What are the most important changes in the Revised Guidance for New Chemical Substance Notification and Registration (2015 Draft)

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New Chemical Substance Notification and Registration | Revised Guidance

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The revision of the Guidance for New Chemical Substance Notification and Registration has been the major focus of most enterprises over the last two years. On June 25, 2015, MEP-SCC issued the "Registration Guidance of New Chemical Substance Notification (Draft)". We would like to share with enterprises about the hot topics arising from this revision. Enterprises are free to contact experts in MEP-SCC and propose their own opinions.

This revision is mainly concentrated in the following aspects: notification substance and scope of applicable territories; notifier and representative; notification type; notification procedure, notification materials, testing institutions, test organism and test methods; data requirements; special requirements; data waiving and risk assessment report and simplified notification, etc. The details that are closely linked to enterprises will be analyzed one by one in the following section.

1. Notification Substance and Scope of applicable territories

1. In the exempted substance category, fertilizer has been added to the finished products which have already been regulated by other laws and regulations.
2. In the exempted substance category, biological macromolecules of natural existing substances can be exempted, except for those which have been chemically modified. In addition, enzymes are separately listed as biological macromolecules besides protein, RNA and DNA.
3. For other special categories, an extra requirement for articles is added: not only the intentionally to be released substance in articles shall be notified, but also the new chemical substance in articles leading to environmental and/or human exposure shall

be notified as well, such as outside paint of articles, etc.

4. For scope of applicable territories, the enterprises in free trade zones shall also comply with the No.7 decree.

After five years' execution of Regulation No.7, detailed provisions have been made for the previously ambiguous points such as fertilizers and enzymes. Besides, update has also been made on whether the "Regulations" is applicable in free trade zones. Unfortunately, there is still no clear answer on the matter that whether the active substances in pesticide and medicine should be exempted from notification as they are already regulated by other laws and regulations.

2. Notifier and Representative

1. For domestic notifiers, the industrial and commercial registration with legal personality institution has been changed to the industrial and commercial registration institution.

2. Previously an overseas notifier can only entrust one domestic Representative as the holder, but now the overseas notifier shall act as the holder. In addition, if the overseas notifier is unable to or will not perform the responsibilities as a registration certificate holder, the Representative should be able to perform instead. The timeliness should be declared clear on the agreement.

3. At least 3 million RMB registered capital is removed for Representative qualification, meanwhile, higher requirements have been put forward including the company's quality assurance system and professional technical ability. Besides, it is worth noting that the representative still needs to be a domestic industrial and commercial registration institution with legal personality rather than the industrial and commercial registration institution.

4. It is made clear that a registration certificate holder can only hold one registration certificate for the same new chemical substance.

Industrial and commercial registration institutions can act as a domestic notifier, meaning that the domestic branch of some multinational companies (no independent legal person) can also act as the notifier, as well as effectively protecting their trade secrets.

Overseas notifiers being the holder can effectively reduce the subsequent problems caused by the change of Representatives. For overseas notifiers, their rights can be protected. However, the Representative will take on more responsibilities and obligations. The removal of the over 3 million RMB registered capital requirement means there may be a lot of shell companies arising. Therefore, enterprises are advised to seek for professional institutions with successful experiences to effectively reduce the risk.

The clarity that a registration certificate holder can only hold one registration certificate for the same new chemical substance can effectively prevent the trouble of government regulation to a certain extent caused by enterprises with more than one registration certificate at the same time.

3. Notification Type

1. Previous general notification needs to be performed in form of specific amount, while in the revised draft, it can be notified in form of either specific amount or tonnage level, but the fourth level can only be notified according to the specific amount.
2. For repeated notification, joint notification, serial notification or the joint serial notification, the level of notified amount is still determined through the accumulation of each notifier and each notified substance.

The registration certificate of notification is required for enterprises before the manufacture or import activities. As the exact amount is difficult to estimate before enterprises perform relevant activities, therefore, notifier is recommended to choose tonnage level notification. In the present revision process of the Guidance, enterprises can notifiy the new substance as the highest amount of the tonnage level.

4. Notification procedure

1. In the stage of completeness review, specific content of cases where notifications will not be accepted, accepted, and temporarily not accepted has been made clear.

2. In the stage of expert review, it has been made clear about the necessary content included in the expert assessment opinions of the evaluation committee.

3. In the stage of publicity, the public information will be announced on the website of MEP-SCC, and the public notice on the website of MEP.

This can standardize the conventional registration process and procedures of notification. However, the notifier whether has the chance to make direct communications with experts hasn't been mentioned. In addition, considerable improvements have been made on the feedback of expert opinions compared to previous review.

5. Notification materials

1. Notification form is completed via software, and submitted as electronic data. Previously, only general notification was not submitted through software.
2. Paper notification form can be signed by legal representative (or person in charge). Previously, it must be signed by legal representative or authorized person with the letter of authorization.
3. Chromo-scan is needed for the original copy with signature, such as the home page of notification form, Power of Attorney or authorization letter, test report, expert statement and verification materials under special circumstances, etc. Previously, chromo-scan was not necessary.
4. Paper notification form shall be retained by the notifier, while it must be submitted before.
5. The order of notification materials for general notification has been adjusted, where the material list is being put ahead.

The home page of notification form can be signed by the person in charge, which increases feasibility. It is worth noting that the home page needs to be chromo-scanned. Moreover, the submission of paper notification form is not necessary any more, which reduces the cost and improves the efficiency of notification.

6. Testing institutions, test organism and test methods

1. Domestic testing institutions announced by the Department of Agriculture (comply with the GLP requirements) can also provide corresponding toxicology test reports.
2. All laboratories can only provide test projects or data within their qualification validity period.
3. If the original test guideline has been updated for over 5 years, re-test is needed following the updated test methods. The original test report is submitted as support information for expert review.
4. As for the China test organism, previously *Gobiocypris rarus, Xiphophorus helleri, Brachydanio rerio*, and activated sludge are all allowed to use. In order to better protect the environment in China, and understand the potential impact of new materials on the environment, only *Gobiocypris rarus* and domestic activated sludge are allowed to be used as test organism in the revised draft of the Guidance.

All laboratories must complete their tests within the qualification validity period, meaning any experiment completed outside the qualification validity period will be invalid. This should raise concern of enterprises to pay attention to the qualification validity period of laboratories when making a choice. If the original test guideline has been updated for over 5 years, latest guideline should be adopted fortest report, while the latest test method currently applies the "The guidelines for the Testing of Chemicals", published in 2013 by the Ministry of Environmental Protection. This means that many experiments carried out at home and abroad may not be able to meet the requirements as their guidelines have been updated for over 5 years. Therefore, before enterprises entrust laboratories to carry out experiment, it is very important to confirm whether their test guidelines have been updated. In addition, when conducting fish acute toxicity test in China, *Gobiocypris rarus* should be chosed as the only test organism.

7. Data requirement

Data requirement is the most concern during this time, which has been revised the most frequency. Problems raised in the previous notification processes have all been reflected in this revision.

Physico-chemical data

1. For physico-chemical data, the flash point of liquid substances shall be conducted by closed-cup method.

2. For organic substances, at least two graphs within the infrared, nuclear magnetic resonance (NMR) and mass spectrometry shall be provided; optical information of chiral substances shall be provided as far as possible. Information on test conditions shall be included when submitting spectrum.

Toxicology data

1. Acute toxicity: at level 1, test data of acute oral toxicity, skin irritation, eye irritation, skin sensitization should be submitted. Besides, the corresponding test data of acute dermal toxicity and acute inhalation toxicity shall be provided according to physic-chemical properties and main exposure pathways.(In the original guidance, all data shall be submitted, while here provides the possibility for the exemption of acute dermal and inhalation toxicity)
2. Mutagenicity: at level 1, two in vitro experiments should be conducted. If any result is positive, and the substance is widely dispersive used, then high level mutagenicity experiment shall be submitted. From level 2, phased experiments on mutagenicity may be conducted. In vitro genetic mutation test data or several in vivo mutagenicity test data shall be submitted based on the results of two in-vitro experiments. In vivo gene mutation test data refers to Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells in vivo and Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays, etc. In vivo chromosome aberration test data refers to Mammalian Erythrocyte Micronucleus Test and Mammalian Bone Marrow Chromosomal Aberration Test, etc.

Notification class	**Bacterialreverse mutation OECD471**	**In vitro chromosome aberration / in vitro micronucleus OECD473/OECD487**	**In vitro gene mutationOECD476**	**In vivo chromosome aberration / in vivo micronucleus OECD475/OECD474**	**In vivogene mutation OECD486/OEC**
Level 1	√negative	√negative			
Level 1(no widespread exposure)	√negative	√positive			
Level 1(no widespread exposure)	√positive	√negative			
Level 1(widespread exposure)	√negative	√positive			
Level 1(widespread exposure)	√positive	√negative			

Notification class	**Bacterialreverse mutation OECD471**	**In vitro chromosome aberration / in vitro micronucleus OECD473/OECD487**	**In vitro gene mutation OECD476**	**In vivo chromosome aberration / in vivo micronucleus OECD475/OECD474**	**In vivogene mutation OECD486/OECD488**	**No**
level 2 and above	√negative	√negative	√negative			The hig par cor acc the cor tes
level 2 and above	√negative	√negative	√positive		√	
level 2 and above	√negative	√positive	√negative	√		
level 2 and above	√negative	√positive	√positive	√	√	
level 2 and above	√positive	√negative			√	
level 2 and above	√positive	√positive		√	√	

"√"refers to project that needs to be conducted.

1. The requirement of 90d repeated dose toxicity test has changed: at level 2, 90d repeated dose toxicity data shall be provided under these circumstances: other available data indicate that the substance may have a dangerous property that cannot be detected in a short- term toxicity study, or appropriately designed toxicokinetic studies reveal accumulation of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short-term toxicity study but which are liable to result in adverse effects after prolonged exposure.

2. Toxicokinetics: at level 2, relevant information on toxicokinetics is required(not only absorption information). From level 3, if there is no health hazard classification (i.e. non-toxic)of the substance, then relevant information on toxicokinetics is enough. From level 3, if there is health hazard classification (i.e. toxic) of the substance, the complete toxicokinetics test report shall be submitted.

3. Information on when carcinogenicity experiment is needed: the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure, and the substance is classified as germ cell mutagen category 2 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-neoplastic lesions. , carcinogenicity test data shall be submitted. Carcinogenicity evaluation report can also be submitted if the substance doesn't fit the conditions mentioned above. However, if the evaluation result determines further carcinogenicity, experiment is still needed, carcinogenicity test data shall also be submitted. The definition of widespread dispersive use was also given.

In Ecological toxicology, changes are mainly concentrated in the toxicity testing on fish and earthworm breeding experiment:

4. The prolonged 14 days toxicity testing on fish has been deleted during level 2 notifications.

5. For level 4 notification, Enchytraeid reproduction test or Earthworm reproduction test is needed when the acute terrestrialtoxicity test result shows hazard classification.

The most obvious changes are the acute dermal and inhalation toxicity, the 28d and 90d repeated dose toxicity, mutagenicity test, toxicokinetics and carcinogenicity, as well as the prolonged 14 days toxicitytestingon fish. For the acute dermal and inhalation toxicity, different exposure routes shall be considered when choosing corresponding tests. Both of them are not always required .In the level 2 notification, special attention should be paid for whether the 90d repeated test is still necessary when the 28d repeated test report is available, which may be contrary to the previous Guidance. Formutagenicity, the new Guidance gives full consideration of in-vitro experiments being as reliable screening results in the classification process, which fits the demand of manufacturers. For toxicokinetics, explicit provision has been made on when the test is necessary considering the difficulties of experiments. For carcinogenicity, it has stated when the test is necessary, and that carcinogenicity assessment is acceptable when the test is not mandatory, which is quite similar to the requirements of REACH regulation. The prolonged 14 days toxicity testing on fish has been removed because it can't provide adequate chronic data. It reduces the data requirement at level 2. In addition, currently popular international in-vitro test method hasn't been mentioned in this revision.

8. Special requirements

1. Pyrophoric chemicals: data requirements added, not only testing data of density shall be submitted, toxicology and ecological toxicology data derived from estimation, read-across or literature are also necessary.
2. Ecotoxicological tests required to be conducted in China: for substances need considering soil environmental risk, terrestrial toxicity data are recommended but not mandatory. (Previously for indissolvable compounds, if the aquatic toxicity test has already been completed overseas, terrestrial toxicity data can be submitted.)

Pyrophoric new chemicals normally have little impact on enterprises as they are rarely encountered. Ecotoxicological experiments mandatory in China are mainlyaquatic toxicity and biodegradability data, while terrestrial toxicity data is no longer mandatory, which offers more options for enterprises.

9. Data waiving

Physical data

1. Auto-ignition temperature: interpretation of non-flammable liquids in air has been added, i.e. "such as when substances do not belong to flammable liquids or the flash point of liquids is greater than 200°C."
2. Oxidising properties: interpretation of the substance is incapable of reacting exothermically with combustible materials has been added, for example on the basis of the chemical structure (e.g. organic substances not containing oxygen or halogen atoms and these elements are not chemically bonded to nitrogen or oxygen, or inorganic substances not containing oxygen or halogen atoms).

Toxicological data

1. Acute dermal toxicity: the "skin corrosion" has been added as awaiving condition.
2. Eye irritation: it has been made clear that skin irritation toxicity category 2 (including above) is the medium level (or above)for skin irritation.
3. Acute inhalation toxicity: the waiving condition has been adjusted, namely "vapor pressure < 10^{-1} pa at 20 °C (previously, it was 10^{-2} pa)".
4. 28d repeated dose dermal toxicity: the "skincorrosion" has been added as awaiving condition.
5. 28d repeated dose inhalation toxicity: the waiving conditionhas been adjusted, namely "vapor pressure < 10^{-1} pa at 20 °C (previously, it was 10^{-2} pa)".
6. 90d repeated dose toxicity: new waiving conditions have been added, i.e. (1) " toxic effect has been observed in 28d repeated dose test using the same test animal and exposure route, or the no-observed-effect-level (NOEL) is very low"; (2) "Carcinogenicity category 1 or 2".

7. Carcinogenicity: waiving conditions have been adjusted, i.e." the substance is classified as Germ Cell Mutagenicity Category 1A or 1B", or "combined test of chronic toxicity and carcinogenicity is available" can be exempted, while the condition "when substances with reproductive toxicity can be exempted" has been deleted.

8. Chronic toxicity: the waiving condition has been adjusted, i.e. "combined test of chronic toxicity and carcinogenicity is available". While previous exemption conditions are: (1) the no-observed-effect-level(NOEL) of repeated dose toxicity is high; (2) no specific target organ toxicity (repeated exposure) classification.

Ecotoxicological data

1. Aquatic toxicity: the interpretation of waiving conditions have been added, i.e. "biological membrane permeability test report shall be provided, and if not available, the reason should be stated, and meanwhile description or summary of predictive test reports or literature data should be provided".

2. Terrestrial toxicity: the interpretation of waiving condition has been added: "substances with very low soil adsorption means logKoc< 1.5".

3. Adsorption/desorption: the interpretation of waiving condition has been added: "half-life < 12 h in hydrolysis"

Changes in data waiving are mainly concentrated in the 90d repeated dose toxicity, carcinogenicity and chronic toxicity. In the previous Guidance, 90d repeated dose toxicity data shall be provided when 28d repeated dose test results show severe irreversible damage or no-observed-effect-level(NOEL) is low. While in the revised Guidance, 90d repeated dose toxicity test can be exempted in those circumstances, which is contrary to the previous Guidance. That means, in the revised Guidance, for the level 2, level 3 and level 4 notifications, 90d repeated dose toxicity test can be waived when 28d repeated dose toxicity test shows toxic effect or NOEL is low. For level 2 notification, 90d repeated dose toxicity test is required if the result of 28d repeated dose toxicity test shows potential hazard considering exposure.

The main change in carcinogenicity lies in that substances with reproductive toxicity shall also provide carcinogenicity data other than exemption. Extra data requirements have been added in chronic toxicity as most waiving conditions have been removed, meaning that for level 4 notification, separated or combined tests with carcinogenicity should be carried out. Moreover, some previously ambiguous items have been clarified, such as the explanation of low soil adsorption, the explanation of"unable to pass through biological membrane", etc.

10. Risk assessment

1. Higher requirement has been put forward for compiling organizations, which should including professional technicians. Relevant information of compiling personnel should be included at the head page of risk assessment report, including professional background, work experience and relevant training experience, etc.

2. The identification of persistent, bioaccumulative and toxic(PBT) or very persistent and very bioaccumulative (vPvB) substances has been added.

3. Classification criteria have been changed from GB 2006 to the latest GB 30000.

4. Identification and physic-chemical data of serialnotification substances are not shared. Relevant information of each substance should be provided respectively, that means, one set of physic-chemical data for each substance shall be provided.

5. In the description of uses, the code table of uses for chemicals has been introduced in the Annex. Enterprises can easily choose relevant code based on the usage information of substances.

6. Template of risk assessment report is given in the Annex, which provides as far information as possible on data, classification, exposure and risk according to the requirements of risk assessment. It also provides information on the production, discharge and flow of the "three wastes" to facilitate the evaluationof risk assessment report by the review committee.

The risk assessment report puts forward higher requirements for compiling organizations, focusing more on the professional technical ability and background, which is conducive to the better quality of the risk assessment report. The improvement of template allows the evaluation experts to review the report in a more optimized way.

11. Simplified notification

1. Polymers do not meet the requirements of simplified notification such as degradable or unstable polymers and water absorbent polymers, have been proposed and the corresponding conditions are given. For example, (1) degradable or unstable polymers refer to polymers that are easily degraded, decomposed and depolymerized. Polymers that decomposes after production or use cannot apply for simplified notification as well; (2) water absorbent polymers refer to polymers whose number-average molecular weight is greater than or equal to 10000.
2. There is restriction on the amount of polymers when applying for simplified notification.

A lot of polymers were notified in simplified notification. It's clear that some particular polymers cannot apply for simplified notification. This avoids extra risk arising from the use of some special polymers. For risk-free polymers, there is no restriction on the notification amount, which is good for enterprises.

12. Supervision and management after registration

1. Change of uses: For regular hazardous substances except the priority environmental management hazardous substances, the registration certificate holders have to recompile the risk assessment report and submit updating materials to MEP-SCC if the uses of substances have changed. In addition, for non-hazardous substances and substance notified in simplified notification, the change application is not required.
2. Change of activity type: It is clearly stated that for regular notification, the risk assessment report needs to be recompiled and relevant materials shall be submitted to MEP-SCC if the type of activity has been changed from import to production. While for those enterprises that change activity from production to import, only modification filing is needed. For simplified notification, the change of activity type can be noted in the annual report, and the change application is not required. This reduces the burden of enterprises.
3. Name change of registration certificate holder/representative and the change of registration representative: Previous representatives are registration certificate holders in the previous Guidance, it's clear that change application is required only if the name of registration certificate holder changes. In the newly revised Guidance, it is made clear that change application is necessary for the change of either the name of registration certificate holder or representative. In addition, the procedure of changing representatives is also clearly stated.
4. The change of amount within the same registration tonnage level: For level 2 to 4 notification, if the amount within the same registration tonnage level changes, risk assessment report needs to be recompiled. And the change application shall be submitted. While for regular level 1 notification or simplified notification, only change application needs to be submitted, the same as before.

For all the changes mentioned above, the change of registration certificate is not necessary. That means the original registration certificate combined with the receipt issued by MEP or MEP-SCC is valid for enterprise new activities.

13. Information delivery, reporting and data keeping

1. The templates of report on each activity of new chemical substances (Annex 3), new chemical substance annual report (Annex 4), and 5 years' activity report of registered new chemical substance (Annex 5) are given.
2. Report of each activity: the report of each activity is needed every time the registration certificate holder of priority environmental management hazardous new chemical substances transfers more than 10 kg of the substance to different processers and users.

It is made clear about the amount of report of each activity for priority environmental management hazardous substances, and new templates related to those activities are also given, which facilitates enterprise to comply with the obligations after registration.

In conclusion, there have been many changes in the revised version of New Chemical Substance Notification Guidance (Draft). Changes with the most impact on enterprises lie in the data requirements and risk assessment report. For those relatively clear aspects currently, enterprises can prepare for them in advance with corresponding measures. For those ongoing projects, there is no rush for enterprises as the Guidance is still seeking for advice, and there is still time before the final version is published.

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