



20 June 2017

(17-3283)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| 1. Notifying Member: <u>REPUBLIC OF KOREA</u> If applicable, name of local government involved (Article 3.2 and 7.2): |
| 2. Agency responsible: Ministry of Environment Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: Chemicals Policy Division, Ministry of Environment, Building #6, 11, Doum 6-ro, Sejong, 330103, Republic of Korea Tel: 82-44-201-6783 Fax: 82-44-201-6786 E-mail: minaseo@korea.kr Website: www.me.go.kr |
| 3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other: |
| 4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Non-phase-in substance, existing substance subject to registration, substance subject to authorization, restricted and banned substance |
| 5. Title, number of pages and language(s) of the notified document: <ul style="list-style-type: none">Revised version of the Enforcement Rules of the Act on Registration and Evaluation, etc. of Chemical Substances (22 pages, in Korean)Revised version of the Enforcement Decree of the Act on Registration and Evaluation, etc. of Chemical Substances (15 pages, in Korean) |
| 6. Description of content: <u>Enforcement Rules of the Act on Registration and Evaluation, etc. of Chemical Substances</u> <ol style="list-style-type: none">Extended notice period for registration and registration update (Article 6(1)2, Article 9(3)2 as amended) Currently, the number of registered new substances in small volume (less than one ton) amounts to around 10 per day and 2,000 substances per year. However, the regulatory authorities only have three days to screen each application for updating registration information, which results in technical difficulties and concerns over insufficient review. Under the draft amendment, the regulatory authorities extend the notice period for registration and registration update up to 10 days (maximum 20 days) so as to ensure enough review time and prudent information management.Abrogated provision on submission of written contract with testing institute when submitting a test plan (Article 14(2)2 is removed) |

Submitted test plan includes specific test methods, timeline and the date when relevant test data will be submitted. Therefore, the draft amendment does not ask a written contract that is concluded with testing institute when submitting a test plan.

3. Enhanced process for test plan review and for informing the result (Article 15(1) & Article 15(3) as amended)

1) NIER should review test plans within the notice period of registration.

2) When the head of NIER decides that a test plan has nothing to modify or complement in accordance with Article 15(2), potential registrants submit testing data as prescribed in the test plan.

4. Joint submission of registration dossier, including risk data (Article 16(2) as amended)

Even though not all members of consultative group reach an agreement, some members who agree is allowed to submit risk data or safe-use guidance document in a joint manner.

5. Enhanced method and procedure for joint submission of registration dossier (Article 17(1) as amended, Article 17(3) as new)

When lead registrant is not appointed or when members of consultative group are hard to reach an agreement for joint submission of existing substance, joint submission of registration dossier is delayed. In this case, the Minister of Environment may recommend an appropriate representative or arrangement for the registration.

6. Improved procedure of hazard review (Article 23(1) as amended)

Of those substances registered, the regulatory authorities perform screening on their hazard and risk by using the registered information such as intended use, classification and labeling, quantity to be manufactured or imported.

Then, the regulatory authorities may carry out hazard review and take necessary measures on the substances according to the priority of them when they are suspected to have higher hazard or risk.

7. Expanded scope of those who should follow an order of withdrawal, etc. & Deadline for submitting written plan and result of the order (Article 48 as amended)

The draft amendment expands the scope of those should follow an order of products withdrawal from the market: from producer and importer to business entity who manufactures the products by means of original equipment manufacturing or original development manufacturing, main contractor or subcontractor, and seller. In this case, the scope of seller is limited to superstore (e.g. department store, large retailer and so forth) in accordance with Article 2(3) of the Distribution Industry Development Act. This is to enhance consumer convenience and make sure that withdrawal measure is implemented in a swift manner.

8. Updated instruction for preparing application of registration exemption confirmation (Appendix 5 as revised)

1) For chemical substance used for R&D, business entity should submit a result of follow-up measure within three months after the R&D period ends, if there is remaining quantity of the substance or R&D achievement.

2) When changing a period taken for R&D, intended quantity manufactured or imported, or researcher or developer, the business entity should request to update the change to the Korea Environment Corporation with evidence documents.

Enforcement Decree of the Act on Registration and Evaluation, etc. of Chemical Substances

1. Expanded scope of chemical substances subject to registration exemption (Article 11(2)2 as amended)

Currently, polymer that has number average molecular weight of less than 10,000 should be registered if it contains more than 2% of monomer that is a new substance. Under this draft amendment, polymer can receive confirmation of registration exemption if the polymer contains new substance that its information such as hazard data was already registered as manufactured or imported over one ton per year and

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| <p>went through hazard review, except the cases when the new substance has risk concerns (e.g. designation as hazardous substance).</p> <p>2. Expanded waiving of data requirements when submitting substance registration dossier (Article 13(6)2 as new)</p> <p>When hazard of chemical substance are known by referring to hazard data that foreign governments or international organizations already made available to the public, the draft amendment allows waiving of the relevant data requirements in registration dossier.</p> <p>3. Expanded scope of individual data submission when submitting registration dossier of existing substances subject to registration (Article 14(3) as new)</p> <p>The draft amendment states that individual submission is allowed in certain cases where the Minister of Environment specifies and announces. For example, when potential registrant who wants individual submission agrees to share its individually-submitted data with others for free, the potential registrant is allowed for individual submission.</p> <p>4. Designation & Public Notice of substance subject to authorization, restricted or banned substance (Article 19(3) and Article 20(4) as new)</p> <p>Of those substances that foreign government or international organization already regulates or decides to regulate, substances having higher risk concerns and sufficient data may be designated as substance subject to authorization, restricted or banned substance without socioeconomic analysis or risk assessment in accordance with the draft amendment.</p> <p>5. Additional and updated works that the Minister of Environment assigns or entrusts to the head of the National Institute of Environmental Research, the heads of local environment offices, the Korea Environment Corporation and the Korea Chemicals Management Association (Article 31(1)7(2), Article 31(4)1(2), and Article 31(4)2(2) as new, etc.)</p> <p>1) Head of the National Institute of Environmental Research carries out works related to designation and Public Notice of toxic substances.</p> <p>2) Heads of local environment offices receive applications for registration exemption confirmation and, if necessary, perform an inspection on relevant place of business.</p> <p>3) The Korea Environment Corporation conducts works related to receiving notifications for informing OR appointment or dismissal, and receiving requests on data protection, which was entrusted to the Korea Chemicals Management Association before.</p> |
| <p>7. Objective and rationale, including the nature of urgent problems where applicable: To encourage registration of chemical substances and protect public health from any harms caused by chemical substances of risk concerns.</p> |
| <p>8. Relevant documents:</p> <ul style="list-style-type: none"> • MoE Public Notice No. 2017-467 • MoE Public Notice No. 2017-466 |
| <p>9. Proposed date of adoption: 30 September 2017 Proposed date of entry into force: 30 September 2017</p> |
| <p>10. Final date for comments: 60 days from notification</p> |

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:

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