Guidance for New Chemical Substance Notification

(First version)

Chemical Registration Center of SEPA
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Guidance for New Chemical Substance Notification

The Guidance for New Chemical Substance Notification (hereinafter cited as "Guidelines") have been drawn up to the implementation of the Provisions on the Environmental Administration of New Chemical Substances (hereinafter cited as the "*Provisions*"), enable a notifier to understand of the norms and procedures for undergoing new chemical substance notification registrations, and standardize the operations of the agency that handles new chemical substance notification registrations.

1. The Applicable Scope of New Chemical Substance Notifications

1.1. The Scope of Applicable Chemical Substances

Any chemical substance that is not listed in the Inventory of Existing Chemical Substances manufactured or imported in China (hereinafter cited as "IECSC") that is published by the State Environmental Protection Administration (SEPA) is a new chemical substance.

Prior to the manufacture or import of a new chemical substance (including the import from the Hong Kong Special Administrative Region [SAR], the Macao SAR, and the Separate Customs Territory of Taiwan, Penghu, Jinmen, and Mazu, and similarly below), one shall undergo new chemical substance notification registration, apply for and receive a Registration Certificate for the Environmental Management of New Chemical Substances (abbreviated below as the "Registration Certificate". For a sample, see Attachment 1).

As to the manufacture or import of a chemical product containing new chemical substances, the contained new chemical substances, despite the amount of the content, are subjected to the preceding paragraph, but the said chemical product per se is not. These chemical products include pesticides, veterinary drugs, pharmaceuticals, cosmetics, foods and food additives, feed and feed additives, chemical fertilizers, detergents, inks, paints, stabilizers, dyes, flavoring agents, antioxidants, solvents, fillings, carriers, surface active agents, plasticizers, preservatives, defoaming agents, dispersing agents, antiprecipitants, drying agents, dehydrators, emulsifiers, anti-emulsifiers, thickeners, acid/base neutralizers, fire retardants, lubricants, coagulants, flocculants, chelating agents,

agglutinates, and other products of chemical reactions that occur to give substances (materials) particular physical or chemical properties so that they can perform their specific functions.

None of the types of chemical substances or chemical product listed in Attachment 2 is subjected to the Paragraph 2 of this section.

1.2. The Scope of Applicable Region

The activities of manufacturing/exporting new chemical substances or chemical products containing new chemical substances within/into the customs territory of the People's Republic, or importing new chemical substances or chemical products containing new chemical substances from abroad are subjected to the Paragraph 2 and 3 of Section 1.1.

The activities of importing new chemical substances or of chemical products containing new chemical substances from the free trade zones or export processing zones into other regions of the customs territory of China are subjected to the Paragraph 2 and 3 of Section 1.1.

The activities of manufacturing/exporting new chemical substances or chemical products containing new chemical substances within/into the boundaries of the Hong Kong SAR, the Macao SAR, and the Separate Customs Territory of Taiwan, Penghu, Jinmen, and Mazu are not subjected to the Paragraph 2 and 3 of Section 1.1.

The activities of manufacturing/exporting new chemical substances or chemical products containing new chemical substances within/into the free trade zones or export processing zones, or importing new chemical substances or chemical products containing new chemical substances from abroad to the free trade zones or export processing zones are not subjected to the Paragraph 2 and 3 of Section 1.1.

1.3. The Notifier

A notifier shall be a domestic corporation that plans to manufacture a new chemical substance (hereinafter cited as "the manufacturer"), a domestic corporation that plans to import a new chemical substance (hereinafter cited as "the importer"), or a foreign trader that plans to export a new chemical substance to China (including corporations from the Hong Kong SAR, the Macao SAR, and the Separate Customs Territory of Taiwan, Penghu, Jinmen, and Mazu.

hereinafter cited as "a foreign trader").

2. Categories of New Chemical Substance Notifications

There are five categories of new chemical substance notifications. They are typical notification, serial notification, joint notification, simplified notification, and notification exemption.

2.1. Typical Notification

A typical notification refers to a notification of a new chemical substance that is submitted independently by one notifier, in which the said new chemical substance is not within the scope of a serial notification, a simplified notification, nor a notification exemption.

2.2. Serial Notification

A serial notification refers to a notification of a series of new chemical substances (two or more) as a whole, in which the said series of new chemical substances is simultaneously characterized by a similar molecular structure, identical or similar uses, and similar test data.

When a serial notification is approved, an independent Registration Certificate will be issued for each notified new chemical substance in the said series acquires.

After a serial notification is approved, any new chemical substance that was not submitted in the said serial notification, whether or not it is characterized by a similar molecular structure, identical or similar uses, or similar test data as the said series, does not belong to the said series, may not be incorporated into the said series, and still remains a new chemical substance.

2.3. Joint Notification

A joint notification refers to a typical notification or a serial notification that is jointly submitted by two or more notifiers.

When a joint notification is approved, an independent Registration Certificate will be issued for each notifier in the joint notification.

After a joint notification is approved, any one that was not included in the joint notifiers of the said joint notification could not be a joint notifier of the said joint notifiers at any time, and may not acquire the said joint notification

registration.

2.4. Simplified Notification

A simplified notification refers to a notification of a new chemical substance that is already listed in four or more inventories of existing chemical substance of other countries or regional economic integration organizations, but that has not yet been listed in the IECSC.

2.5. Notification Exemption

A notification exemption refers to a specific notification type in which it is not required to apply for and receive a Registration Certificate but it is required to apply for notification exemption due to reasons such as the uses or amounts of the new chemical substances as provided in Article 13 of the Provisions. In any one of the following cases, the manufacturer or importer may apply for a notification exemption:

(I) When the quantity of the new chemical substance that is manufactured or imported annually for scientific research purposes does not exceed 100 kg;

(II) When it is a polymer containing a new chemical substance monomer of less than 2 percent;

(III) When the amount of the new chemical substance that is manufactured or imported for technological research and development does not exceed 1,000 kg, the manufacturer or importer may apply for a one-year notification exemption, but no extension will be granted;

(IV) When the test sample of the new chemical substance is imported for new chemical substance ecotoxicological testing within China.

3. New Chemical Substance Notification Procedures

3.1. Determination of Whether a Notification Is Required

Before making a new chemical substance notification, the following steps are recommended to determine whether a notification is required:

Step 1: Does the notifier meet the requirements of Section 1.3? If so, it can submit a notification; if not, it is not accepted to submit a notification.

Step 2: If the activity of manufacture or import of the notifier meet the conditions provided in Paragraphs 1 or 2, Section 1.2, a notification shall be

submitted; if it meets the conditions provided in Paragraphs 3 or 4, Section 1.2, a notification is not accepted.

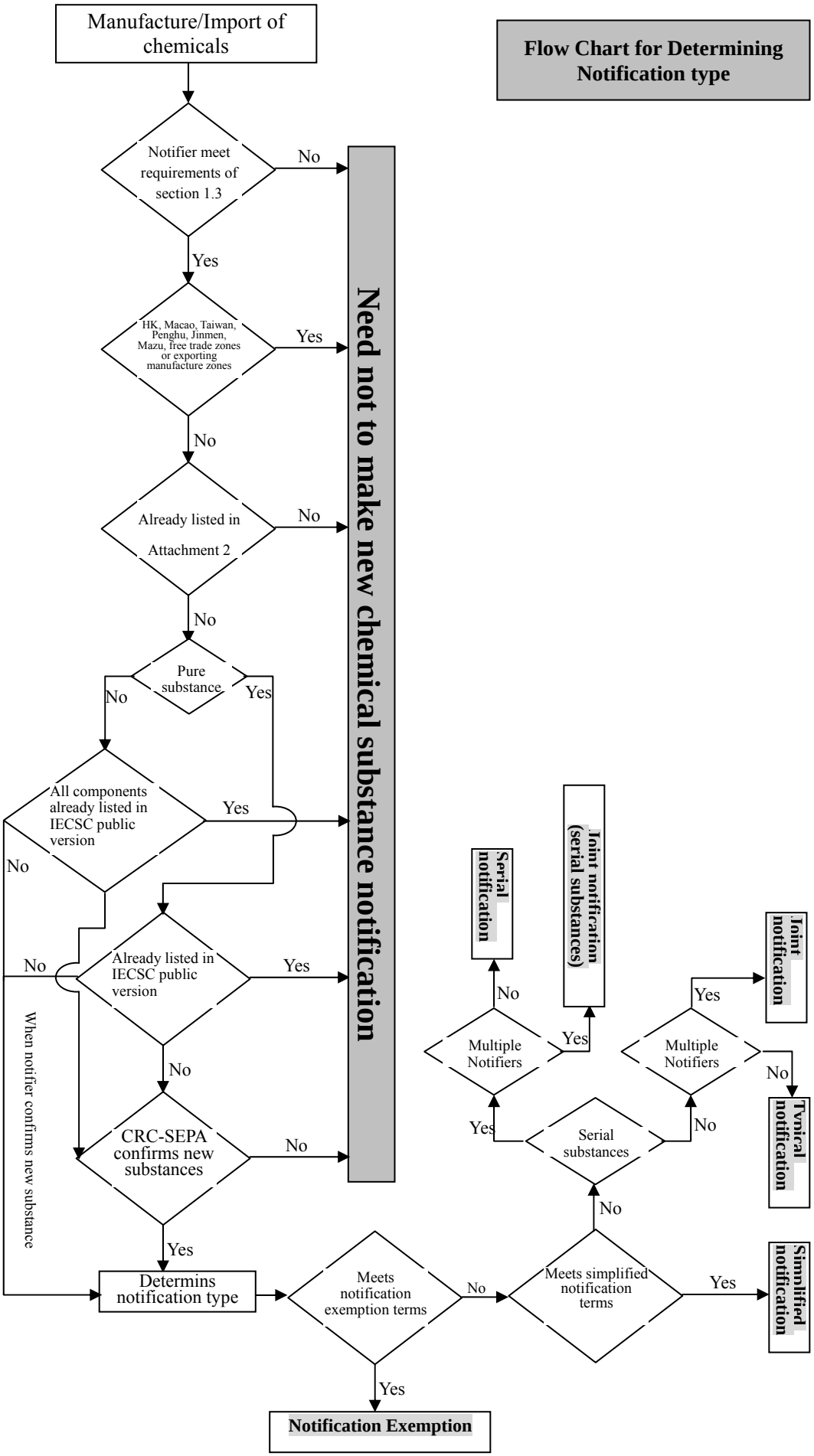
Step 3: Does the chemical substance that is to be notified meets the requirements of Paragraph 4, Section 1.1? If it does not, a notification shall be submitted; if it does, a notification is not accepted.

Step 4: Is the chemical substance that is to be notified listed in the IECSC (the public version)? If so, a notification is not accepted. If not, the next step is recommended to be taken. The public version of the IECSC can be searched on the website of the Chemical Registration Center of SEPA (hereinafter cited as "CRC-SEPA").

Step 5: Consult CRC-SEPA to identify whether the chemical substance that is to be notified is a new chemical substance (See Attachment 3). If it is, a notification is required. If it is not, a notification is not accepted.

Step 6: Based on Section 2 and 7 of this Guidance, determine the type of new chemical substance notification, namely, a typical notification, a serial notification, a joint notification, a simplified notification, or a notification exemption.

A flow chart for determining the type of a new chemical substance notification is shown as follows.


Flow Chart for Determining Notification type
Manufacture/Import of chemicals
Notifier meet requirements of section 1.3
No
Yes
HK, Macao, Taiwan, Penghu, Jinmen, Mazu, free trade zones or exporting manufacture zones
Yes
No
Already listed in Attachment 2
No
No
Pure substance
No
Yes
All components already listed in IECSC public version
Yes
No
Already listed in IECSC public version
Yes
No
CRC-SEPA confirms new substances
No
Yes
When notifier confirms new substance
Need not to make new chemical substance notification
Determins notification type
Meets notification exemption terms
No
Yes
Notification Exemption
Meets simplified notification terms
Yes
Simplified notification
No
Serial substances
Yes
No
Multiple Notifiers
Yes
Joint notification (serial substances)
No
Serial notification
Multiple Notifiers
Yes
Joint notification
No
Typical notification

3.2. Preparation of New Chemical Substance Notification Documents

Step 1: Based on the determination in *Step* 6 of Section 3.1, download the corresponding forms and materials from CRC-SEPA website.

Step 2: When the type is a typical notification, serial notification, joint notification, or simplified notification, it is necessary to apply for notification exemption to manufacture or import a testing sample of the new chemicals substance and entrust a qualified test institution to conduct ecotoxicological test with Chinese testing organisms.

Step 3: When the type is a typical notification, serial notification, joint notification, or simplified notification, the notifier shall prepare and gather the corresponding information and materials in accordance with the New Chemical Substance Notification Form (Attachment 4) or entrust a qualified test institute to conduct the corresponding testing, including ecotoxicological testing in China with Chinese testing organisms; when the type is a notification exemption, the notifier shall prepare and gather the corresponding information and materials in accordance with the New Chemical Substance Notification Exemption Application Form (See Attachment 5).

Step 4: When the type is a typical notification, serial notification, joint notification, or simplified notification, the New Chemical Substance Notification Form shall be filled out in accordance with the Guidance for Filing in the New Chemical Substance Notification Form (Attachment 6). Pay attention to providing the data sources for some of the information that is required for the test data (namely, items 6, 7, and 8 on the notification form in Attachment 4), which may be publicly published papers and/or test reports and evidentiary materials on test institute qualification. For the item 8, the data and test report(s) on ecotoxicological testing which is performed in China with Chinese testing organisms shall be provided.

When the type is a notification exemption, the New Chemical Substance Notification Exemption Application Form shall be filled out in accordance with the Guidance for Filing in the New Chemical Substance Notification Exemption Application Form (Attachment **7**). Evidentiary materials that conform to the relevant circumstances of Article 13 of the Provisions shall be provided (See Section 4.2.4).

3.3. Submission of a New Chemical Substance Notification

A notifier shall deliver or mail complete notification documents to CRC-SEPA once only. At the same time, the notification registration fee shall be paid to the bank account of CRC-SEPA.

when applicant fails to offer entire declaration documents, he can consign the third party to present but consignment announcement from applicant must be offered. When necessary, the applicant, registration center and the third party shall define substitute names for information communication of declaration substance. Contact mode to CRC-SEPA:

Branch of New Chemical Substance Management
Chemical Registration Center of SEPA
No. **8,** Dayangfang, Beiyuan, Andingmenwai, Chaoyang District
Beijing, P. R. China
Zip Code: 100012
Telephone and Fax: (+86-10) 8491-7656
Email: ncn@crc-sepa.org.cn
Website: http://www.crc-sepa.org.cn
Or: http://化学品登记中心.中国

Notification documents that are delivered in person shall be delivered to Room 304, Third Floor, North Wing, Building 2, the Chinese Research Academy of Environmental Sciences, No. 8 Dayangfang , Beiyuan, Chaoyang District, Beijing. The work hours of notification acceptance are 08:30~12:00am and 13:30~16:30pm (except for legal holidays).

4. Requirements for New Chemical Substance Notification Documents

The complete notification documents consist of the notification form and the notification attachments.

4.1. Requirements on Format for New Chemical Substance Notification Documents

A notification document contains a notification form and notification form attachments.

4.1.1. Notification Form

The New Chemical Substance Notification Form and the New Chemical Substance Notification Exemption Application Form (abbreviated below as the "notification form") shall be typewritten. Handwritten forms will not be accepted. The written language shall be Chinese (encoded in simplified Chinese GB2312, and similarly below).

The notification form shall be identical in format to the notification form published on CRC-SEPA website, namely, it shall be identical as to the number of pages and the columns on all pages. When necessary, it is permitted to retain the format through adjusting the font size and line spacing, but it shall be ensured that the form is clear and legible.

The places on the forms where the notifiers' signatures and stamps are specified must have the signatures and stamps of the notifiers. The signatures and stamps must be the originals. Copied or scanned signatures and stamps are invalid.

At notification, both a hard copy and an electronic version must be submitted simultaneously. The electronic version and the hard copy shall be completely identical as to both contents and format (except for the signatures and stamps), and A4 paper or paper nearest to the A4 format must be used for the hard copy. The electronic version shall be prepared with Kingsoft WPS, Microsoft© Word, or Excel. Electronic versions of the notification form that are prepared with other word processing software will not be accepted. The electronic version may be sent to the email address of CRC.

4.1.2. The Notification Form Attachments

The notification form attachments refers to materials that describe or verify the sources of all notification data that are entered on the notification form, including verifications of quotations or test reports and the credentials of the test agencies that prepare the test reports, as well as other materials that must be submitted in attachment form.

At notification, three copies of all notification form attachment materials must be submitted.

Only the six working languages of the United Nations (namely, Chinese, English, French, Russian, Spanish, and Arabic) may be used in the notification form attachments. Any of the above-described languages may be used for any

materials in the notification form attachments, but only one language may be used for any separate material in the notification form attachments.

All test reports in the notification form attachments shall have abstracts. The substance of the abstracts shall include the test indexes, test methods, and test results of the test. The abstracts shall either be in Chinese or have Chinese translations attached, and the Chinese abstract shall be the first page of the said materials.

Some notification form attachments such as test reports, verifications of test agency credentials, and quotations from openly published documents may be copies, but for the attachment that are provided by the notifier itself, there shall be at least one original.

4.2. The Explanation and Special Materials Requirements for All Types of Notifications

In addition to the requirements of Section **4.1**, the explanation and special materials requirements for all types of notifications are as follows:

4.2.1. Serial Notifications

The notifier shall submit an attachment containing the information to specify substances such as the name, **CAS** number, molecular formula, molecular weight, and structural formula of each new chemical substance in the series. Based on the knowledge of the notifier, when an information item required on the notification form are different for each new chemical substances in the series (such as detection method), an attachment shall also be submitted, in order to specify the corresponding information for each new chemical substance in the series.

All test data on the notification form may be for the same new chemical substance in the series, as well as for different new chemical substances in the series.

4.2.2. Joint Notifications

Each notifier in a joint notification shall fill out a cover-page and a first-page of the notification form, and shall sign them separately.

The cover-pages filled out by each notifier shall be placed in order in the position of the cover-page of the notification form, and the first-pages shall be

placed in the position of the first page of the notification form in the order of the cover-pages of the notifiers.

4.2.3. Simplified Notifications

The notifier shall enter the inclusion status in four or more inventories of existing chemical substance of countries or regional economic integration organizations in Item 2.8 of the notification form. If less than four, the terms for a simplified notification are not met.

CRC will verify the inclusion status of all notified new chemical substances in the above-described inventories. When CRC cannot verify it, the notifier must submit an attachment verifying the information that was entered in Item 2.8 of the notification form. When submitting the notification materials, the notifier may simultaneously submit an attachment verifying the information that is entered in Item 2.8 of the notification form.

4.2.4. Undergoing Notification Exemption

When undergoing notification exemption , the notifier shall also submit evidentiary materials that conform to the terms of Article 13 of the *Provisions* pertaining to notification exemptions. For the requirements on the format and substance of the said evidentiary materials, see Attachment **8**.

4.3. Data Requirements for New Chemical Substance Notifications

This section does not apply to the notification exemption.

4.3.1. Data Requirement Principle

The quality and quantity of the information and materials filled on the notification form shall be sufficient for the Expert Committee on the Environmental Management of New Chemical Substances (abbreviated below as the "Expert Committee") to make an objective assessment of the environmental and public health impact of the notified substance.

The notifier itself may make an preassessment of the new chemical substance that is to be notified with reference to the *Guidance for the Hazard Assessment of New Chemical Substances (HJ/T 154-2004)* that was promulgated by SEPA.

4.3.2. Minimum Information Requirements

When filling out declaration form, applicant should provide information as follows

(I) Applicant information: head page and first item of declaration form;

(II) Information used to identify information of declared substance: Items 2, 3, and 4 of the declaration form;

(III) Information used to understand disclosure of declared substance: item 5 of the declaration f form;

(IV)Text data used for assessment for hazard in declared substance: Items 6, 7, and 8 in declaration form;

(V) Recommended prevention methods and emergency measures: Item 9, 10, 11,12 in declaration form.

It is required to provide all items in above information categories (I), (II), (III) (V) (except for items showing no information is allowed in declaration form).

The applicant shall provide information in category (IV) according to the following principles:

i. Based on the characteristics of declarated substance, to select the indexes that reflect the properties of declared substance and its impact on environment and public health;

ii. Selected indexes should fully reflect the impact of declared substance on environment and public health

iii..Do not select indexes in which declared substance has no attributes of it

The minimum data requirement of category (IV) is as follows and in case that declared substance has no index of property , “Not applicable” shall be noted.

i. Item 6 in declaration form

Solid matter: density, flash point, and natural temperature, explosibility, article diameter, water solubility and partition coefficient

Gas matter: explosion limit, oxidizability

Liquid matter: density, oxidation (causticity), steam pressure, combustibility, and water solubility partition coefficient PH value

ii. Item 7 in declaration form

According to quantity in declaration, data shall be provide as New Chemical Substance Hazard Assessment Guideline (HJ/T154-2004)

iii. item 8 in declaration form

As per quantity in declaration, data shall be provide as per New Chemical Substance Hazard Assessment Guideline (HJ/T154-2004) with a basic level, including acute toxicity test of hydrophilic creature (finny catalogue is first to be chosen) completed with supply offered by Chinese within China's territory and biological degradation test; The first level requires test data of basic level and in case that biological degradation meets difficulty, the creature accumulating test data completed by supply and test offered by China within China's territory shall be provided; the second level shall be implemented as per the first level.

Registration center may accept new chemical substance declaration complying with above-mentioned requirement.

When the information provided by applicant is insufficient to enable assessment committee to make an objective assessment of environmental impact upon declaration substance or no registration is allowed for assessment result, applicant is permitted to supply the information by one time in hope of obtaining an assessment result that is helpful to the declaration intentions of applicant.

4.3.3. The Recommended Data Requirements

In order to get better evaluation result favorable to applicant, applicant is suggested to provide data in accordance with Guidance for Assessment of Hazard New Chemical Substances (HJ/T 154-2004)

4.3.4. The Data Sources

The data and materials filled in the notification form may originate in openly published documents or test reports by test agencies. Both openly published documents and test reports by test agencies shall be submitted together as attachments. Openly published documents shall be the full texts of the original documents that provide the data, neither quotations nor abstracts; test reports shall simultaneously include attached evidentiary materials on the accreditation of the test agency.

4.4. New Chemical Substance Tests

4.4.1. Test Agency Accreditation

Domestic or oversea test agencies that have one of the following credentials

may provide test data for new chemical substance notifications:

(I) National Laboratory Accreditation

(II) Ministry of Public Health recognition as a test agency for health related products

(III) GLP Accreditation by the State Food and Drug Administration

(IV) measurement attestation at State level (limited to physical and chemical property test).

The accreditation evidentiary materials are copies of recognized certificates.

Oversea test agencies that have one of the following credentials may also provide test reports for new chemical substance notifications:

(I) National or highest level authentication or accreditation by the national authorities concerned with new chemical substance management of one's home country to provide test data for new chemical substance notifications; or

(II) Authenticated or accredited by the authorities concerned with quality inspection, customs, public health, or agriculture of one's own country, when the national authorities concerned with new chemical substance management of one's home country to provide test data for new chemical substance notifications has not yet make authentication or accreditation.

The accreditation evidentiary materials are copies of the corresponding recognized credentials or documentary evidence provided by the competent authorities.

However, when the test data provided by a test agency for new chemical substance notifications is not recognized by the national authorities concerned with new chemical substance management of one's own country, CRC will not recognize it as a test agency for new chemical substance notifications.

Both domestic and overseas test agencies may only provide the test items/indexes that are permitted by their credentials.

4.4.2. Test Methods

Domestic and overseas test organizations which provide new chemical substance declaration for test data shall complete test as per Chemical Test Guidelines(HJ/T153－2004).Test outside China can use OECO and ISO standards popular internationally.

4.4.3. Chinese creature for test:

“Chinese creature for test ”refer to creatures cultivated and bred in China complying with standard for designated test, including crucial helleri, Zebra fish, active mud, etc. Other requirement for testing creatures referred to Chemical testing method of Chemical Test Guidelines(HJ/T153－2004).

4.5. Information Confidentiality

Information that is permitted to be kept confidential on the notification form may be asked to be kept confidential; information that is not permitted to be kept confidential on the notification form will not be kept confidential.

A confidentiality option has been provided on the notification form for information that is permitted to be kept confidential. Information that is asked to be kept confidential shall be marked in the corresponding position on the notification form, and unmarked items will all be regarded as not having been asked to be kept confidential by the notifier. Information with no confidentiality option may not be asked to be kept confidential.

CRC will simultaneously keep confidential the corresponding notification form attachment materials for the information that is asked to be kept confidential.

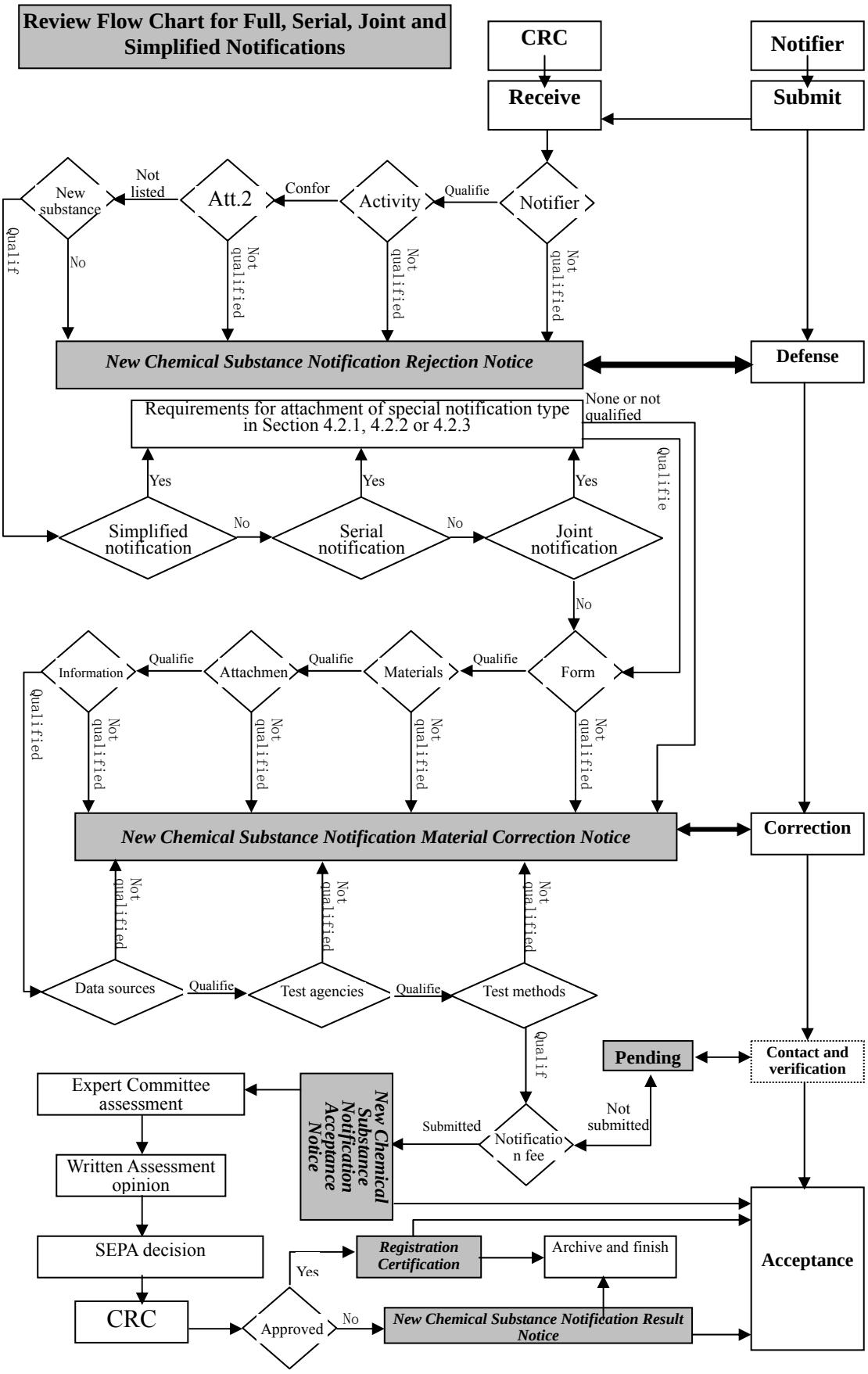
Notifiers that wish to waive information confidentiality shall submit to CRC a *New Chemical Substance Information Confidentiality Waiver* (see Attachment 9) that is stamped or signed by the original notifier. CRC will release the said information on the date that it receives the *New Chemical Substance Information Confidentiality Waiver*. Released information may not be asked to be made confidential again.

5. New Chemical Substance Notification Reviews

5.1. New Chemical Substance Notifications

This section applies to new chemical substance typical notifications, serial notifications, joint notifications, and simplified notifications. It does not apply to the notification exemption.

The flow chart for new chemical substance notifications is shown as follows.


Review Flow Chart for Full, Serial, Joint and Simplified Notifications
CRC
Notifier
Receive
Submit
New substance
Not listed
Att.2
Confor
Activity
Qualifie
Notifier
Qualif
No
Not qualified
Not qualified
Not qualified
New Chemical Substance Notification Rejection Notice
Defense
Requirements for attachment of special notification type in Section 4.2.1, 4.2.2 or 4.2.3
None or not qualified
Qualifie
Yes
Yes
Yes
Simplified notification
No
Serial notification
No
Joint notification
No
Information
Qualifie
Attachmen
Qualifie
Materials
Qualifie
Form
Qualified
Not qualified
Not qualified
Not qualified
Not qualified
New Chemical Substance Notification Material Correction Notice
Correction
Not qualified
Not qualified
Not qualified
Data sources
Qualifie
Test agencies
Qualifie
Test methods
Qualif
Pending
Contact and verification
Expert Committee assessment
New Chemical Substance Notification Acceptance Notice
Submitted
Notification fee
Not submitted
Written Assessment opinion
SEPA decision
Registration Certification
Archive and finish
Acceptance
Yes
CRC
Approved
No
New Chemical Substance Notification Result Notice

5.1.1. Formal Reviews

Within 15 days of the date of receipt of declaration material for new chemical substance materials, the register center will conduct a formal review of declaration. The formal review will include the following:

i. Whether applicant conforms to the provisions in section 1.3, and whether all applicants in a joint declaration meet the requirements of Section 1.3;

ii.Manufacturing or import operations are beyond the cases at same time provided in article 3 and article 4 in Section 1.2

iii. Declared substance is beyond the cases provided in article 4 in Section 1.1

iv. Declared substance is in the category of a new chemical substance;

v. Whether declaration form has been filled out in accordance with the requirements of article 4 in Section 3.2.

vi. Whether declaration materials meet the requirements of Section 4.1.1;

vii. Whether declaration form attachments meet the requirements of Section 4.1.2;

viii. For a serial declaration joint declaration, or simplified declaration, whether the these declaration materials respectively include the materials required in Section 4.2.1, 4.2.2, or 4.2.3;

ix. Whether the information on declaration form meets the requirements of Section 4.3.2;

x. weather the sources of the data on declaration form meet the requirements of Section 4.3.4

xi.Whether in declaration form, test agency providing test agency meets requirement in section 4.4.1

xii. Whether test methods for test data meet the requirements in Section 4.4.2; and

xiii. Applicant has paid declaration registration fee in full (subject to the date of receipt).

The results of formal reviews may appear following cases:

Case I: In case of declaration that meets all of requirements above 13 items, registration center will issue applicant Acceptance Notice for New Chemical Substance declaration (for a sample, see Attachment 10) for a formal acceptance of new chemical substance declaration and submit the said new chemical

substance declaration to Assessment Committee within five working days. For a joint declaration, registration center will issue each applicant a Acceptance Notice for New Chemical Substance Declaration with the identical content (similarly below). For a series of declaration, it will issue only one Acceptance Notice for New Chemical Substance declaration. If applicant fails to pick it up, registration center will mail Acceptance Notice for New Chemical Substance declaration to liaison person whose name filled in declaration form (similarly below).

Case II: In case that declaration cannot meet the requirements of Items i to IV, registration center will issue applicant Rejection Notice for New Chemical Substance declaration, (see a sample in Attachment 11) for termination of formal review.

Case III: In case of declaration that do not meet the requirements of Items v to xii (one or more items), registration center will issue applicant a New Chemical Substance declaration Materials Correction and Supplement Notice (for sample, see Attachment 12), which will specify all of items in need of amendment. Registration center will wait for amend material of applicant and the waiting time will not be included in the term for formal review.

Case VI: In case that declaration can not meet the requirements of Items v to xii (one or more items), registration center will issue applicant a New Chemical Substance declaration Materials Correction and Supplement Notice (for sample, see Attachment 12), which will specify all of items in need of amendment. Registration center will wait for amend material of applicant and the waiting time will not be included in the term for formal review.

case V: In case that declaration can not meet the requirements of Item xiii, or the amount of declaration registration fees paid by applicant is insufficient, the registration center will wait for the receipt of registration center registration fee or supplement. The waiting time will not be included in the term for formal review.

The above described case III, IV and Case V may occur simultaneously.

For case I, applicant may wait for registration center to issue further information.

For case II, in case that applicant may consider that the facts do not comply with case II, the applicant may submit a written excuse to registration center within 60 days, asking for a reexamination. Within 15 days of the receipt

of a written excuse from applicant, registration center will conduct an examination, and the result of examination will be issued to applicant by a written notice. When the examination results indicate that the facts comply definitely with case II, or applicant fails to deliver a written defense to registration center within the term, registration center will terminate the review process and this declaration ends; when the examination results indicate that facts do not comply with case II, registration center will continue the formal review process and it will recalculate the time limitation for formal review.

For case III , applicant shall correct and supplement all information and registration center shall restart examination procedure after the receipt of corrected and supplement material and expiration and corrected and supplement material. In case of failing the examination registration center shall reject the information

For case IV, applicant may

① The correction and supplement of the materials shall be completed within three months;

② In case that the correction and supplement information can not be completed within three months, applicant should first notify the registration center in writing within three months explaining the reasons and correction term with one time ; correction and supplement must be completed on time in a limit term. The limit term cannot exceed 12 months.

③Registration center within three months will be informed that no more correction and supplement material are needed

After receipt of correction and supplement material and written notice or expiration of correction and supplement, registration center shall restart formal examination procedure and submit it to Assessment Committee after acceptance

For case V, applicant should remit declaration registration fee to the designated account as soon as possible, or check to see if the remitted sum corresponds to charge standard. When applicant considers that the facts do not comply with case IV, he may contact registration center for an examination. A response from applicant will enable the registration center to restart the formal review process of this section.

5.1.2. Materials Supplementation

When registration center receives an opinion from Assessment Committee in

which declaration materials are insufficient to support a review decision, registration center will issue a *Notice for New Chemical Substance Declaration Correction and Supplement Permission* (for sample, see Attachment **13**) to applicant within two working days, which will permit applicant to make a one-time supplementation of the materials within three months, in order to explain the environmental impact of declared substance. Applicant should:

① The correction and supplement of the materials shall be completed within three months;

② In case that the correction and supplement information can not be completed within three months, applicant should firstly notify the registration center in writing within three months explaining the reasons and make correction and supplement in limited term with one time ; Limited term can not exceed 12 months

③ Registration center will be informed that no more correction and supplement material are needed within three months

After receipt of correction and supplement material and written notice or expiration of correction and supplement, registration center shall review the correction and supplement material and submit it to Assessment Committee.

Before conclusion of assessment stage, if applicant shall make correction and supplement for represented declaration material for its own sake *Correction and Supplement Statement for New Chemical Substance Declaration* (for sample, see attachment 14) shall be submitted to registration center by applicant. *Correction and Supplement Statement for New Chemical Substance Declaration* shall relate the reason, item and term of correction and supplement (except correction and supplement are submitted as same time); correction and supplement term can not excess 12 months.

In correction and supplement term described in preceding paragraph, applicant shall present correction and supplement material to register center by one time. Receiving correction and supplement material, register center shall restart formal review procedure and recalculate time limit. In case that applicant fails to present correction and supplement material or partly present it to register center, register center shall succeed review procedure of declaration by itself. In case that the result of final review conclusion goes against the purpose of declaration, its consequence shall be accepted by applicant.

Chance for correction and supplement of presented declaration material for

the sake of applicant is one time.

In case IV ③ in Section 5.1.1, in case that applicant inform registration center that no more correction and supplement of material are needed , the chance stated in this section shall not be offered any longer

5.1.3. Notices

Within 2 work days of the receipt of a decision from SEPA on whether or not it has approved a registration, CRC will issue a written notice on the decision to the notifier.

When a notification is approved, CRC will issue a *Registration Certificate* to the contact person that is named on the notification form. When a notification is rejected, the Notification Center will issue a *New Chemical Substance Notification Results Notice* (for a sample, see Attachment **15**) to the contact person that is named on the notification form.

5.2. Notification Exemptions

This section applies to applications for notification exemption, but it does not apply to other types of notifications.

5.2.1. Formal Reviews

Within 15 days of the date of receipt of application for notification exemption formalities, CRC will conduct a formal review of the application materials. The formal review substance includes:

i. Whether the applicant has conformed to the provisions of Section 1.3;

ii. Whether the manufacturing or import operations are at the same time not in the category of the cases provided in Section 1.2, Paragraphs 3 and 4;

iii. Whether the notified substance is not in the category of the cases provided in Section 1.1, Paragraph 4;

iv. Whether the notified substance is in the category of a new chemical substance;

v. Whether the notification form has been filled out in accordance with the requirements of Section 3.2, Paragraph 5;

vi. Whether the application materials include the evidentiary materials provided in Section 4.2.4;

vii. Whether the substance of the evidentiary materials has been verified; and

viii. Whether the notifier has paid the notification registration fee in full (by the date of receipt).

Formal reviews may result in one of the five cases listed below:

Case I: When the application conforms to the requirements in all of the above eight items, CRC will accept it, make a handling proposal, and report it to SEPA.

Case II: When the application does not meet one of the requirements of Items i through iv, CRC will not accept it, to inform applicant with written notice and registration center terminates reviewing procedure.

In Case II, when the applicant believes that the facts do not correspond to Case II, it may ask the CRC for a reexamination within 15 days by telephone, fax, email, or in writing. CRC will conduct a reexamination within 5 work days of receipt of the request from the applicant, and it will notify the applicant of the reexamination results in the contact method that was used by the applicant. When the reexamination results indicate that the facts correspond to Case II, CRC will terminate the review process, end the application, and not save the application materials. They will be destroyed, unless the applicant declares that it wishes to have the said materials and retrieves them on its own within 5 work days. When the reexamination results indicate that the facts do not correspond to Case II, CRC will continue the review process.

Case III: When the application does not meet the requirements of Items v or vi, CRC will notify the applicant by telephone, fax, or email, indicate all of the substance that does not meet the requirements only once, and cancel the application. CRC will not save the said application materials. It will be destroyed, unless the applicant declares that it wishes to have the said application materials and retrieves them on its own within 5 business days. When the applicant asks to continue the application, after it corrects all of the parts that do not meet the requirements, it shall resubmit the entire application materials and pay the notification registration fee in full.

Case IV: When the application does not meet the requirements of Item viii, or when the notification registration fee paid by the notifier is insufficient, CRC will wait for the notification registration fee to be received or supplemented, and the waiting time will not be calculated in the time limits for the formal review.

The above described Case III and Case IV may occur simultaneously.

Case V: When the results of the verification of the evidentiary materials in

Item vii indicate that the new chemical substance applied for notification exemption is subject to one of the cases listed below, CRC will reject it and Inform applicant of end of review procedure with a written notice and registration center terminates review procedure.

(I) The application is undergone notification exemption as provided in Item (I), Paragraph 1, Article 13 of the *Provisions*, but it is not for scientific research purposes or the agency listed in the evidentiary materials that is to conduct the scientific research refuses to corroborate it;

(II) The application is undergone notification exemption as provided in Item (II), Paragraph 1, Article 13 of the *Provisions*, but it is for a polymer containing a new chemical substance monomer of 2 (including 2) or more percent;

(III) The application is notification exemption as provided in Item (III), Paragraph 1, Article 13 of the *Provisions*, but it is not used for technological research and development or the agency listed in the evidentiary materials that is to conduct the technological research and development refuses to corroborate it;

(IV) The application is notification exemption as provided in Item (IV), Paragraph 1, Article 13 of the *Provisions*, but it is not for ecotoxicological test of new chemical substances in China with Chinese testing organisms or the agency listed in the evidentiary materials that is to conduct the tests refuses to corroborate it;

(V) The application is polymer notification exemption in accordance with Section 7.2, but the said polymer does not conform to the provisions of Section 7.2;

Under the cases stated in the preceding paragraph, the applicant may notify CRC within 30 days by telephone, fax, email, or in writing to request a reexamination. CRC will conduct the reexamination within 15 days of receipt of the request from the applicant, and it will notify the applicant of the results of the reexamination in the contact method that was used by the applicant. When the reexamination results indicate that the facts do not correspond to Case V, CRC will continue the review process. When the reexamination results indicate that the facts do correspond to Case V or the applicant does not request a reexamination, CRC will announce its illegal action on CRC website, record its bad record, and refuse to accept its application for notification exemption for three years, unless it applies to cancel notification exemption in accordance with Section 5.3.2. The announcement substance will include at least the name of the

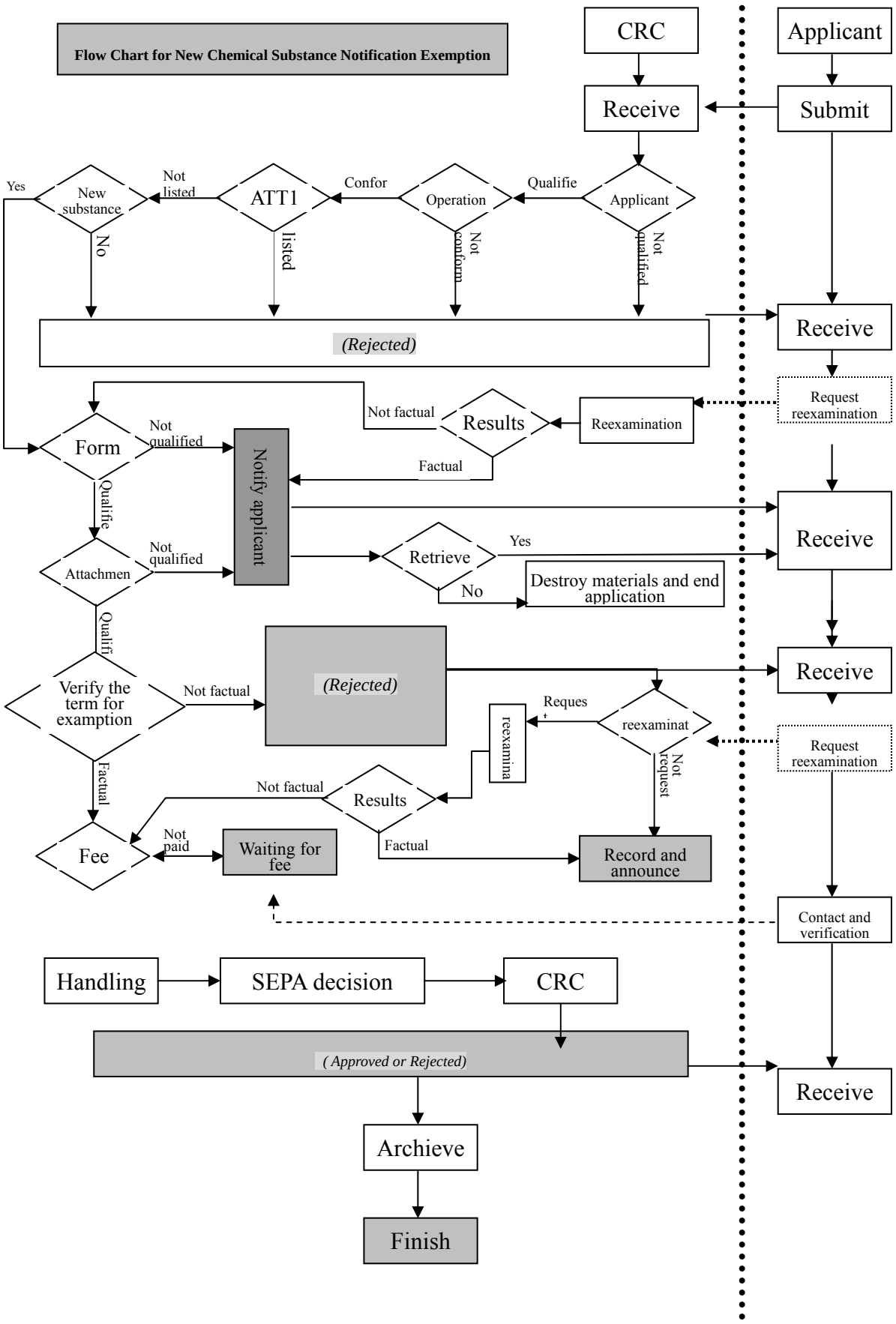
unit that committed the violation, the name of the person in charge, the name of the contact person, and the action/substance of the violation.

Article 13 of the *Provisions* has quantitative restrictions on new chemical substance notification exemption. When the quantity that the applicant applies for is smaller than provided, it will be handled in accordance with the quantity that is applied for by the applicant; when the quantity that the applicant applies for is larger than provided, it will be handled in accordance with the provided quantity; when the applicant asks to undergo the exemption in accordance with a quantity that is larger than provided, the applicant shall submit other types of notifications such as a typical notification.

5.2.2. Notices

Within 2 work days after receiving a SEPA decision on whether or not it has approved a notification exemption, CRC will issue a *New Chemical Substance Notification Exemption Results Notice* to the contact person that is named on the notification form.

The flow chart for undergoing notification exemption formalities is shown as follows.


Flow Chart for New Chemical Substance Notification Exemption
CRC
Applicant
Receive
Submit
Yes
New substance
No
Not listed
ATT1
listed
Confor
Operation
Not conform
Qualifie
Applicant
Not qualified
(Rejected)
Receive
Request reexamination
Not factual
Results
Reexamination
Factual
Form
Not qualified
Qualifie
Notify applicant
Attachmen
Not qualified
Retrieve
Yes
No
Destroy materials and end application
Receive
Qualifi
Verify the term for examption
Not factual
(Rejected)
Receive
Reques
reexaminat
reexamina
Not request
Request reexamination
Not factual
Results
Factual
Fee
Not paid
Waiting for fee
Record and announce
Contact and verification
Handling
SEPA decision
CRC
(Approved or Rejected)
Receive
Archieve
Finish

5.3. Notification Cancellations

5.3.1. Cancellations of New Chemical Substance Notification

This section is not applicable for cancellations of applications for notification exemptions.

After submitting a typical notification, a serial notification, a joint notification, or simplified notification, the notifier may submit *Statement for Cancellations of New Chemical Substance Notifications* (for a sample, see Attachment 17) in written form to CRC at any time to withdraw the new chemical substance notification registration.

For a joint notification, each of the joint notifiers may transact a cancellation independently, but his cancellation does not have any influence on the notification of the other notifier(s) in the joint notification.

For a serial notification, the notifier may withdraw any one or more substances in the serial substance.

If a notifier delivers a *Statement for Cancellations of New Chemical Substance Notifications* to CRC before the *Registration Certificate* is issued, the cancellation will take effect immediately, and CRC will terminate the review process for the notification.

If a notifier delivers a *Statement for Cancellations of New Chemical Substance Notifications* to CRC after the *Registration Certificate* issued, the *Registration Certificate* should be returned to CRC. On the date that CRC receives the returned *Registration Certificate*, the cancellation takes effect.

Since the date that the cancellation takes effect, the notifier or the holder of the *Registration Certificate* will no longer take the responsibilities stipulated in Chapter 4 of the *Provisions* and in this *Guidance*, but his responsibilities before the cancellation takes effect do not be exempted. When the holder of the *Registration Certificate* has manufactured or imported the notified new chemical substance before the cancellation takes effect, his responsibilities for the manufactured or imported new chemical substance, which are stipulated in national laws and Regulations, the *Provisions*, and this *Guidance,* do not be exempted.

If a cancellation takes effect, CRC does not have the responsibilities to keep the said notification materials. All the notification materials will be

destroyed, unless the notifier wishes to keep the materials and retrieves them on his own within 5 work days.

5.3.2. Cancellations of Notification Exemption Applications

This section is applicable for cancellations of applications for the exemption notification, but not for other types of notifications.

After submitting an application for a new chemical substance exemption notification, the notifier may submit a *Cancellation Statement for the Exemption Notification* (for a sample, see Attachment 18) in written form to CRC at any time to withdraw the application for the exemption notification.

If the applicant delivers the *Cancellation Statement for Exemption Notification* to CRC before the *Results Notice for New Chemical Substance Exemption Notification* is issued, the cancellation will take effect immediately, and CRC will terminate the review process for the notification.

If the applicant delivers the *Cancellation Statement for Exemption Notification* to CRC after the *Results Notice for New Chemical Substance Exemption Notification* is issued, the *Results Notice for New Chemical Substance Exemption Notification* should be returned to CRC. The cancellation will take effect when CRC receives the returned *Results Notice for New Chemical Substance Exemption Notification*.

Since the date of the cancellation taking effect, the applicant or the holder of the *Results Notice for New Chemical Substance Exemption Notification* will no longer take the responsibilities stipulated in Chapter 4 of the *Provisions* and in this *Guidance*, but his responsibilities before the cancellation taking effect do not be exempted. If the holder of the *Results Notice for New Chemical Substance Exemption Notification* has manufactured or imported the notified new chemical substance before the cancellation taking effect, his responsibilities for the manufactured or imported new chemical substance, which are stipulated in national laws and Regulations, the *Provisions*, and this *Guidance,* do not be exempted.

When the cancellation application asked by the applicant corresponds to the Section 5.2.1, Case V, CRC will record its conditions of application, cancellation, and reasons internally, but will not publish externally.

As soon as the cancellation takes effect, CRC is not responsible for keeping the application materials. The application materials will be destroyed, unless the

notifier wishes to keep the application materials and retrieves them on his own within 5 work days.

6. Management after New Chemical Substance Notification Registration

6.1. Allowable Scope

6.1.1. Registration Certificate

The *Registration Certificate* includes the name of its holder and the name, uses, and quantities of the notified new chemical substance.

The valid period of the *Registration Certificate* begins from the date of issue to the date of publication of the new chemical substance by SEPA.

The holder of the *Registration Certificate* shall manufacture or/and import the new chemical substance according to the contents provided in the *Registration Certificate*. If the holder of the *Registration Certificate* wants to exceed the quantity and/or change the uses stipulated in the *Registration Certificate* to manufacture or/and import the new chemical substance, he need to reapply for the new chemical substance notification.

All the requirements of the re-notification are identical to those of the original notification. The original notification materials kept in CRC is still valid. In this case, the notifier needs not to resubmit, unless he declares the cancellation of all or part of the notification materials of the original notification.

6.1.2. Exemption Notification

In the *Results Notice for New Chemical Substance Exemption Notification*, includes the name of its holder, the names, uses, and quantities of the new chemical substances.

The valid period of the *Results Notice for New Chemical Substance Exemption Notification* is one year from the date of issue.

The holder of the *Results Notice for New Chemical Substance Exemption Notification* shall manufacture or/and import the new chemical substance according to the contents provided in the *Results Notice for New Chemical Substance Exemption Notification*. If the holder of the *Results Notice for New Chemical Substance Exemption Notification* wants to exceed the quantity and/or change the uses stipulated in the *Results Notice for New Chemical Substance Exemption Notification* to manufacture or/and import the new chemical

substance, he need to reapply for the new chemical substance exemption notification.

If the valid period of the *Results Notice for New Chemical Substance Exemption Notification* has been exceeded and it does not belong to the provisions of Item (III), Paragraph **1**, Article 13 of the *Provisions*, the applicant may re-transact the exemption notification formalities.

All the exemption re-notification formalities are required to be identical to those of the original exemption notification formalities.

6.2. Changes of Information

When the holder of the *Registration Certificate* or the *Results Notice for New Chemical Substance Exemption Notification* changes his name, he may submit a *Declaration of Certificate/Notice Holder Name Change* (for a sample, see Attachment 19) to CRC to change his name. If the cases are true, CRC will grant the name change, issue a *Holder Name Change Certificate* (for a sample, see Attachment 20) to the holder and record it in the files of the new chemical substance notification or exemption notification formalities; however if the case are not true, CRC will not grant the name change.

After the name change mentioned above, the *Registration Certificate* or the *Results Notice for New Chemical Substance Exemption Notification* can only be used by holder of the changed name, and the name before the change will automatically lose its authority stipulated in the *Registration Certificate* or the *Results Notice for New Chemical Substance Exemption Notification*. CRC will not issue the holder a changed *Registration Certificate* or a *Results Notice for New Chemical Substance Exemption Notification* under the changed name, and the original certificate/notice may continue to be used together with the *Holder Name Change Certificate*.

When the holder of the *Registration Certificate* or the *Results Notice for New Chemical Substance Exemption Notification* changes his information such as address and contact method etc., he may submit the *Declaration of Certificate/Notice Holder Information Change* (for a sample, see Attachment 21) to CRC to require to change. CRC will update the relevant information in the files of the new chemical substance notification or exemption notification application.

When the holder of the *Registration Certificate* or the *Results Notice for*

New Chemical Substance Exemption Notification acquires new information about the new chemical substance as described in Categories (III), (IV), or/and (V) of Section 4.3.2, he may provide it to CRC. CRC will check the facticity of it. If the information is true after checked, CRC will merge it into the files of the new chemical substance notification or exemption notification application; however if the said information cannot be checked or is found to be wrong, CRC will shelve the said information.

6.3. Filing

This section is only applicable for the holder of the *Registration Certificate*.

If one of the following cases happens, the holder of the *Registration Certificate* shall fill in the *Record Form of the Manufacture, Import, and Circulation of New Chemical Substances* (Attachment 23) according to the *Filing Guidance of it* (Attachment 22), and submit it to the environmental protection administrative department of the county where the manufacturer or importer is located.

(I) When each batch is actually manufactured in China, the holder of the *Registration Certificate* shall, within 5 work days after the products come off from the production line, report to the environmental protection department of the county where the manufacturer locates;

(II) When the new chemical substance produced in China or imported from foreign countries is transferred outside of the county level administrative area of the manufacturer or domestic importer, each time the holder of *Registration Certificate* shall, within **5** work days after the shipment from the location of the manufacturer or domestic importer location, report to the environmental protection department of the county where the manufacturer or the domestic importer locate

(III) The holder shall, within **5** work days after the customs clearance formalities have been finished or the goods reach the domestic importer, report each export to the environmental protection department of the county at the location of the domestic importer.

In Item (I) of this section, continuous production and mass production is regarded as a single production, however each restart of production after a long stop (over 12 months) is regarded as another production; in Item (II) of this section, a number of transfers to the same receiver is regarded as a single

transfer, however any transfer to a new receiver is regarded as another transfer; in Item (III) of this section, a number of goods deliveries to the same domestic importer is regarded as a single import, however a goods delivery to any different domestic importer is regarded as another import.

When the *Registration Certificate* holder is a foreign trading firm, he may entrust the domestic receiver of this import of new chemical substances to fill in the *Record Form of the Manufacture, Import, and Circulation of New Chemical Substances*. The domestic trustee may transact the filing matters in the name of the foreign trading firm with a proxy provided by the foreign trading firm and a copy of the *Registration Certificate*, and the *Record Form of the Manufacture, Import, and Circulation of New Chemical Substances* may be signed or stamped by the trustee.

The *Record Form of the Manufacture, Import, and Circulation of New Chemical Substances* shall be typewritten in Chinese, the font must be simplified Chinese, and the format and contents of the form must be identical to that published on CRC website.

A filled out, signed or stamped *Record Form of the Manufacture, Import, and Circulation of New Chemical Substances* will be similarly valid when it is faxed to the environmental protection department, however the original form must be delivered or mailed on the same day to the environmental protection department. The filing form shall be faxed to CRC at the same time.

The contact methods of environmental protection departments in all areas can be found on CRC website.

6.4. Materials Preservation

The data of new chemical substance notification, records of the quantity and flow of the manufacture or import, and the environmental impact shall be kept by the holder of the *Registration Certificate* until the date of the publication of this new chemical substance.

When an exemption notification is approved, the applicant shall properly keep the data of exemption notification application, records of the quantity and flow/customer names of the manufacture or import of the new chemical substance, and the environmental impact for at least three years.

6.5. Publication of Notified New Chemical Substances

New chemical substances that are approved for registration will be published by SEPA timely.

As soon as new chemical substances approved for registration are published by SEPA, they are immediately regarded as chemical substances listed in the IECSC, and no longer managed as new chemical substances.

New chemical substances that have not obtained a *Registration Certificate*, including new chemical substances approved for exemption notification are not applicable for the publication procedures stipulated in this section, and they will not be listed in the IECSC.

7. Supplementary Provisions on Polymer Notification

In this *Guidance*, polymers are considered as a kind of chemical substances. Beside the Provisions on polymers of Article 13 of the *Provisions* (that is, when the content of the new chemical substance monomer is less than 2 percent, an application may be submitted to transact exemption notification formalities), Provisions in this section shall also be abided when manufacturing or importing.

A *Registration Certificate* or the *Results Notice for New Chemical Substance Exemption Notification* for a polymer notification is applicable for the regulation of Section **6.1**.

For matters that are not stipulated in this section, please consult Provisions on nonpolymer new chemical substances in the *Provisions* and this *Guidance*.

7.1. Condition of Not Required Notification

If a polymer is already listed in IECSC, a new chemical substance notification is not required.

7.2. Transacting Exemption Notification

If Polymers that do not correspond to the *Guidance* of Section **7.1** and when one of the following cases happens, they will be regarded as being in conformance with the Item (II), Article 13 of the *Provisions*, and exemption notification formalities is required:

(I) All of monomers are already included in the IECSC;

(II) In polymer, two monomers/ reacction body or above with max. content (on base of weight ratio) has existed in another or multiple polymer as a largest

monomer/ reaction body in “Name List” and other new chemical substance monomer content shall be lower 2%.

(III) All of blocks of the block copolymerization are already included in the IECSC;

(IV) The precursors and branched chains of the graft polymers are already included in the IECSC;

(V) Low concern polymers

The low concern polymers described in Item (V) above are polymers that meet one of the conditions listed below:

i. The average molecular weight (MW) of the polymer is between 1,000~10,000 daltons. At the same time, the content of oligomer is less than 10 percent at MW<500, and less than 25 percent at MW<1,000. This polymer still shall not have an obvious content of active functional groups;

ii. The MW of the polymer is more than 10,000, and the oligomer content is less than 2 percent at MW<500, and the oligomer content is less than 5 percent at MW<1,000;

iii. Polyester polymer

When transacting exemption notification formalities stipulated in this section, not only the materials for exemption notification are required, but also the evidentiary materials specified in the attachment that correspond to the above cases necessary are required to submit.

7.3. Simplified Notifications

If a polymer does not correspond to the *Guidance* of 7.1 and 7.2, a simplified notification is required if:

(I) the polymer is already included in the existing chemical substance inventory of 4 or more than 4 countries or regional economic integration organizations, or

(II) the molecular structure of the polymer is similar to that of one or more other polymers in the IECSC.

When transacting the notification stipulated in this section, not only the notification materials for a simplified notification that are required, but also the attachment including the following information on the notified polymer is required:

i. The condition listed in the above paragraph of this section;
ii. Its average molecular weight;
iii. Molecular weight distribution;
iv. Its monomers/reactants list, and names and chemical abstract numbers shall be specified (if known);
v. The residual monomers/reactants;
vi. The percentage of monomers/reactants in the polymer (if known);
vii. The percentage of oligomer content at a molecular weight of less than1000;
viii. Molecular formula and/or structural formula (if known);
ix. Polymerization process and conditions (if known).

7.4. Typical Notifications of Polymer

When it does not correspond to the *Guidance* of sections **7.1**, **7.2**, and **7.3**, a typical notification is required.

When transacting the notification stipulated in this section, not only the notification materials for a typical notification that are required, but also the attachment including the following information on the notified polymer is required:

i. The average molecular weight;
ii. The molecular weight distribution;
iii. Its monomers/reactants list, and names and chemical abstract numbers shall be specified (if known);
iv. The residual monomers/reactants;
v. The percentage of monomers/reactants in the polymer (if known);
vi. The percentage of oligomer content at a molecular weight of less than1000;
vii. Molecular formula and/or structural formula (if known);
viii. Polymerization process and conditions (if known).

7.5. Serial Notifications and Joint Notifications

When the polymer notification corresponds to the Sections 2.2 or 2.3, a serial notification or a joint notification may be transacted.

8. OTHER

The website of CRC publishes all of the relevant materials and information for implementing the *Provisions*, including the *Provisions*, standards, the *Guidance*, IECSC, forms, filing instructions, flow charts, the progress status of new chemical substance notification reviews and so on. All of these information and materials are provided free for downloading or searching.

The further notice will provide information about the charge standards and specific requirements for new chemical substance notification registrations.

Attachment **1**

New Chemical Substance Registration Certificate

(Registration Number)

Notifier Name：

Name of Registered Substance

Chinese:

English:

CAS Number:

Registered Quantity (Tons/Year)：

Major Uses：

State Environmental Protection Administration
(Stamped)

Issued date(yy/mm/dd):

Attachment **2**

Exemption Categories for New Chemical Substance Notifications

I. Chemicals already under the Management of Other Existing Laws and Regulations

1. Radioactive substances;
2. Military industry products;
3. Pyrotechnics;
4. Biological substances;
5. Pesticides;
6. Veterinary drugs;
7. Pharmaceuticals;
8. Cosmetics;
9. Foods;
10. Food additives;
11. Feed;
12. Feed additives;
13. Tobacco and tobacco products.

II. Substances Existing in Nature

1. Substances that are unprocessed, or that are manufactured or processed only through the methods listed below:
   1) Manual;
   2) Mechanical;
   3) Gravitational;
   4) soluble in water;
   5) Floatation in water;
   6) Heat dehydration.
2. Extracted from the atmosphere through various means;
3. Natural polymers, except for ones that are processed through physical or chemical processing.

III. Special Categories

1. Glass;
2. Frit
3. Pottery raw materials and ceramic ware;
4. Steel and steel products;

5. High-alumina cement;
6. Portland cement;
7. Articles, namely, finished goods that conform to the following three standards:
   1) Articles that form a specific shape or pattern when manufactured;
   2) Articles that have final use functions and objectives, which functions are dependent entirely or partially on their shape or pattern;
   3) Articles that have not generated chemical change at final use time, or that have only generated chemical change of a commercial value that is independent of the article.

For instance, batteries, fibers, thin film, leather, paper, yarn, and pencils are articles.

Articles that generate a surface chemical reaction but still maintain their overall structure and shape are still regarded as articles. These surface chemical reactions include: chemical reactions to increase their strength, hardness, and fire resistance, and reactions such as ones to improve their ion exchange capacity, resilience, and antibiotic properties.

8. Homogeneous and heterogeneous alloys, except for metal compounds and precisely defined intermetallic compounds.

Alloys refer to solids or liquids formed through the mixing of two or more metals or of one metal with other nonmetallic elements.

IV. Categories of Noncommercial Purpose or Unintentionally Produced, except when they are put directly onto the market as commodities

1. Impurities;
2. Products of random reactions that occur when a certain chemical substance accidentally comes into contact with another substance or when an article comes into contact with an environmental factor (such as air, steam, a microorganism, or sunlight);
3. Products of random reactions that occur when a chemical substance, mixture, or article is in storage;
4. Products of reactions that occur when a chemical substance, mixture, or article is in final use;
5. Waste water, waste gas, solid waste, and by-products.

Attachment **3**

Procedures to entrust CRC to affirm a new chemical substance

If a notifier cannot find a notifying chemical substance from the public version of IECSC, he is recommended to entrust CRC to affirm if it is a new chemical substance. In accordance with international practice, some of the chemical substance identifiers (referring to the Chinese and English names and structural formulas in the systematic nomenclature that can reflect the molecular structure of the substance) in IECSC are confidential. The openly published printed version, PC version, and Internet version of IECSC list only the generic names and aliases of the confidential substances, not the confidential names. Therefore, even though the notifier has determined that the chemical substance to be notified is not included in the public version of IECSC, this does not mean that the said chemical substance is definitely a new chemical substance. In order to prevent notifiers from submitting notifications of existing chemical substances that are already included in IECSC, CRC provides a service to affirm if a chemical substance is a new one. The procedures to entrust CRC to affirm a new chemical substance are as follows:

1. A notifier

- Fills out, in typewriting, and signs a *Entrustment to Affirm a New Chemical Substance* (abbreviated below as "the *Entrustment*". for a sample, see Annex, which can be downloaded from the CRC's website).
- Delivers or mails the original of the *Entrustment* to CRC. Submits the electronic version to CRC by email: ncn@crc-sepa.org.cn.

2. CRC

1、Will complete the confirmation of new chemical substances within 5 work days of receiving the *Entrustment*, and it will hand over or send the results by registered mail to the contact person that is named in the *Entrustment*.

2、In order to avoid confusion, CRC will make a copy of the original *Entrustment*, write the result of affirmation on the copy, sign and send it to the notifier.

Annex

Entrustment to Affirm a New Chemical Substance

<table>
<tr><td>Name of Entrusting Party</td><td colspan="4">(Affix official seal or signature of person in charge)</td></tr>
<tr><td>Mail Address & Zip Code</td><td colspan="4"></td></tr>
<tr><td>Contact person</td><td colspan="2"></td><td>Telephone</td><td></td></tr>
<tr><td>Email Address</td><td colspan="2"></td><td>Fax</td><td></td></tr>
<tr><td>Means to Send the Result</td><td>Registered mail</td><td>Pickup (Specify person)</td><td colspan="2">Entrust CRC to send by Express</td></tr>
<tr><td>CAS Noumber</td><td colspan="4"></td></tr>
<tr><td>Name of the substance
Chinese
English</td><td colspan="4"></td></tr>
<tr><td>Molecular formula</td><td colspan="4"></td></tr>
<tr><td>Structural formula</td><td colspan="4"></td></tr>
<tr><td colspan="5">Entrustment Statement：
The true purpose of the signer of this form in entrusting CRC to affirm if the said substance is a new chemical substance is to manufacture or import the said chemical substance, and to submit a new chemical substance notification when the said chemical substance is not included in IECSC. If the signer of this form uses the affirmation result for any other purposes or discloses it to any third party, the signer of this form will bear all of the liability.
The signer of this form must copy by hand the line in the quotation marks below into the following space and sign it in order for this form to be valid:
"The signer has read and accepts all of the contents of the 'Entrustment statement' in this column."

Signer：
Year Month Day</td></tr>
<tr><td colspan="5">Acknowledgement Affirmation number：

Upon searching IECSC database, CRC has affirmed that the said substance is/is not listed in IECSC, and that it is/is not a new chemical substance.

(CRC Official Seal)
Person in charge：(signature)
Year Month Day</td></tr>
</table>

Attachment **4**

State Environmental Protection Administration New Chemical Substance Notification Form	Acceptance number: Acceptance time:

Ⅰ、Name of notification unit:

Ⅱ、Name of notified substance:

Ⅲ、Substance category:

☐Substance with a unique and defined molecular structure ☐Substance without a unique and defined molecular structure ☐Polymer

Ⅳ、Notifier declaration

We declare that,

(1) We consent to the listing of the notified substance in the Inventory of Existing Chemical Substances in China [IECSC], and we agree to strictly observe the stipulations of the *Regulations on the Environmental Management of New Chemical Substances*;

(2) All of the materials that are submitted in the notification form and attachments are accurate and reliable, come from lawful sources, and do not infringe on the rights and interests of others. If there are found to be inaccuracies, we will assume all of the resulting legal consequences;

(3) The submitted electronic documents are completely identical in content to the hard copies;

(4) We agree to engage in manufacture or importing within the approved limits in accordance with the requirements of the Registration Certificate for the Environmental Management of New Chemical Substances;

Legal representative of notification unit (signature):

Seal of notification unit

Notification date:

Ⅴ、Type of notification: ☐General notification ☐Serial notification ☐Joint notification ☐Simplified notification

Ⅵ、Type of operation: ☐Manufacture Planned date of manufacture: _____ ☐Importing Planned date of import: _____

Anticipated place of manufacture: ____Anticipated port of import: _____

Notified manufacture quantity (tons/year): __Notified import quantity (tons/year): __

Ⅶ、Name list of the test agencies that provided the data required for the form:

Agency Name	Test Item	Number of Pages of Accreditation Certifications

Ⅷ、List of notification materials:	All notification materials total____ pages, attachments total____ pages		
Attachment number	Attachment number	Attachment number	Attachment number

<table>
<tr><th colspan="4">Part I. Identification Information About the Notification unit and the Notified Substance</th></tr>
<tr><td colspan="4">1、Basic information about the notification unit</td></tr>
<tr><td colspan="3">1.1 Full name of the notification unit
Chinese：

English：</td><td>1.2 Address of the notification unit：</td></tr>
<tr><td colspan="4">1.3 Internet website address of the notification unit：</td></tr>
<tr><td colspan="4">1.4 Contact person</td></tr>
<tr><td>Name：</td><td>Telephone：</td><td colspan="2">Fax：</td></tr>
<tr><td colspan="2">Email：</td><td>Mobile number：</td><td rowspan="2">Postal address (with zip code)</td></tr>
<tr><td colspan="3">Other contact methods：</td></tr>
<tr><td colspan="4">1.5 Description of the status of the notification unit：</td></tr>
</table>

2、Identification of the notified substance

2.1 Chemical name of the notified substance (☐Confidential)

English：

Chinese：

2.2 Class name of the notified substance

English：

Chinese：

2.3 Other names：

2.4 US Chemical Abstracts Service (CAS) registry number (☐Confidential)：

2.5 Description of the appearance of the notified substance：

2.6 Molecular formula (☐Confidential)：

2.7 Molecular weight：

2.8 Inclusion status in other inventories

Country or Region	Inventory Name	Inventory Registry Number	Notes

2.9 Polymer information (☐Confidential) (Provided in attachment form)

2.10 Molecular structure(☐Confidential)：

2.11 Impurities (☐Confidential)

Name of Impurity	Molecular Weight	CAS Number	(%)Maximum Percentage Content (%)

2.12 By-Products (☐Confidential)

Name of By-Product	Molecular Weight	CAS Number

2.13 Additives (☐Confidential)

Name of Additive	CAS Number	Properties	Content	Additive Effect

2.14 Banned Agents

Name of Banned Agent	CAS Number	Consequences of Contact or Mixture with Notified Substance

2.15 Spectroscopic Data (☐Confidential)

☐Ultraviolet ☐Infrared ☐Nuclear Magnetic Resonance ☐Mass Spectrometric ☐HPLC ☐GC ☐Other

3、Description of the detection method for the notified substance (☐Confidential) **：**

4、Technological process for the manufacture of the notified substance (☐Confidential) **：**

5、Uses and exposure status of the notified substance

5.1 Name of the marketed commodity of the notified substance：

5.2 Form of the marketed commodity of the notified substance (☐Confidential)	☐Pure Substance	☐Product Concentration (unit)	☐Mixture Concentration (unit)

5.3 Anticipated application field： ☐Industry ☐Agriculture ☐Daily necessities ☐Handicraft industry ☐ Scientific research ☐Other

5.4 Possible final whereabouts of the notified substance：
☐Water body ☐Air ☐Soil ☐Disposal ☐Recycling ☐Other

5.5 Exposure concentration estimate for the work environment from the use or manufacture of the notified substance：	5.6 Estimated number of persons exposed in the operation：
5.7 Exposure concentration estimate for the notified substance in the environment：	5.8 Estimated number of persons exposed in the public：

5.9 Major uses of the notified substance(☐Confidential)：

5.10 Functions and expected effects of the notified substance (☐Confidential)：

5.11 Technical procedures at the time of use of the notified substance (☐Confidential)：

5.12 Waste generation and composition at the time of use of the notified substance (☐Confidential)：

Part 2. Inherent Characteristics of the Notified Substance

6、Physiochemical properties

Item	Results	Data sources	Attachment Number	Test	Confidential
6.1 Melting point (° C)				☐	☐
6.2 Boiling point (° C)				☐	☐
6.3 Density (kg/m3)				☐	☐
6.4 Vapor pressure (kPa)				☐	☐
6.5 Surface tension (N/m)				☐	☐
6.6 Natural temperature (° C)				☐	☐
6.7 Flash point (open loop and closed loop) (° C)				☐	☐
6.8 N-octanol/water distribution system (dimensionless)				☐	☐
6.9 Water solubility (g/L)				☐	☐
6.10 Lipid solubility (g/1000g solvent)				☐	☐
6.11 Oxidability				☐	☐
6.12 Flammability				☐	☐
6.13 Explosibility				☐	☐
6.14 Particle size (μm)				☐	☐
6.15 Other				☐	☐

6.16 Overall assessment of physiochemical properties：

7、Toxicology

Toxicology Item	Results	Data sources	Attachment Number	Test	Confidential
7.1 Acute toxicity				☐	☐
7.2 Short-term recurrent toxicity				☐	☐
7.3 Subchronic toxicity				☐	☐
7.4 Chronic toxicity				☐	☐
7.5 Reproductive/ developmental toxicity				☐	☐
7.6 Neurotoxicity				☐	☐
7.7 Mutagenicity				☐	☐
7.8 Teratogenicity				☐	☐
7.9 Carcinogenicity				☐	☐
7.10 Toxic metabolic dynamics				☐	☐
7.11 Other_____				☐	☐

7.12 Overall toxicological assessment：

8、Ecotoxicology

Ecotoxicology Item	Results	Data sources	Attachment Number	Test	Confidential
8.1 Algal growth inhibition toxicity				☐	☐
8.2 Flea acute toxicity				☐	☐
8.3Fish acute toxicity				☐	☐
8.4 Bird toxicity				☐	☐
8.5 Higher plant seed germination and growth toxicity				☐	☐
8.6 Earthworm acute toxicity				☐	☐
8.7 Activated sludge respiration inhibition toxicity				☐	☐
8.8 Adsorption/desorption				☐	☐
8.9 Degradation				☐	☐
8.10 Bioaccumulation				☐	☐
8.11 Other_____				☐	☐

8.12 Overall ecotoxicological assessment：

Part 3. Environmental Protection and Environmental Safety Information About the Notified Substance
9、Recommended safe usage of the notified substance
9.1 Operational attention matters and recommendations：
9.2 Storage attention matters and recommendations：
9.3 Transport attention matters and recommendations：
9.4 Staff protection information and recommendations：
9.5 Packaging instructions：
9.6 Safety and Risk warnings：

10、Emergency measures
10.1 Measures for times of staff injuries：
10.2 Measures for times of accidental leakage：
10.3 Measures for times of fires and natural disasters：
10.4 Other：
11、Pollution prevention and abatement methods：
12、Waste disposal measures：
13、Material Safety Data Sheet(MSDS)： ☐ (provided)
14、Sample of Commodity label： ☐(provided)

Prepared by the State Environmental Protection Administration in October 2003 (First Edition)

Attachment **5**

<table>
<tr><td colspan="4">State Environmental Protection Administration New Chemical Substance Notification Exemption Application Form</td><td colspan="2">Acceptance number：

Acceptance time：</td></tr>
<tr><td colspan="3">1. Full name of the notification unit：</td><td colspan="3">2. Address of the notification unit：</td></tr>
<tr><td colspan="6">3. Contact person</td></tr>
<tr><td>Name：</td><td colspan="2">Postal address (with zip code)：</td><td>Telephone：
Fax：</td><td colspan="2">Email：</td></tr>
<tr><td colspan="6">4. Name of the notified substance(☐Confidential)
English：
Chinese：</td></tr>
<tr><td colspan="3">5. Chemical Abstracts Service (CAS) registry number(☐Confidential)：</td><td colspan="3" rowspan="4">9. Structural formula (☐Confidential)：</td></tr>
<tr><td colspan="3">6. Molecular formula：</td></tr>
<tr><td colspan="3">7. Purity (%)：</td></tr>
<tr><td colspan="3">8. Molecular weight：</td></tr>
<tr><td colspan="6">10. Notified quantity：</td></tr>
<tr><td>11. Notification exemption grounds</td><td colspan="5">☐ For scientific research purposes and, under controlled conditions, an annual new chemical substance manufacture or import quantity of no more than 100 kg
☐ Polymer with less than 2% monomer content of new chemical substance
☐ A quantity of new chemical substance of no more than 1000 kg manufactured or imported for technical research and development
☐ Sample provided for performance of new chemical substance test
☐ Other</td></tr>
<tr><td>12. Status under ambient temperature and pressure
☐Solid ☐Liquid ☐Gas</td><td>13. Melting point (° C)：</td><td>14. N-octanol/water distribution system：</td><td>15. Water solubility：</td><td colspan="2">16. Other physiochemical properties：</td></tr>
<tr><td colspan="2">17. Packaging instructions：</td><td>18. Toxicity and degradation information：</td><td colspan="2">19. Environmental safety information：</td><td>20. Acceptance number of last notification exemption：</td></tr>
<tr><td colspan="6">Person in charge of the notification unit (signature):
Signature or seal of the notification unit
Notification date：</td></tr>
</table>

Prepared by the State Environmental Protection Administration in October 2003 (First Edition)

Filing Guide for the New Chemical Substance Notification Form

The notification form contains tabular materials that are required for the submission of a general notification, serial notification, joint notification, and simplified notification. It consists of 12 pages in five parts: 1) The title page and filing instructions; 2) The table of contents cover page; 3) Part 1. The information about the notification unit and the identifier information about the notified substance; 4) Part 2. The inherent characteristics of the notified substance; 5) Part 3. The environmental protection and environmental safety information about the notified substance. The contents of the form are explained page by page below (The names of the items in the notification form are italicized in this attachment):

1、 Title Page

Name of notification unit: Enter the full Chinese/English name of the notification unit. Note: The name of the notification unit that is entered here must be identical to the name on the registration certificate.

Name of notified substance: Enter the Chinese chemical name of the notified substance. If the identifier is confidential (2.1), enter the Chinese class name (2.2) of the notified substance. Note: The Chinese name of the notified substance that is entered here must be identical to the name on the registration certificate and the name of the registered substance in regulatory notices.

Notification submission time: After preparing all of the notification materials, it is necessary to enter the time of the notification submission, indicated in "year/month/day."

2、 Table of Contents Cover Page

Acceptance number: This will be entered by CRC-SEPA. The notifier is requested to please not enter it.

I. Name of notification unit:

Enter the full Chinese/English name of the notification unit. The name must be identical to the name of the notification unit on the title page.

II. Name of notified substance:

Enter the Chinese/English chemical name of the notified substance. The

Chinese name must be identical to the name of the notified substance on the title page.

III. Substance category:

Substance with *a unique and defined molecular structure:* A chemical substance whose molecular structure can be defined.

Substance without a unique and defined molecular structure: A chemical substance whose molecular structure cannot be defined.

Polymer: Referring to a chemical substance composed of monomers.

Entering a "_," an "**X,**" or a "□" indicates yes or selected, and a blank space indicates no or not selected (similarly below).

IV. Notifier declaration***:***

Legal representative *of notification unit (signature):* The name of the legal representative must be typewritten below the handwritten signature. Note: The signature must be handwritten.

Seal of notification *unit:* A domestic notification unit must stamp with its official seal. A foreign notification unit that does not have an official seal is not required to stamp.

Notification date: The date may be handwritten or typed in here. Note: This time is not the time of the start of the registration period.

V. Type of notification***:***

Select the type of notification. For serial, joint, and simplified notifications, it is also required to provide attachments to give the corresponding explanations.

VI. Type of operation***:***

Select the type of operation, and enter the relevant information.

Planned date of manufacture: Enter the planned date of manufacture, indicated in "year/month/day.

Anticipated place of manufacture*:* Enter the anticipated place of manufacture, including the province name and the city name.

Notified manufacture quantity *(tons/year):* Enter the anticipated manufacture quantity, indicated in "tons/year."

Planned date of import*:* Enter the planned date of import, indicated in "year/month/day."

Anticipated port of import: Enter the name of the anticipated port of import.

Notified import quantity *(tons/year):* Enter the anticipated import quantity, indicated in "tons/year."

VII. Name list of the test agencies that provided the data required for the form:

Enter in accordance with the format that is required for the form. Indicate one test agency on each line. If one agency performed a number of test items, enter the names (or form numbers) of all of the items in the test item, separated by semicolons. This list may be provided as an attachment. The accreditation certifications and test reports that are referred to in the list should be provided together in the attachment.

Agency name: The full Chinese/English name of the test agency.

Test item: Enter the name or form number of the test item.

Number of pages of *accreditation certifications:* Enter the number of pages of accreditation certifications that are provided for each test agency.

VIII. List of notification materials:

Enter complete attachment numbers in the sequence of the attachment numbers (for the composition of the attachment numbers, see the "Filing Instructions"). Specify the number of pages and number of attachments in the complete set of notification materials. This list may be provided as an attachment.

Part 1. Identification Information About the Notification unit and the Notified Substance

1. Basic information about the notification unit

1.1 Full name of the notification unit

For a domestic unit, enter only the Chinese name of the unit. This name must be identical to the registered business name. For a foreign unit, enter the English name.

1.2 Address of the notification unit:

A domestic unit must enter in Chinese; a foreign unit must assure contact (It is recommended that it enter the name in both the language of the native country and in English). Address information should include: The country name, province name, city name, county name, street name, house number, and zip code.

1.3 Internet website address of the notification unit:

If one exists, enter the Internet address of the notification unit; if there is not one, enter "none." Note: Entering the contents in this item is of value to the

receiving unit or the Expert Committee in understanding the background information about the notification unit.

1.4 Contact person

Name: Type in the name of the contact person here. Note: This person represents the notification unit and is the designated individual for CRC-SEPA to contact the notification unit in reference to the new chemical substance registration.

Telephone: The telephone number of the contact person, including the national and regional area codes.

Fax: The fax number of the contact person, including the national and regional area codes

Email: The email address of the contact person. Specify upper or lower case and backslash or forward slash.

Mobile number: The mobile phone number of the contact person. A domestic contact person should provide it (if it has one), in order to ensure smooth communications in emergency situations.

Postal address: The postal address of the contact person. For a domestic unit, it must be entered in Chinese; for a foreign unit, it is necessary to ensure that the receiving unit is able to mail the relevant materials to the contact person at this address (It is recommended that it be entered in both the language of the native country and in English). The contents include: The country name, province name, city name, county name, street name, house number, and zip code.

Other contact methods*:* Other contact methods by which the contact person can be reached.

1.5 Description of the status of the notification unit:

Enter here a brief explanation of the main information about the notification unit for the local unit. It may include public information such as the size, organizational structure, product mix, subordinate organizations, employee distribution scale, and credit standing of the notification unit. There are no limitations on the number of words, but they may be entered only within this form, and may not be provided in an attachment. When it is the first submission of a new chemical substance notification, this information helps all parties to fully understand the status of the notification unit. When it is not the first notification of a new chemical substance, the acceptance number and (or) the

registration certificate number of a previous notification registration may be entered here, and a supplementary explanation of the status of the notification unit may also be entered.

2. Identification of the notified substance

2.1 Chemical name of the notified substance (may be confidential):

English: Enter its English name as in the International Union of Pure and Applied Chemistry (IUPAC) or in the US Chemical Abstracts Service (CAS).

Chinese: Enter its Chinese name in accordance with the *Organic Chemistry Nomenclature Principles* and the *Inorganic Chemistry Nomenclature Principles* that were recommended for use by China in 1980.

2.2 Class name of the notified substance

When 2.1 requires confidentiality, enter the class name of the notified substance in English and Chinese here. When this notified substance is published, it will appear under the class name that is entered here.

2.3 Other names:

Enter other Chinese and English names such as the common name and the abbreviated name of the notified substance. The common name refers to the name that is generally used for the said chemical substance; the abbreviated name refers to the simplified name that is used for the notified substance.

2.4 US Chemical Abstracts Service (CAS) registry number (may be confidential)*:*

The CAS number is the search service number for the chemical substance registry of the US Chemical Abstracts Service. If known, it must be entered.

2.5 Description of the appearance of the notified substance;

Enter a description of the color, state, and odor of the notified substance.

2.6 Molecular formula (may be confidential):

The molecular formula should be entered in accordance with the requirements for molecular formula expression, and it should be the standard expression.

2.7 Molecular weight:

The molecular weight of the notified substance should be expressed in Arabic numerals.

2.8 Inclusion status in other inventories:

An attachment may be provided in accordance with the tabular form.

Country or region: The name of the country or region of the inventory.

Inventory name: The full name of the inventory, expressed in English or the original language.

Inventory registry *number:* The registry number or identifier of the notified substance as recorded in the inventory.

Notes: Other explanations.

2.9 Polymer information (may be confidential):

i. Whether its structure is similar to one or more other polymers already listed in the inventory;

ii. Its average molecular weight;

iii. Its molecular weight distribution;

iv. Its monomers/reactants list. Specify names and chemical abstract numbers (if known):

v. Its content of residual monomers/reactants;

vi. The percentage of the monomers/reactants in the polymer (if known);

vii. Its percentage oligomer content at a molecular weight of <1000;

viii. Its molecular formula and/or structural formula (if known).

2.10 Molecular structure (may be confidential):

For a substance with a unique and defined molecular structure, it is required to draw a complete and correct molecular structure diagram. For a substance without a unique and defined molecular structure: (1) List the CAS numbers for all of the substances used to manufacture the said substance; (2) Describe the reaction process; (3) Describe the composition scope and composition type of the said substance; (4) If it can be reasonably defined, please provide the chemical structure diagram for its typical portion. For a substance in a serial notification, give the common structural information, and express the structures of all of the notified substances in the series, which may be provided in an attachment.

2.11 Impurities (may be confidential):

If there are any, enter the impurities that coexist with the notified substance. Enter the information for each impurity on one line. This may be provided as an attachment.

Name of impurity*:* The chemical name of the impurity.

Molecular weight*:* The molecular weight of the impurity.

CAS number: The CAS number of the impurity (if there is one)

Maximum percentage content (%): The percentage content of the

impurity.

2.12 By-products (may be confidential):

If there are any, enter the by-products that might be generated in the course of the manufacture, processing, use, or treatment and disposal of the notified substance, including isomers. Enter the information for each by-product on one line. This may be provided as an attachment.

Name of by-product: The chemical name of the by-product.

Molecular weight: The molecular weight of the by-product.

CAS number: The **CAS** number of the by-product (if there is one).

2.13 Additives (may be confidential):

If they exist, enter the additives at the time of marketing of the notified substance.Enter the information for each additive on one line. This may be provided as an attachment.

Name of additive: The chemical name of the additive.

CAS number: The **CAS** number of the additive (if there is one).

Properties: The basic properties of the additive.

Content: The percentage content of the additive.

Additive effect: The effect of the additive.

2.14 Banned agents (if there are any):

If the notified substance cannot come into contact with or mix with other banned agents, enter the relevant information. Enter the information for each banned agent on one line. This may be provided as an attachment.

Name of banned *agent:* The chemical name of the banned agent.

CAS number*:* The **CAS** number of the banned agent (if there is one).

Consequences *of contact or mixture with notified substance:* Describe the consequences of contact by the notified substance with the banned agent under definite conditions.

2.15 Spectroscopic data (may be confidential):

The provided spectroscopic data may be the specific types of data on the form, as well as other types of data. When other types of data are provided, they must be specified. The provided spectroscopic data should include the test conditions. The spectroscopic data for the notified substance must be provided as an attachment. spectrum data provided shall show the structure of declared substance.molecule structure must be consistent with spectrum and name must be consistence with molecule structure.

3. Description of the detection method for the notified substance (may be confidential):

It must provide test measure for environment media in which declared substance may enter (air, water, residence, soil, living beings and goods) and to supply their test measures for its degradation and translation in relative media, the measure description shall refer to relative process description about sampling and equipment in state standard. Include a detailed description of detection methods such as the names of the instruments, the major reagents, the test conditions and concise operating procedures, the quantitative methods, the data statistical methods, and the reference documents. If bioanalysis is involved, provide the relevant methods and operating procedures. This may be provided as an attachment.

4. Technological process for the manufacture of the notified substance (may be confidential):

Enter mainly the technological process for the manufacture of the notified substance, as well as the major reaction equations and reaction conditions, including the by-products that might be generated. This may be provided as an attachment.

5. Uses and exposure status of the notified substance

Exposure refers to the circumstances that might occur in the course of the manufacture,processing, transport and storage, preparation, and use of the notified substance.

5.1 Name of the marketed commodity of the notified substance:

Enter the name of the commodity when the notified substance is marketed, including the names of the marketed products or commodities of the notified substance.

5.2 Form of the marketed commodity of the notified substance (may be confidential)

Select the form of the notified substance in the marketed commodity from the three options of pure substance, product, or mixture. If it is a product or a mixture, it is necessary to provide the concentration of the notified substance in the product or mixture, and to indicate the unit.

5.3 Anticipated application field:

Select from industry, agriculture, daily necessities, handicraft industry, scientific research, and other. If other is selected, it is required to indicate the

specific field.

5.4 Possible final whereabouts of the notified substance:

Choose from water body, air, soil, disposal, recycling, and other. If other is selected, it is necessary to indicate the specific whereabouts.

5.5 Exposure concentration estimate for the work environment from the use or manufacture of the notified substance:

The exposure estimate for the work environment refers to the possible exposure concentration of the notified substance in the work environment. If known, provide this concentration, and indicate the concentration unit.

5.6 Estimated number of persons exposed in the operation:

The number of persons exposed in the operation refers to the number of persons that come into contact with the operations of the notified substance within the unit time.If known, provide this data.

5.7 Exposure concentration estimate for the notified substance in theenvironment:

The exposure estimate for the environment refers to the projected value of the concentration of the notified substance that could possibly be released into the environment. If known, provide this concentration, and indicate the concentration unit.

5.8 Estimated number of persons exposed in the public:

The number of persons exposed in the public refers to the number of the public that comes into contact with the notified substance within the unit time. If known, provide this data.

5.9 Major uses of the notified substance (may be confidential):

Enter the expected uses of the marketed commodity of the notified substance, such as a degreaser, catalyst, and ultraviolet absorber, and fungicide.

5.10 Functions and expected effects of the notified substance (may be confidential):

Enter the functions of the notified substance when its marketed commodity is used, and the expected effects after use. This may be provided as an attachment.

5.11 Technical procedures at the time of the use of the notified substance (may be confidential):

Enter the methods, forms, and detailed procedures and processes when the marketed commodity of the notified substance is used, as well as information

such as the major tools that are required when used. If the said notified substance has multiple expected uses, please provide the corresponding technical procedures in connection with each use separately. This may be provided as an attachment.

5.12 Waste generation and composition at the time of the use of the notified substance (may be confidential):

Enter information on the final total waste generation that might be produced and on the constituents of the notified substance when its marketed commodity is used for its expected uses. This may be provided in an attachment.

Part 2. Inherent Characteristics of the Notified Substance

This part covers Items 6, 7, and 8. It covers the 3 items of basic information on the inherent physiochemical properties, toxicology, and ecotoxicology of the notified substance. The information in this part is mainly certain specific data, which is also part of the notification materials for the sources of the data and the materials of the data test agency.

6. Physiochemical properties

Physiochemical property *items:* There are a total of **16** items, and each line should have information on one item. If there are no data, indicate with a "none." If there are data, the data test reports or reference documents must be provided in attachment form.

Results: For the results, it is necessary to enter empirical data. If there are no numerical values, the results must be expressed in concise language. If there are data, specify the unit.

Data sources: Enter the data test organization or reference documents.

Attachment number: Enter the number of the attachment that provides the test report or reference documents for the said data.

Test: The data must be specified as being either test or estimated. Selected indicates test, and unselected indicates estimated.

Confidentiality: It must be specified whether the data is confidential.

6.1 Melting point (°C): See SEPA chemical testing method **102**

6.2 Boiling point (°C): See SEPA chemical testing method **103**

6.3 Density (kg/m3): See SEPA chemical testing method **109**

6.4 Vapor pressure (k/Pa): See SEPA chemical testing method **104**

6.5 Surface tension (N/m): See SEPA chemical testing method **115**

6.6 Natural temperature (°C): Enter the natural temperature of the notified

substance.

6.7 Flash point (open loop and closed loop) (°C): Enter the flash point and test conditions of the notified substance.

6.8 N-octanol/water distribution system: See SEPA chemical testing methods 107 and 117

6.9 Water solubility (g/L): See SEPA chemical testing method **105**

6.10 Lipid solubility (g/1000g solvent): See SEPA chemical testing method 116

6.11 Oxidability: Enter the characteristics of the oxidability of the notified substance.

6.12 Flammability: Enter the characteristics and required conditions of the flammability of the notified substance.

6.13 Explosibility: Enter the characteristics and required conditions of the explosibility of the notified substance.

6.14 Particle size: See SEPA chemical testing method 110

6.15 Other: If there are other items, enter their names and corresponding information.

6.16 Overall assessment of physiochemical properties:

Enter a comprehensive written description of the physiochemical properties of the notified substance, including a discussion of the behavior of the physiochemical properties of the notified substance in the environment and the possibility of reversion. This may be provided as an attachment.

7. Toxicology

Toxicology items There are a total of 12 items, and each line should have information on one item. If there are no data, indicate with a "none." If there are data, it is necessary to provide the data test reports or reference documents.

Results: For the results, it is necessary to enter empirical data. If there are no numerical values, the results may be expressed in concise language. If there are data, specify the unit.

Data sources: Enter the data test organization or reference documents.

Attachment number: Enter the number of the attachment that provided the test report or reference documents for the said data.

Test: The data must be specified as being either test or estimated.

Confidentiality: It must be specified whether the data is confidential.

7.1 Acute toxicity: See SEPA chemical testing methods 401, 402, 403, 404, 405, 406, 420, and 423

7.2 Short-term recurrent toxicity: See SEPA chemical testing methods 407 and 410

7.3 Subchronic toxicity: See SEPA chemical testing methods 408, 409, and 411

7.4 Chronic toxicity: See SEPA chemical testing methods 452 and 453

7.5 Reproductive/developmental toxicity: See SEPA chemical testing methods 415, 416, and 421

7.6 Neurotoxicity: See SEPA chemical testing methods 418, 419, and 424

7.7 Mutagenicity: See SEPA chemical testing methods 471, 473, 474, 475, and 476

7.8 Teratogenicity: See SEPA chemical testing method **414**

7.9 Carcinogenicity: See SEPA chemical testing methods **451** and **453**

7.10 Toxic metabolic dynamics: See SEPA chemical testing method **417**

7.11 Other: If there are other items, enter their names and relevant information.

7.12 Overall toxicological assessment:

Make an overall *toxicological* assessment based on the provided data. From a toxicological perspective, assess the possible impact of the notified substance on human health. This may be provided as an attachment.

8. Ecotoxicology

Ecotoxicology items: There are a total of **12** items, and each line has information on one item. If there are no data, indicate with a "none." If there are data, it is necessary to provide test data reports or reference documents as an attachment. Add a ★ in front of data from tests performed in China with the use of test organisms that are provided by China.

Results: For the *results*, it is necessary to enter empirical data. If there are no numerical values, the results may be expressed in concise language. If there are data, specify the unit.

Data sources: Enter data test organizations or reference documents.

Attachment number: Enter the number of the attachment that provided the test report or reference documents for the said data.

Test: The data must be specified as being either test or estimated.

Confidentiality: It *must* be specified whether the data is confidential.

8.1 Algal growth inhibition toxicity: See SEPA chemical testing method 201

8.2 Flea acute toxicity: See SEPA chemical testing method 202

8.3 Fish acute toxicity: See SEPA chemical testing method 203

8.4 Bird toxicity: See SEPA chemical testing methods 205 and 206

8.5 Higher plant seed germination and growth toxicity: See SEPA chemical testing methods 208 and 299

8.6 Earthworm acute toxicity: See SEPA chemical testing method 207

8.7 Activated sludge respiration inhibition toxicity: See SEPA chemical testing method 209

8.8 Adsorption/desorption: See SEPA chemical testing method 106

8.9 Degradation: See SEPA chemical testing methods 301A, 301B, 301C,301D, and 301E

***8.10* Bioaccumulation:** See SEPA chemical testing methods 305 and 399

8.11 Other: If there are other items, enter their names and relevant information.

8.12 Overall ecological assessment:

Based on the obtainable data, assess the possible impact of the notified substance on the ecological environmental from an ecotoxicological perspective. This may be provided as an attachment.

Part 3. Environmental Protection and Environmental Safety Information About the Notified Substance

This part covers Items **9** and **10**. It covers environmental protection and environmental safety information such as the recommended safe usage of the notified substance, emergency measures, pollution prevention and abatement, and waste disposal in **14** items on **2** pages.

9. Recommended safe usage of the notified substance

The information in this part is mainly written descriptions, combined with explanations of related data. If there are references, please specify.

9.1 Operational attention matters and recommendations:

Enter attention matters and recommendations at time of operation. This may be provided in an attachment.

9.2 Storage attention matters and recommendations:

Enter attention matters and recommendations at storage time, including essential facilities, emergency equipment, and storage method at storage time. This may be provided as an attachment.

9.3 Transport attention matters and recommendations:

Enter attention matters and recommendations for the notified substance at transport time. This may be provided as an attachment.

9.4 Staff protection information and recommendations:

Enter specific staff protection equipment names, use methods, and

corresponding use recommendations. This may be provided as an attachment.

9.5 Packaging instructions:

Provide information such as packaging materials, minimum packaging, and packaging categories. This may be provided as an attachment.

9.6 Safety and Risk warnings:

Enter the internationally universal **R** [risk] and **S** [safety] phrases and other related safety warnings. This may be provided as an attachment.

10. Emergency measures

10.1 Measures for times of staff injuries:

Enter the treatment processes and methods for times when the notified substance triggers accidents that cause staff injuries. This may be provided as an attachment.

10.2 Measures for times of accidental leakage:

Enter the treatment processes, methods, and procedures for times of accidental leakage of the notified substance. This may be provided in an attachment.

10.3 Measures for times of fires and natural disasters:

Enter the treatment processes, methods, and procedures for the notified substance in times of fires and natural disasters. This may be provided as an attachment.

10.4 Other:

Enter other emergency measures, such as treatment information for times of reactions by banned agents. This may be provided in an attachment.

11. Pollution prevention and abatement methods

Enter feasible abatement methods and pollution prevention measures for times when the notified substance pollutes the environment. This may be provided in an attachment.

12. Waste disposal measures

Include possible means of harmless disposal and specific measures for harmless disposal of the notified substance and its packaging after use. When handling measure is burning or burying, the burning and burying standard shall illustrated. This may be provided in an attachment.

13. Material Safety Data Sheets (MSDS)

This refers to Material Safety Data Sheets **(MSDS)** for marketed goods containing the notified substance and/or this declaration substance. They must

be compiled in accordance with the requirements of **GB16483-2000** and they must be provided as an attachment.

14. Commodity label sample:

A label sample for a commodity that contains the notified substance and that is planned to be marketed in China, provided as an attachment.

Attachment **7**

Filing Guide For The New Chemical Substance Notification Exemption Application Form

The New Chemical Substance Notification Exemption Application Form applies to notification exemptions. The application form has **3** pages, and the specific filing instructions and requirements are as follows:

Page 1. Title Page

Name of the notification unit: Enter the full Chinese/English name of the notification unit.

Name of the notified substance: Enter the Chinese chemical name of the notified substance.

Time of the notification submission: After preparing all of the materials, it is necessary to provide the notification submission time, indicated in "year/month/day."

Page 2. Table of Contents Page

Acceptance number: The acceptance number is entered by CRC-SEPA. The notifier is requested to please not enter it.

1. Full name of the notification unit:

Enter only the Chinese organization name for a domestic unit, which name should be identical to the registered business name. For a foreign unit, it is permissible to use either English or the language of the native country.

2. Address of the notification unit:

A domestic unit must enter in Chinese; a foreign unit may enter in either English or the language of the native country. The address contents should include the country name, province name, city name, county name, street name, house number, and zip code.

3. Contact person

Name: Type in the name of the contact person here.

Postal address (with zip code): If the postal address of the contact person is for a domestic unit, it is necessary to enter it in Chinese; if it is for a foreign unit,

it is necessary to ensure that the receiving unit can mail relevant materials to the contact person at this address (It is recommended that it be entered in both the language of the native country and in English). The contents include: The country name, province name, city name, county name, street name, house number, and zip code.

Telephone: The telephone number of the contact person, including the national and regional area codes.

Fax: The fax number of the contact person, including the national and regional area codes.

Email: The email address of the contact person. Specify upper or lower case and backslash or forward slash.

Note: This contact person represents the notification unit, and is the designated individual for CRC-SEPA to contact the notification exemption unit.

4. Name of the notified substance (may be confidential)

English: Enter its English name as in the International Union of Pure and Applied Chemistry **(IUPAC)** or in the US Chemical Abstracts Service **(CAS)**.

Chinese: Enter its Chinese name in accordance with the *Organic Chemistry Nomenclature Principles* and the *Inorganic Chemistry Nomenclature Principles* that were recommended for use in China in **1980**.

5. US Chemical Abstracts Service (CAS) registry number (may be confidential):

The **CAS** number is the search service number for the chemical substance registry of the US Chemical Abstracts Service. If known, it must be entered.

6. Molecular formula (may be confidential):

The molecular formula should be entered in accordance with the requirements for molecular formula expression, and it should be the standard expression. For instance, it should use superscript and subscript.

7. Purity (%):

The purity at the time of the manufacture or import of the exemption notification substance.

8. Molecular weight:

The molecular weight of the notification exemption substance.

9. Structural formula (may be confidential):

For a substance with a unique and defined molecular structure, it is required to draw a complete and correct molecular structure diagram. For a substance

without a unique and defined molecular structure: (1) List the CAS numbers for all of the substances used to manufacture the said substance; (2) Describe the reaction process; (3) Describe the composition scope and composition type of the said substance; (4) If it can be reasonably defined, please provide the chemical structure diagram for its typical portion. For a polymer, separately list the structures and CAS numbers for all of its monomers, and give the polymer structure, which may be provided as an attachment.

10. Notified quantity:

The quantity of the substance in the notification exemption application, calculated in accordance with the pure substance quantity. The unit is kg/year.

11. Notification exemption grounds

"Other" refers to polymers that are subject to one of the following cases: (1) All of their monomers are already included in the *Regulations*; (2) Two or more of their monomers/reactants with the highest content in the polymer (by weight) already exist in one or more other polymers in the *Inventory*; (3) All of their blocks are already included in the block copolymerization in the *Inventory*; (4) Their precursors and branched chains are already included in the graft polymers in the *Inventory*; (5) They are polymers of low concern. Evidentiary materials that correspond to the selected items must be provided, and they may be provided as attachments.

12. Status under ambient temperature and pressure:

Select the status under ambient temperature and pressure.

13. Melting point (°C):

See the corresponding substance provided in the *Filing Guide for the New Chemical Substance Notification Form.*

14. N-octanol/water distribution system:

See the corresponding substance provided in the *Filing Guide for the New Chemical Substance Notification Form.*

15. Water solubility:

See the corresponding substance provided in the *Filing Guide for the New Chemical Substance Notification Form.*

16. Other physiochemical properties:

See the corresponding substance provided in the *Filing Guide for the New Chemical Substance Notification Form.*

17. Packaging instructions:

See the corresponding substance provided in the *Filing Guide for the New Chemical Substance Notification Form.*

18. Toxicity and degradation information:

Provide the toxicity information and degradation information for the notified substance, which may be provided as an attachment.

19. Environmental safety information:

Provide the environmental safety information for the notified substance, including recommended safe usage and pollution prevention and abatement measures, which may be provided as an attachment.

20. Acceptance number of last notification exemption:

If the applicant underwent notification exemption formalities for this chemical substance in the past, enter the acceptance number of the last notification exemption here.

Person in charge of the notification unit (signature):

The person in charge of the notification unit should provide both its handwritten and typewritten name. For a domestic unit, the person in charge of the notification unit generally refers to the legal representative of the notification unit.

Signature or seal of the notification unit:

A domestic notification unit in China must affix its official seal. A foreign unit may affix its official seal or the signature of the person in charge.

Notification date:

Enter the notification exemption date, indicated in year/month/day.

Attachment **8**

Evidentiary Document for exemption form Declaration of New Chemical Substance

1、Name of declared substance

(Note: name of declared substance must be identical to the substance exempted from declaration form indicating the certificate is corresponding to the declaration form)

2、**Declaration operation type**

☐Manufacture expected manufacture date expected manufacture place

☐import expected date expected import port (noted: imported for the first time) expected place

3、**Reason description for exemption form declaration**

(Note:

A . Description content for exempt from declaration 1 (for scientific research) shall be: Scientific research name them); research content ; the function and role of the substance in this research; quantity in this research; application field of the Research. The relative information about the research entity shall be filled out in item 6

B Reason description of declaration exempt from declaration 2 (in polymer new chemical substance monomer lower than 2%): name (in Chinese and in English) of new chemical substance in polymer, CAS number, content and monomer name in polymer (in Chinese and in English) CAS number and content and reflection principle of generating the polymer; if it is imported please fill out the relating information of domestic entity that employ the substance as per item 6

C Reason description of declaration exempt from declaration 3 (procedure research and development) shall include at least the following: the procedure research and development name (or theme); the procedure research; the function and role of the substance in this procedure and development; quantity of the substance in this procedure and development; available fields which the procedure may be applied to. Please fill out the relating information of the entity for this procedure and development in item 6.

D Reason description of declaration exempt from declaration 4 (sample test) includes expected test item and fill out relative information of test agency in item 6.

E Reason description of declaration exempt from declaration 5 (other) includes all monomers in polymer list in which monomers name, CAS number, content and weather it is included in the description of " Name list ."; in case that it is imported from abroad, please fill out the relating information of the entities which employ this substance in item 6.)

4. **Existing form of substance for declaration**

(Note: in case of imported substance, to show the status of substance as being imported such as with the form of solution, mixture and pure substance or multiple forms; in case of being manufactured, show the reservation and transportation status after production of declaration substance, such as with the form of solution, mixture and the form of adding stabilizer)

5. **Other name of declaration substance:**

(note: Other name of declaration substance may includes numbers titled by declaration entity , commodity name and general name)

6. **The information of the imports and exports trade counterpart**	Unit name(if trader from abroad registered, fill out the entity name after the first imported commodity into China; if domestic importer registered, fill out trader name abroad.		
	Unit Address (incl. post code)		
	Contact person	Tel (note: incl. Area No.)	E-mail: (note: if not, fax number available)

7. **Description for certificate**

This is to certify that above mentioned exemption from declaration document about new chemical substance is true and realiable without any infringing upon others' interests; we shall accept any legal duty arising herefrom.

We agree to manufacture or import from abroad within the sanctioned scope as per the requirement of new chemical substance exempting from declaration for environment management registration

Declaration unit (stamp or signature)

(Note: A unit that applies for exemption from declaration shall provide information as per form requirement with the form of printing and electrical document and application list of exemption from declaration to chemistry registration center).

Attachment **9**

New Chemical Substance Information Confidentiality Waiver*

Confidentiality Waiver:

This is to certify that my party waives the confidentiality of the confidential information listed below.

Name of party to confidentiality waiver (affix official seal or signature of person in charge)

Person in charge of party:

Date:

Contact Person： Telephone：

Fax： Email：

Mail Address & Zip Code：

New Chemical Substance Notification Acceptance Number：

Registration Certificate Number：

Confidentiality Waived Items

Number on Notification Form	Item Name

Acknowledgement (Reply from CRC)

CRC has recognized your party's confidentiality waiver for the above-described confidential items. From the date of issue of this acknowledgement, CRC will no longer assume the responsibility for the confidentiality of the information in the above described items.

Chemical Registration Center of SEPA

Year Month Day

* The stamped or signed original of this form must be submitted to CRC.

Attachment **10**

New Chemical Substance Notification Acceptance Notice

Name of Notifier:	
Mail address:	
Contact person：	Telephone：
Email：	Fax：

(Name of Notifier):

CAS Number of the New Chemical Substance Notified by Your Party: _____

Chinese Name：

_____

English Name：

_____

upon review by CRC, has been found to meet the requirements, and it is hereby accepted with

Acceptance Number：**xxxxxxxxxxxx**

and

Acceptance Date： **xxxxxxxxxxxx**.

(Stamp)

Year Month Day

Attachment **11**

New Chemical Substance Notification Rejection Notice

Name of Notifier:	
Mail address:	
Contact person：	Telephone：
Email：	Fax：

(Name of Notifier):

CAS Number of the New Chemical Substance Notified by Your Party: _____

Chinese Name：

_____

English Name：

_____

upon review by CRC, has been rejected for the reasons listed below:

□ The said chemical substance is not within the scope of a new chemical substance notification.
□ The notifier does not have notification qualifications.
□ The said manufacture or import does not require a new chemical substance notification.

If your party disagrees, you may submit a written defense to CRC within **60** days, asking for a review.

(Stamp)

Year Month Day

Attachment **12**

NEW Chemical Substance Notification Materials Supplementation/Correction Notice

Name of Notifier:	
Mail address:	
Contact person：	Telephone：
Email：	Fax：

(Name of Notifier):

CAS Number of the New Chemical Substance Notified by Your Party: _____

Chinese Name：

_____

English Name：

_____

upon review by CRC, is requested to supplement/correct the materials listed below:

□ XXXXX
□ XXXXX.

After CRC receives the above-described materials, the formal review process will be restarted.

(Stamp)
Year Month Day

Attachment **13**

New Chemical Substance Notification Supplementation/Correction Allowance Notice

Name of Notifier:	
Mail address:	
Contact person：	Telephone：
Email：	Fax：

(Name of Notifier):

CAS Number of the New Chemical Substance Notified by Your Party: _____

Chinese Name：

_____

English Name：

_____

is believed by the Expert Committee that the notification materials are insufficient to support a review decision, and you are hereby granted an allowance to supplement/correct the information listed below:

1. XXXXXX
2. XXXXXX.

Please deliver the supplemented/corrected materials to CRC once only within three months. If you cannot supplement/correct the above-described materials within 3 months, please firstly send a letter describing the time that you will require to supplement/correct the materials (it may not exceed 12 months).

(Stamp)

Year Month Day

Attachment **14**

New Chemical Substance Notification Materials Supplementation/Correction Statement*

Chemical Registration Center of SEPA:

This is in reference to the new chemical substance notification application (acceptance number: **XXXXXX)** that my party submitted on _____ year _____ month _____ day. Due to the reasons described below:

(The reasons for the materials supplementation/correction request)

We were required to supplement/correct the materials listed below:

Number on Notification Form	Contents of Original Form	Supplemented/Corrected Contents

* Please submit at least one signed hard copy and one electronic version of the said statement.

(Name of Notifier, same as on the notification form, signature)
(Name of person in charge, same as on the notification form)

Year Month Day

Attachment **15**

New Chemical Substance Notification Results Notice

Acceptance number：	Acceptance date：
Name of Notifier:	
Mail address:	
Contact person：	Telephone：
Email：	Fax：

(Name of Notifier):

CAS Number of the New Chemical Substance Notified by Your Party: _____

Chinese Name：

_____

English Name：

_____

upon decision through review by SEPA, is hereby rejected for the environmental management registration of a new chemical substance, for the following reasons:

1、XXXXX
2、XXXXX.

(Stamp)
Year Month Day

Attachment **16**

State Environmental Protection Administration

XinMianTong[2004] No.

Notice for Exemption from Declaration Procedure

Unit Name

As per the regulation in article 13 and 17 of Measure of New Chemical Substance Environment Management issued by State Environmental Protection Administration, the notice of verification for exemption from declaration procedure application, your unit is hereby informed as follows

Verification for Exemption from Declaration Procedure of New Chemical Substance

Acceptance No	Substance or CAS No.	Verification	Quantity	Usage verification(scope)

If you have any objection for this notice , an explain shall be presented with written form to chemistry registration of our office . Much attention will be paid to your statement.

Thank you

State Environmental Protection Administration

New Chemical Substance Registration Stamp

Dated

Attachment **17**

New Chemical Substance Notification Cancellation Statement

Chemical Registration Center of SEPA

My party declares to cancel the new chemical substance notification submitted on Year/Month/Day (with the registration certificate number: **XXXXXX) (**the notification acceptance number: **XXXXXX)**. Moreover, I agree to the following provisions of CRC on the cancellation of notification registrations.

1. When a notifier delivers a *New Chemical Substance Notification Cancellation Statement* to CRC before CRC issues the *Registration Certificate*, the cancellation takes effect immediately, and CRC will terminate the review process for the said notification.

2. When a notifier delivers a *New Chemical Substance Notification Cancellation Statement* to CRC after CRC issues the *Registration Certificate*, it shall return the *Registration Certificate* to CRC. The cancellation takes effect on the date that CRC receives the returned *Registration Certificate*.

3. On the date that the cancellation takes effect, the holder of the *Registration Certificate* no longer assumes the responsibilities that are provided in Chapter 4 of the *Regulations on the Environmental Management of New Chemical Substances* and in the *New Chemical Substance Notification Guidelines*, but the validity of the cancellation does not exempt it from its responsibilities before the cancellation takes effect.

4. When a cancellation takes effect, CRC is not responsible for saving the said notification materials. The said notification materials will be destroyed, unless the notifier declares that it wishes to have the said application materials and retrieves them on its own within **5** work days.

Name of Notifier (Stamp)
Person in charge of Notifier (signature)
Year Month Day

Attachment **18**

New Chemical Substance Notification Exemption Cancellation Statement

Chemical Registration Center of SEPA

My party declares to cancel the Application for Exemption from New Chemical Substance Notification that it submitted on Year/Month/Day (with notification acceptance number: **XXXXXX)**. Moreover, I agree to the following provisions of CRC on the cancellation of notifications.

1. When an applicant delivers a *Notification Exemption Cancellation Statement* to CRC before CRC issues the *New Chemical Substance Notification Exemption Results Notice*, the cancellation takes effect immediately, and CRC will terminate the review process for the said notification.

2. When an applicant delivers a *Notification Exemption Cancellation Statement* to CRC after CRC issues the *New Chemical Substance Notification Exemption Results Notice,* it should return the *New Chemical Substance Notification Exemption Results Notice* to CRC. The cancellation takes effect on the date that CRC receives the *New Chemical Substance Notification Exemption Results Notice* that was returned by the notifier.

3. On the date that the cancellation takes effect, the applicant or the holder of the *New Chemical Substance Notification Exemption Results Notice* no longer assumes the responsibilities that are provided in Chapter 4 of the *Regulations on the Environmental Management of New Chemical Substances* and in the *New Chemical Substance Notification Guidelines*, but the validity of the cancellation does not exempt it from its responsibilities before the cancellation takes effect.

4. When a cancellation takes effect, CRC is not responsible for saving the said application materials. The said application materials will be destroyed, unless the applicant declares that it wishes to have the said application materials and retrieves them on its own within **5** work days. Of which, this is special notification.

Name of Notifier (Stamp)

Person in charge of Notifier (signature)

Year Month Day

Attachment **19**

Certificate/Notice Holder Name Change Statement

Chemical Registration Center of SEPA

My party applied for and received on Year/Month/Day a *Registration Certificate* for the environmental management of new chemical substances/*New Chemical Substance Notification Exemption Results Notice* with the *Registration Certificate*/*New Chemical Substance Notification Exemption Results Notice* number: **XXXXXXXX.** Due to

(**XXXXXXX** reasons),

I hereby submit a name change for the holder of the *Registration Certificate*/*New Chemical Substance Notification Exemption Results Notice*. The specific instructions are as follows:

The original name of "**XXXXXXX**" of the notifier on the *Registration Certificate*/*New Chemical Substance Notification Exemption Results Notice* is changed to "**XXXXXXX**".

Name of Notifier (Stamp)
Person in charge of Notifier (signature)
Year Month Day

Attachment **20**

Certificate/Notice Holder Name Change Certificate

Notifier, XXXXXX, applied for and received on Year/Month/Day a *Registration Certificate* for the environmental management of new chemical substances/*New Chemical Substance Notification Exemption Results Notice* (number: **XXXXXXX)**. The name of the *Registration Certificate/New Chemical Substance Notification Exemption Results Notice* holder is hereby changed from the original of:

(original name)

to

(new name).

The original *Registration Certificate*/*New Chemical Substance Notification Exemption Results Notice* may continue to be used in conjunction with this *Certificate*.

This certificate takes effect on its date of signing and issue.

(Stamp)
Year Month Day

Attachment **21**

Certificate/Notice Holder Information Change Declaration

Chemical Registration Center of SEPA:

My party applied for and received on Year/Month/Day a *Registration Certificate* for the environmental management of new chemical substances/*New Chemical Substance Notification Exemption Results Notice* (number: **XXXXXXXX).** Due to

(**XXXXXXX** reasons),

I hereby submit a relevant information change for the holder of the *Registration Certificate*/*New Chemical Substance Notification Exemption Results Notice*. The specific instructions are as follows:

1. The original information of **"XXXXXXX"** on the *Registration Certificate*/*New Chemical Substance Notification Exemption Results Notice* is changed to **"XXXXXXX".**
2. (Analogized in accordance with the above described form)

Name of Notifier (Stamp)
Person in charge of Notifier (signature)
Year Month Day

Attachment **22**

Guidance to Fill in Filing Form for the New Chemical Substance Manufacture, Import, and Flow Status

The Filing Form for the New Chemical Substance Manufacture, Import, and Flow Status (abbreviated below as the "filing form") contains materials that the notifier is required to submit to the local environmental protection bureau for each actual operation after acquiring a registration certificate, so that the environmental protection bureau can control the whereabouts of the registered substance and understand the real environmental impact of the registered new chemical substance. The actual operations can be divided into three cases: the actual manufacture; the actual import; and the transfer of the registered substance to the user. The same filing form is used for all three cases.

In Case **1**, fill out, sign, and stamp Column **1** of the filing form, and enter other explanations in Column **4**. In Case **2**, fill out, sign, and stamp Column **2**, and enter other explanations in Column **4**. Case **3** can be divided into two subcategories: 1) Post-manufacture transfers; 2) Post-import transfers. Fill out, sign, and stamp Column **3**, and enter other explanations in Column **4**. The instructions for filling out each column on the form are given below:

Registration Certificate number: Enter here the registration certificate number on the new chemical substance registration certificate.

1. ***Actual Manufacture of Registered Substance***

1.1 *Name and address of manufacturer*: The manufacturing organization refers to the registration certificate holder, and the name and address must be identical to that of the notification party.

1.2 *Manufacturing capacity*: Enter the notification party's existing manufacturing capacity for the registered new chemical substance, indicated in tons/year.

1.3 *Manufacturing start date*: Enter the date of the actual start of manufacturing, indicated in year/month/day. Manufacturing includes trial manufacturing.

1.4. *Cumulative manufacturing quantity (tons)*: Enter the cumulative manufacturing quantity of the company from the time of start of manufacturing to the time of submission of this filing form, indicated in tons.

2. ***Actual Import of Registered Substance***

2.1 *Name and address of import organization*: The import organization

refers to the registration certificate holder, and the name and address must be identical to that of the notification party.

2.2 *Import volume*: Enter the actual import volume of the registered new chemical substance, indicated in tons.

2.3 *Date of Import*: Enter the date of the actual import (the customs clearance date) of the registered new chemical substance. The entry format is year/month/day.

2.4 *Port of import*: Enter the name of the customs port of entry.

3. *Transfer of Registered Substance to User*

Enter this substance in accordance with the format of the form. Enter one post-transfer user on each line.

Name of the receiving organization: Enter in Chinese the name of the organization that will receive and use the registered substance.

Person in charge: The person in charge of the receiving organization, who is also the contact person.

Contact method and address: Enter contact information such as telephone and cell phone numbers for the methods of contacting the person in charge. The contact address should include the province name, county name, street name, house number, and zip code.

Transfer quantity (tons): The single transfer quantity.

Transfer date: The date of the actual start of the transfer, indicated in year/month/day.

Operation type: Such as transport, storage, sale, use, reproduction, or discard.

4. *Other Circumstances That Need To Be Explained*: Enter other circumstances that need to be explained.

Person in charge of filing (signature): Provide both the signature and typewritten name of the person in charge.

O*fficial seal of party*: A domestic notification party must affix its official seal, but a foreign party may affix its official seal or the signature of the person in charge.

Filing date: The filing date should be within **5** days after the date of the actual operation.

Contact method for the person in charge of filing: Enter the method by which the person n charge of the filing can be contacted, such as telephone, mobile phone number, and email.

Attachment **23**

Filing Form for Chemical Substance Manufacture, Import, and Flow Status	Registration Certificate No.:
1. Actual Manufacture of Registered Substance	2. Actual Import of Registered Substance
1.1 Name and address of manufacturer	2.1 Name and address of import organization
1.2 Manufacturing capacity	2.2 Import volume
1.3 Manufacturing start date	2.3 Date of import
1.4 Cumulative manufacturing quantity (tons)	2.4 Port of import

3、Transfer of Registered Substance to User

Name of receiving organization	Person in charge	Contact method and address	Transfer quantity (tons)	Transfer date	Operation type

4、Other Circumstances That Need To Be Explained

Person in charge of filing (signature): (Official seal of party)

Filing date:

Contact method:

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