2 Content of active ingredients;

2.6.1.3 Content of relevant impurities;

2.6.1.4 Content of other restrictive components;

2.6.1.5 Water;

2.6.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.6.1.7 Emulsion stability;

2.6.1.8 Persistent foaming;

2.6.1.9 Low-temperature stability: After storage, the volume of the separations at the bottom of the centrifuge tube is not greater than 0.3mL;

2.6.1.10 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, emulsion stability, etc. shall meet the requirements of the product quality specification.

2.6.2 The physic-chemical property items of an EC product should include:

2.6.2.1 Appearance (color, physical state and odor);

2.6.2.2 Density;

2.6.2.3 Viscosity;

2.6.2.4 Oxidation/reduction properties;

2.6.2.5 Corrosiveness to packing material;

2.6.2.6 Explosibility;

2.6.2.7 Flash point.

2.7 Emulsion in Water (EW)

2.7.1 EW product quality specification should include:

2.7.1.1 Appearance;

2.7.1.2 Content of active ingredients;

2.7.1.3 Content of relevant impurities;

2.7.1.4 Content of other restrictive components;

2.7.1.5 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.7.1.6 Emulsion stability;

2.7.1.7 Pourability;

2.7.1.8 Persistent foaming;

2.7.1.9 Low-temperature stability: After storage, the volume of the separations at the bottom of the centrifuge tube is not greater than 0.3mL;

2.7.1.10 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, emulsion stability, etc. shall meet the requirements of the product quality specification.

2.7.2 The physic-chemical property items of an EW product should include:

2.7.2.1 Appearance (color, physical state and odor);

2.7.2.2 Density;

2.7.2.3 Viscosity;

2.7.2.4 Oxidation/reduction properties;

2.7.2.5 Corrosiveness to packing material;

2.7.2.6 Explosibility;

2.7.2.7 Flash point.

2.8 Capsule Suspension (CS)

2.8.1 CS product quality specification should include:

2.8.1.1 Appearance;

2.8.1.2 Content of active ingredients;

2.8.1.3 Content of free active ingredients (as to ≤%);

2.8.1.4 Content of relevant impurities;

2.8.1.5 Content of other restrictive components;

2.8.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.8.1.7 Rate of release of active ingredient (applicable to slow release formulations);

2.8.1.8 Wet sieve test;

2.8.1.9 Suspensibility;

2.8.1.10 Spontaneous dispersity;

2.8.1.11 Pourability;

2.8.1.12 Persistent foaming;

2.8.1.13 Freezing-thawing stability: After storage, the content of free active ingredients, acidity/basicity or pH value, wet sieve test, suspensibility, spontaneous dispersity, pourability, etc. shall meet the requirements of the product quality specification;

2.8.1.14 Thermal storage stability: After storage, the content of active ingredients, content of free active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, wet sieve test, suspensibility, spontaneous dispersity, pourability, etc. shall meet the requirements of the product quality specification.

2.8.2 The physic-chemical property items of a CS product should include:

2.8.2.1 Appearance (color, physical state and odor);

2.8.2.2 Density;

2.8.2.3 Viscosity;

2.8.2.4 Oxidation/reduction properties;

2.8.2.5 Corrosiveness to packing material;

2.8.2.6 Explosibility;

2.8.2.7 Flash point.

2.9 Micro-capsule Suspension-Emulsion in Water (ZW)

2.9.1 ZW product quality specification should include:

2.9.1.1 Appearance;

2.9.1.2 Content of active ingredients;

2.9.1.3 Content of free active ingredients (as to ≤%);

2.9.1.4 Content of relevant impurities;

2.9.1.5 Content of other restrictive components;

2.9.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.9.1.7 Rate of release of active ingredient (applicable to slow release formulations);

2.9.1.8 Wet sieve test;

2.9.1.9 Dispersion stability;

2.9.1.10 Pourability;

2.9.1.11 Persistent foaming;

2.9.1.12 Freezing-thawing stability: After storage, the content of free active ingredients, acidity/basicity or pH value, wet sieve test, dispersion stability, pourability, etc. shall meet the requirements of the product quality specification;

2.9.1.13 Thermal storage stability: After storage, the content of active ingredients, content of free active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, wet sieve test, dispersion stability, pourability, etc. shall meet the requirements of the product quality specification.

2.9.2 The physic-chemical property items of a ZW product should include:

2.9.2.1 Appearance (color, physical state and odor);

2.9.2.2 Density;

2.9.2.3 Viscosity;

2.9.2.4 Oxidation/reduction properties;

2.9.2.5 Corrosiveness to packing material;

2.9.2.6 Explosibility;

2.9.2.7 Flash point.

2.10 Micro-capsule Suspension-Suspension Concentrate (ZC)

2.10.1 ZC product quality specification should include:

2.10.1.1 Appearance;

2.10.1.2 Content of active ingredients;

2.10.1.3 Content of free active ingredients (as to ≤%);

2.10.1.4 Content of relevant impurities;

2.10.1.5 Content of other restrictive components;

2.10.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.10.1.7 Rate of release of active ingredient (applicable to slow release formulations);

2.10.1.8 Wet sieve test;

2.10.1.9 Suspensibility;

2.10.1.10 Spontaneous dispersity;

2.10.1.11 Pourability;

2.10.1.12 Persistent foaming;

2.10.1.13 Freezing-thawing stability: After storage, the content of free active ingredients, acidity/basicity or pH value, wet sieve test, suspensibility, spontaneous dispersity, pourability, etc. shall meet the requirements of the product quality specification;

2.10.1.14 Thermal storage stability: After storage, the content of active ingredients, content of free

active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, wet sieve test, suspensibility, spontaneous dispersity, pourability, etc. shall meet the requirements of the product quality specification.

2.10.2 The physic-chemical property items of a ZC product should include:

2.10.2.1 Appearance (color, physical state and odor);

2.10.2.2 Density;

2.10.2.3 Viscosity;

2.10.2.4 Oxidation/reduction properties;

2.10.2.5 Corrosiveness to packing material;

2.10.2.6 Explosibility;

2.10.2.7 Flash point.

2.11 Micro-capsule Suspension-Suspension Emulsion (ZE)

2.11.1 ZE product quality specification should include:

2.11.1.1 Appearance;

2.11.1.2 Content of active ingredients;

2.11.1.3 Content of free active ingredients (as to ≤%);

2.11.1.4 Content of relevant impurities;

2.11.1.5 Content of other restrictive components;

2.11.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.11.1.7 Rate of release of active ingredient (applicable to slow release formulations);

2.11.1.8 Wet sieve test;

2.11.1.9 Dispersion stability;

2.11.1.10 Pourability;

2.11.1.11 Persistent foaming;

2.11.1.12 Freezing-thawing stability;

2.11.1.13 Thermal storage stability: After storage, the content of active ingredients, content of free active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, wet sieve test, dispersion stability, pourability, etc. shall meet the requirements of the product quality specification.

2.11.2 The physic-chemical property items of a ZE product should include:

2.11.2.1 Appearance (color, physical state and odor);

2.11.2.2 Density;

2.11.2.3 Viscosity;

2.11.2.4 Oxidation/reduction properties;

2.11.2.5 Corrosiveness to packing material;

2.11.2.6 Explosibility;

2.11.2.7 Flash point.

2.12 Microemulsion (ME)

2.12.1 ME product quality specification should include:

2.12.1.1 Appearance;

2.12.1.2 Content of active ingredients;

2.12.1.3 Content of relevant impurities;

2.12.1.4 Content of other restrictive components;

2.12.1.5 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.12.1.6 Emulsion stability;

2.12.1.7 Persistent foaming;

2.12.1.8 Low-temperature stability: After storage, the volume of the separations at the bottom of the centrifuge tube is not greater than 0.3mL;

2.12.1.9 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, emulsion stability, etc. shall meet the requirements of the product quality specification.

2.12.2 The physic-chemical property items of an ME product should include:

2.12.2.1 Appearance (color, physical state and odor);

2.12.2.1 Density;

2.12.2.3 Viscosity;

2.12.2.4 Oxidation/reduction properties;

2.12.2.5 Corrosiveness to packing material;

2.12.2.6 Explosibility;

2.12.2.7 Flash point.

2.13 Suspension Concentrate (SC)

2.13.1 SC product quality specification should include:

2.13.1.1 Appearance;

2.13.1.2 Content of active ingredients;

2.13.1.3 Content of relevant impurities;

2.13.1.4 Content of other restrictive components;

2.13.1.5 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.13.1.6 Pourability;

2.13.1.7 Suspensibility;

2.13.1.8 Wet sieve test;

2.13.1.9 Persistent foaming;

2.13.1.10 Low-temperature stability: After storage, suspensibility, wet sieve test, etc. shall meet the requirements of the product quality specification;

2.13.1.11 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, pourability, suspensibility, wet sieve test, etc. shall meet the requirements of the product quality specification.

2.13.2 The physic-chemical property items of an SC product should include:

2.13.2.1 Appearance (color, physical state and odor);

2.13.2.2 Density;

2.13.2.3 Viscosity;

2.13.2.4 Oxidation/reduction properties;

2.13.2.5 Corrosiveness to packing material;

2.13.2.6 Explosibility;

2.13.2.7 Flash point.

2.14 Suspension Emulsion (SE)

2.14.1 SE product quality specification should include:

2.14.1.1 Appearance;

2.14.1.2 Content of active ingredients;

2.14.1.3 Content of relevant impurities;

2.14.1.4 Content of other restrictive components;

2.14.1.5 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.14.1.6 Wet sieve test;

2.14.1.7 Dispersion stability;

2.14.1.8 Pourability;

2.14.1.9 Persistent foaming;

2.14.1.10 Low-temperature stability: After storage, acidity/basicity or pH value, wet sieve test, dispersion stability, etc. shall meet the requirements of the product quality specification;

2.14.1.11 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, wet sieve test, dispersion stability, pourability, etc. shall meet the requirements of the product quality specification.

2.14.2 The physic-chemical property items of an SE product should include:

2.14.2.1 Appearance (color, physical state and odor);

2.14.2.2 Density;

2.14.2.3 Viscosity;

2.14.2.4 Oxidation/reduction properties;

2.14.2.5 Corrosiveness to packing material;

2.14.2.6 Explosibility;

2.14.2.7 Flash point.

2.15 Oil Miscible Liquid (OL)

2.15.1 OL product quality specification should include:

2.15.1.1 Appearance;

2.15.1.2 Content of active ingredients;

2.15.1.3 Content of relevant impurities;

2.15.1.4 Content of other restrictive components;

2.15.1.5 Water;

2.15.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

2.15.1.7 Compatibility with hydrocarbon oil;

2.15.1.8 Low-temperature stability: After storage, the volume of the separations at the bottom of the centrifuge tube is not greater than 0.3mL;

2.15.1.9 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, compatibility with hydrocarbon oil, etc. shall meet the requirements of the product quality specification.

2.15.2 The physic-chemical property items of an OL product should include:

2.15.2.1 Appearance (color, physical state and odor);

2.15.2.2 Density;

2.15.2.3 Viscosity;

2.15.2.4 Oxidation/reduction properties;

2.15.2.5 Corrosiveness to packing material;

2.15.2.6 Compatibility with non-polar organic solvents;

2.15.2.7 Explosibility;

2.15.2.8 Flash point.

3 Seed Treatment

This standard does not consider the influence of seed treatment on the percentage of seed germination. Generally, seed treatment contains a warning color.

3.1 Flowable Concentrate for Seed Coating (FSC)

3.1.1 FSC product quality specification should include:

3.1.1.1 Appearance;

3.1.1.2 Content of active ingredients;

3.1.1.3 Content of relevant impurities;

3.1.1.4 Content of other restrictive components;

3.1.1.5 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

3.1.1.6 Viscosity;

3.1.1.7 Wet sieve test;

3.1.1.8 Suspensibility;

3.1.1.9 Film forming time;

3.1.1.10 Coating uniformity;

3.1.1.11 Coating expulsion rate;

3.1.1.12 Low-temperature stability: After storage, suspensibility, viscosity, etc. shall meet the requirements of the product quality specification;

3.1.1.13 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, wet sieve test and suspensibility shall meet the requirements of the product quality specification.

3.1.2 The physic-chemical property items of an FSC product should include:

3.1.2.1 Appearance (color, physical state and odor);

3.1.2.2 Density;

3.1.2.3 Viscosity;

3.1.2.4 Oxidation/reduction properties;

3.1.2.5 Corrosiveness to packing material;

3.1.2.6 Explosibility;

3.1.2.7 Flash point.

3.2 Powder for Dry Seed Treatment (DS)

3.2.1 DS product quality specification should include:

3.2.1.1 Appearance;

3.2.1.2 Content of active ingredients;

3.2.1.3 Content of relevant impurities;

3.2.1.4 Content of other restrictive components;

3.2.1.5 Water;

3.2.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

3.2.1.7 Dry sieve test;

3.2.1.8 Adhesive property;

3.2.1.9 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, dry sieve test, adhesive property, etc. shall meet the requirements of the product quality specification.

3.2.2 The physic-chemical property items of a DS product should include:

3.2.2.1 Appearance (color, physical state and odor);

3.2.2.1 Density;

3.2.2.3 Oxidation/reduction properties;

3.2.2.4 Corrosiveness to packing material;

3.2.2.5 Explosibility;

3.2.2.6 Solid combustibility test.

3.3 Water Dispersible Powder for Slurry Seed Treatment (WS)

3.3.1 WS product quality specification should include:

3.3.1.1 Appearance;

3.3.1.2 Content of active ingredients;

3.3.1.3 Content of relevant impurities;

3.3.1.4 Content of other restrictive components;

3.3.1.5 Water;

3.3.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

3.3.1.7 Wet sieve test;

3.3.1.8 Wetting time;

3.3.1.9 Persistent foaming;

3.3.1.10 Adhesive property;

3.3.1.11 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, wet sieve test, adhesive property, etc. shall meet the requirements of the product quality specification.

3.3.2 The physic-chemical property items of a WS product should include:

3.3.2.1 Appearance (color, physical state and odor);

3.3.2.2 Density;

3.3.2.3 Oxidation/reduction properties;

3.3.2.4 Corrosiveness to packing material;

3.3.2.5 Explosibility;

3.3.2.6 Solid combustibility test.

3.4 Emulsion for Seed Treatment (ES)

3.4.1 ES product quality specification should include:

3.4.1.1 Appearance;

3.4.1.2 Content of active ingredients;

3.4.1.3 Content of relevant impurities;

3.4.1.4 Content of other restrictive components;

3.4.1.5 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

3.4.1.6 Emulsion stability;

3.4.1.7 Persistent foaming;

3.4.1.8 Adhesive property;

3.4.1.9 Low-temperature stability: After storage, the volume of the separations at the bottom of the centrifuge tube is not greater than 0.3mL;

3.4.1.10 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, emulsion stability, adhesive property, etc. shall meet the requirements of the product quality specification.

3.4.2 The physic-chemical property items of an ES product should include:

3.4.2.1 Appearance (color, physical state and odor);

3.4.2.2 Density;

3.4.2.3 Viscosity;

3.4.2.4 Oxidation/reduction properties;

3.4.2.5 Corrosiveness to packing material;

3.4.2.6 Explosibility;

3.4.2.7 Flash point.

3.5 Flowable Concentrate for Seed Treatment (FS)

3.5.1 FS product quality specification should include:

3.5.1.1 Appearance;

3.5.1.2 Content of active ingredients;

3.5.1.3 Content of relevant impurities;

3.5.1.4 Content of other restrictive components;

3.5.1.5 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

3.5.1.6 Adhesive property;

3.5.1.7 Pourability;

3.5.1.8 Wet sieve test;

3.5.1.9 Suspensibility;

3.5.1.10 Persistent foaming;

3.5.1.11 Low-temperature stability: After storage, wet sieve test, etc. shall meet the requirements of the product quality specification;

3.5.1.12 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, pourability, wet sieve test, suspensibility, adhesive property, etc. shall meet the requirements of the product quality specification.

3.5.2 The physic-chemical property items of an FS product should include:

3.5.2.1 Appearance (color, physical state and odor);

3.5.2.2 Density;

3.5.2.3 Viscosity;

3.5.2.4 Oxidation/reduction properties;

3.5.2.5 Corrosiveness to packing material;

3.5.2.6 Explosibility;

3.5.2.7 Flash point.

3.6 Solution for Seed Treatment (LS)

3.6.1 LS product quality specification should include:

3.6.1.1 Appearance;

3.6.1.2 Content of active ingredients;

3.6.1.3 Content of relevant impurities;

3.6.1.4 Content of other restrictive components;

3.6.1.5 Water;

3.6.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

3.6.1.7 Dilution stability;

3.6.1.8 Adhesive property;

3.6.1.9 Low-temperature stability: After storage, the volume of the separations at the bottom of the centrifuge tube is not greater than 0.3mL;

3.6.1.10 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, dilution stability, adhesive property, etc. shall meet the requirements of the product quality specification.

3.6.2 The physic-chemical property items of an LS product should include:

3.6.2.1 Appearance (color, physical state and odor);

3.6.2.2 Density;

3.6.2.3 Viscosity;

3.6.2.4 Oxidation/reduction properties;

3.6.2.5 Corrosiveness to packing material;

3.6.2.6 Explosibility;

3.6.2.7 Flash point.

4 Other Formulations

4.1 Long-Lasting Anti-mosquito Nets (LN)

4.1.1 LN product quality specification should include:

4.1.1.1 Appearance;

4.1.1.2 Content of active ingredients (as to g/kg);

4.1.1.3 Content of synergists (as to g/kg);

4.1.1.4 Content of relevant impurities;

4.1.1.5 Content of other restrictive components;

4.1.1.6 Release index or retention index of active ingredients;

4.1.1.7 Release index or retention index of synergists;

4.1.1.8 Mesh size (as to hole/cm^2);

4.1.1.9 Shrinkage;

4.1.1.10 Bursting strength;

4.1.1.11 Combustibility;

4.1.1.12 Fabric weight;

4.1.1.13 Tensile strength;

4.1.1.14 Thermal storage stability: After storage, the content of active ingredients, content of synergists, content of relevant impurities, content of other restrictive components, retention index or release index of active ingredients and synergists, shrinkage, bursting strength, etc. shall meet the requirements of the product quality specification.

4.1.2 The physic-chemical property items of an LN product should include:

4.1.2.1 Appearance (color, physical state and odor);

4.1.2.2 Corrosiveness to packing material;

4.1.2.3 Solid combustibility (according to textile requirements).

4.2 Vaporizing Mat (MV)

4.2.1 MV product quality specification should include:

4.2.1.1 Appearance;

4.2.1.2 Content of active ingredients (as to mg/tablet);

4.2.1.3 Content of relevant impurities;

4.2.1.4 Content of other restrictive components;

4.2.1.5 Vaporization rate;

4.2.1.6 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, etc. shall meet the requirements of the product quality specification.

4.2.2 The physic-chemical property items of an MV product should include:

4.2.2.1 Appearance (color, physical state and odor);

4.2.2.1 Corrosiveness to packing material;

4.2.2.3 Relative autoigniting temperature of solid.

4.3 Liquid Vaporizer (LV)

4.3.1 LV product quality specification should include:

4.3.1.1 Appearance;

4.3.1.2 Content of active ingredients;

4.3.1.3 Content of relevant impurities;

4.3.1.4 Content of other restrictive components;

4.3.1.5 Vaporization rate;

4.3.1.6 Minimum effective period;

4.3.1.7 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, etc. shall meet the requirements of the product quality specification.

4.3.2 The physic-chemical property items of an LV product should include:

4.3.2.1 Appearance (color, physical state and odor);

4.3.2.2 Density;

4.3.2.3 Corrosiveness to packing material;

4.3.2.4 Explosibility;

4.3.2.5 Flash point.

4.4 Baits (RB)

4.4.1 RB product quality specification should include:

4.4.1.1 Appearance;

4.4.1.2 Content of active ingredients;

4.4.1.3 Content of relevant impurities;

4.4.1.4 Content of other restrictive components;

4.4.1.5 Water or loss on drying;

4.4.1.6 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, etc. shall meet the requirements of the product quality specification.

4.4.2 The physic-chemical property items of an RB product should include:

4.4.2.1 Appearance (color, physical state and odor);

4.4.2.2 Corrosiveness to packing material;

4.4.2.3 Combustibility (select an appropriate determination method according to the physical state).

4.5 Bait Concentrate (CB)

4.5.1 CB product quality specification should include:

4.5.1.1 Appearance;

4.5.1.2 Content of active ingredients;

4.5.1.3 Content of relevant impurities;

4.5.1.4 Content of other restrictive components;

4.5.1.5 Other technical indicators (determined depending on product composition and processing method);

4.5.1.6 Thermal stability: After storage, the content of active ingredients, content of relevant

impurities, content of other restrictive components, etc. shall meet the requirements of the product quality specification.

4.5.2 The physic-chemical property items of a CB product should include:

4.5.2.1 Appearance (color, physical state and odor);

4.5.2.2 Corrosiveness to packing material;

4.5.2.3 Combustibility (select an appropriate determination method according to the physical state).

4.6 Gas (GA)

4.6.1 Gas product quality specification should include:

4.6.1.1 Appearance (normally refer to package appearance);

4.6.1.2 Content of active ingredients;

4.6.1.3 Content of relevant impurities;

4.6.1.4 Content of other restrictive components;

4.6.1.5 Internal pressure.

4.6.2 The physic-chemical property items of a gas product should include:

4.6.2.1 Appearance (color, physical state and odor);

4.6.2.2 Corrosiveness to packing material;

4.6.2.3 Explosibility;

4.6.2.4 Gas combustibility.

4.7 Repellent Floral Water (RW)

4.7.1 RW product quality specification should include:

4.7.1.1 Appearance;

4.7.1.2 Content of active ingredients;

4.7.1.3 Content of relevant impurities;

4.7.1.4 Content of other restrictive components;

4.7.1.5 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

4.7.1.6 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, etc. shall meet the requirements of the product quality specification.

4.7.2 The physic-chemical property items of an RW product should include:

4.7.2.1 Appearance (color, physical state and odor);

4.7.2.2 Density;

4.7.2.3 Corrosiveness to packing material;

4.7.2.4 Explosibility;

4.7.2.5 Flash point.

4.8 Aerosol (AE)

4.8.1 AE product quality specification should include:

4.8.1.1 Appearance (normally refer to package appearance);

4.8.1.2 Content of active ingredients;

4.8.1.3 Content of relevant impurities;

4.8.1.4 Content of other restrictive components;

4.8.1.5 Water (for alcohol-based or water-based aerosol, this control item may be exempted);

4.8.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value (applicable to alcohol-based or water-based aerosol);

4.8.1.7 Internal pressure (30±2℃);

4.8.1.8 Net content;

4.8.1.9 Condensation rate;

4.8.1.10 Discharge rate;

4.8.1.11 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, discharge rate, etc. shall meet the requirements of the product quality specification.

4.8.2 The physic-chemical property items of an AE product should include:

4.8.2.1 Appearance (color, physical state and odor);

4.8.2.2 Corrosiveness to packing material;

4.8.2.3 AE combustibility.

4.9 Repellent Liquid (RQ)

4.9.1 RQ product quality specification should include:

4.9.1.1 Appearance;

4.9.1.2 Content of active ingredients;

4.9.1.3 Content of relevant impurities;

4.9.1.4 Content of other restrictive components;

4.9.1.5 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

4.9.1.6 Viscosity;

4.9.1.7 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, etc. shall meet the requirements of the product quality specification.

4.9.2 The physic-chemical property items of an RQ product should include:

4.9.2.1 Appearance (color, physical state and odor);

4.9.2.2 Density;

4.9.2.3 Corrosiveness to packing material;

4.9.2.4 Explosibility;

4.9.2.5 Flash point.

4.10 Mosquito Coil (MC)

4.10.1 MC product quality specification should include:

4.10.1.1 Appearance;

4.10.1.2 Content of active ingredients;

4.10.1.3 Content of relevant impurities;

4.10.1.4 Content of other restrictive components;

4.10.1.5 Water;

4.10.1.6 Average mass of coil;

4.10.1.7 Separation of twin coil;

4.10.1.8 Continuous ignition time;

4.10.1.9 Strength of coil;

4.10.1.10 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, separation of twin coil, continuous ignition time and strength of coil shall meet the requirements of the product quality specification.

4.10.2 The physic-chemical property items of an MC product should include:

4.10.2.1 Appearance (color, physical state and odor);

4.10.2.2 Corrosiveness to packing material;

4.10.2.3 Explosibility.

4.11 Fumigants (FU)

4.11.1 FU product quality specification should include:

4.11.1.1 Appearance;

4.11.1.2 Content of active ingredients;

4.11.1.3 Content of relevant impurities;

4.11.1.4 Content of other restrictive components;

4.11.1.5 Water;

4.11.1.6 Range of acidity/basicity (as to H_2SO_4 or NaOH) or pH value;

4.11.1.7 Smoking rate;

4.11.1.8 Autoigniting temperature;

4.11.1.9 Smoking time;

4.11.1.10 Thermal stability: After storage, the content of active ingredients, content of relevant impurities, content of other restrictive components, acidity/basicity or pH value, smoking rate, etc. shall meet the requirements of the product quality specification.

4.11.2 The physic-chemical property items of an FU product should include:

4.11.2.1 Appearance (color, physical state and odor);

4.11.2.2 Oxidation/reduction properties;

4.11.2.3 Corrosiveness to packing material;

4.11.2.4 Explosibility.

Annex 14

Grading Standard for Toxicity of Pesticides

Toxicity level	Median oral lethal dose (mg/kg)	Median dermal lethal dose (mg/kg)	Inhaled median lethal concentration (mg/m^3)
Extreme	≤5	≤20	≤20
High	>5~50	>20~200	>20~200
Moderate	>50~500	>200~2000	>200~2000
Low	>500~5000	>2000~5000	>2000~5000
Mild	>5000	>5000	>5000