

[English Translation]

Guidance on Joint Submission Procedure

**In accordance with Article 15 of “Act on Registration, Evaluation, etc. of Chemical Substances”
Registration Application Submission method for Existing Chemical substances subject to Registration**

August 2015

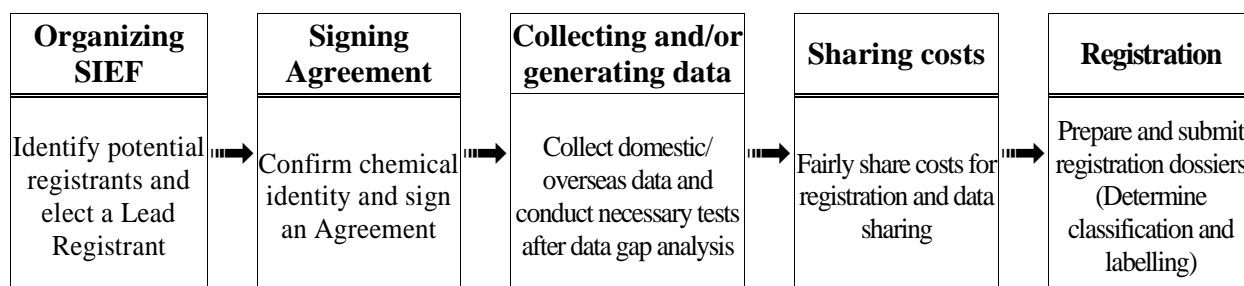
Task Force on Support for Industry in
Complying with Chemical safety Rules

Domestic enterprises who deal with any of 510 “Existing Chemical Substances Subject to Registration” designated under *Act on Registration, Evaluation, etc. of Chemical Substances* shall jointly submit dossier within the grace period after identifying other importers or manufacturers of the same chemical substance through “*Joint Registration Information System*” and received “Notice of Registration” from the authority.

I. Outline

- Those who intend to manufacture/import any of 510 “Existing Chemical Substances Subject to Registration” at the annual volume of ≥ 1 ton, shall elect a Lead Registrant among members of SIEF for the same substance and jointly submit certain part of dossier for the registration within the grace period.
- Jointly submitted dossier: Classification and labelling, physico-chemical properties, hazard data, test plan
- ※ Risk information and safe use guidelines may be submitted for joint submission upon agreement among members.

II. Procedure



<Notes> Timetable for Joint Registration (recommended)

Identify potential registrants	Elect a Lead Registrant	Sign an Agreement	Prepare documents to be jointly submitted	Submit registration dossier
	Sep.31, 2015	Dec.31, 2015	Jun.30, 2016	Dec.31, 2017
Joint SIEF	Confirm chemical identity	Check availability of hazard data, generate / purchase necessary data and prepare risk information		Submit dossier and receive “Notice of Registration” from authority
				Jun.30, 2018

III. Details on Steps for Preparing Joint Submission

Step I: Identification of Chemical Substances

- Check if any chemical substance to be manufactured/imported are included in “the List of Existing Chemical Substances Subject to Registration.” Visit at NCIS (<http://ncis.nier.go.kr/ncis/Index>) website or refer to the Public Notice on “Existing Chemical Substances Subject to Registration.”
 - ※ Enter identification no. (e.g. CAS No.) or chemical name.
 - ※ As for imported mixtures, enter each chemical substance contained as a component in the mixture.
- If any chemical substance is confirmed as one of “Existing Chemical Substances Subject to Registration,” check if the annual volume of manufacture/or import is 1 ton or more.
 - ※ For volume calculation method for imported mixture, refer to “Guidance on Registration of Chemical Substances Subject to Registration.”
- Check if the exemption conditions stated in Article 11 of the Act and Article 11 of Ministerial Decree of the Act are met. If any chemical substance is eligible for exemption, it is exempted from the registration requirement.
 - ※ Refer to details on exemption including the examples described in “Guidance on Registration of Chemical Substances Subject to Registration”.
 - ※ Check if the exemption needs confirmation procedure.

Step II : Organizing SIEF

- In accordance with Article 15 of the Act, the registrants for the joint submission shall appoint a Lead Registrant based on an Agreement among members in principle and proceed with related works. However, mutual confirmation and collaboration are essential among members. To this end, certain organization (SIEF) based on an Agreement shall be established and managed for smooth operation process.
 - ※ Registration obligation falls upon those who intend to register the same substance within the grace period. Therefore, members of SIEF shall be aware of that joint submission is mandatory regardless of SIEF attendance.
 - ※ SIEF shall be constantly and regularly managed so that members can respond to a potential request for the submission of additional data from the authority after the registration application.
 - ※ Prior to placing company information in the system in case of importation of “Existing Chemical Substances Subject to Registration,” whether the registration will be conducted by importer or by Only Representative appointed by the foreign manufacturer/or formulator pursuant to Article 38 of the Act shall be decided.
- Other manufacturers or importers of the same chemical substance can be identified at Joint Registration Information System located in Chemical Substance Information Processing System. For system accessing method, refer to the attached “Method and Procedure for Accessing Joint Registration Information System”.

- ※ Under Joint Registration Information System, enterprise names of the joint submission members can be identified and a Lead Registrant can be elected.
- ※ Joint Registration Support System loaded on Industry Support Center established Act on Registration, Evaluation, etc. of Chemical Substances and Chemicals Control Act supporting features such as “Announcement,” “Information,” “Online Chatting” and “E-mails” to boost communication between members.

Step III : Electing a Lead Registrant

- A Lead Registrant shall be appointed through an Agreement among members as part of the registration documents and dossier shall be jointly submitted by a Lead Registrant pursuant to Article 15 of the Act.
 - ※ Lead registrant is in charge of operation of SIEF established for the autonomous decision-making and proceeding with tasks prescribed in Article 17 of Ministerial Decree of the Act such as selecting and generating jointly submitted data (dossier), managing the operating costs for joint submission and preparing and submitting documents for joint registration application.
 - ※ Process to identify final joint submitters shall be conducted at this step by confirming whether the chemical substance for the registration is identical. For more details, refer to “Guidance on Identification of Chemical Substances.”
- If there is a candidate who wishes to be a Lead Registrant, an agreement from other members is required. If there are two or more candidates, a Lead Registrant will be appointed by a vote by members. However, if no member wishes to be a Lead Registrant, it will be determined by considering factors such as manufacture/import volume or possession of test data.

Step IV : Signing Agreement

- The Agreement is a contract between members who joined SIEF for joint submission and the terms and conditions shall be agreed upon by all members if possible.
 - ※ For a sample Agreement for joint submission, refer to “Guidance on Sharing Registration Data and Costs.” The sample Agreement addresses general standard details on appointment and replacement of Lead Registrant, selection of key data, generation of data, data ownership, cost sharing, time schedule of data submission, confidentiality, etc., which are subject to modification and addition according to the SIEF’s characteristics.

Step V : Preparing Jointly Submitted Information

- Submitted data: According to Article 16 of Ministerial Decree of the Act, jointly submitted data include the matters on classification and labelling, physico-chemical properties, hazard data and test plan. Risk information and safe use guidelines can be also jointly submitted upon agreement among members.
- Data collection: Registrants shall collect all available data on physico-chemical properties and hazards of the chemical substances to be registered. Such data include the ones owned by registrants and secured through open sources such as literature.
 - ※ It is recommended that data of all test items be collected regardless of handled volume.

- Data review: A Lead Registrant shall review the data collected from registrants to confirm their suitability for all test items required for the registration.
 - ※ Such review will be conducted by a Lead Registrant, another appointed members, or outside expert(s) contracted for such work.
- Data purchase and generation:, If certain data/information are not available among the data/information required for the registration, a Lead Registrant shall determine to obtain them by purchasing or generating them through an agreement with other registrants.
- Cost sharing: All costs incurred by securing and purchasing required test data/information shall be shared by the registrants based on fair and clear grounds. In case members fail to reach an agreement, it is recommended that costs be shared based on the number of submitters, volume of manufacture/or import, etc. In this case, such details shall be included in the agreement.
 - ※ Data costs include ① Administrative costs reasonably incurred by SIEF management or outside consultation, ② Costs incurred by purchasing access right or ownership for existing test data/information owned by other person(s) of outside SIEF, ③ Costs incurred by joint data generation, ④ Costs reasonably incurred by preparing and submitting registration documents.
 - ※ Refer to examples of cost sharing described in “Guidance on Sharing Registration Data and Costs.”

Stage VI : Submitting Registration Dossier

- A Lead Registrant shall submit the registration dossier at Chemical Substance Information Processing System (<https://kreach.me.go.kr/opeweb/main.do>) before other registrants who intend to register the same Existing Chemical substance subject to registration.
- Other joint registrants shall individually submit other information such as name and address of manufacturer/importer than the jointly submitted data/information submitted by a Lead Registrant.

[Attachment] Methods and Procedures for Accessing Joint Registration Information System

□ How to access

- Joint Registration Information System is accessible by logging into Chemical Substance Information Processing System. (<https://kreach.me.go.kr/opeweb/main.do>)



□ How to join

- Browse chemical substances manufactured/or imported at Joint Registration Information System.

공통등록정보제공시스템 | 협의체 | 참여 협의체 | 회원가입 | 회원가입 | 회원가입

등록대상기존화학물질의 등록신청 자료 공동제출을 위한 동일 물질 사용자 상호 확인 및 협의체 대표자의 선출

협의체 가입안내
바로가기 >

시스템 소개
바로가기 >

협의체

CAS번호 [] 검색

· 총계시료 10건

번호	CAS번호	물질명	업체수	참여여부
1	50-00-0	Formaldehyde : Formalin	0	신청하기
2	50-00-8	Peracetic Acid : Peroxyacetic Acid	0	신청하기

참여 협의체 더보기 >

· 참여한 협의체가 없습니다.

< Main Page of Joint Registration Information System >

1. Previous Information Submitters

“Previous Information Submitters” mean Submitters included in the list of the comprehensive survey for 518 potential “Existing Chemical Substances Subject to Registration” conducted in April, 2015

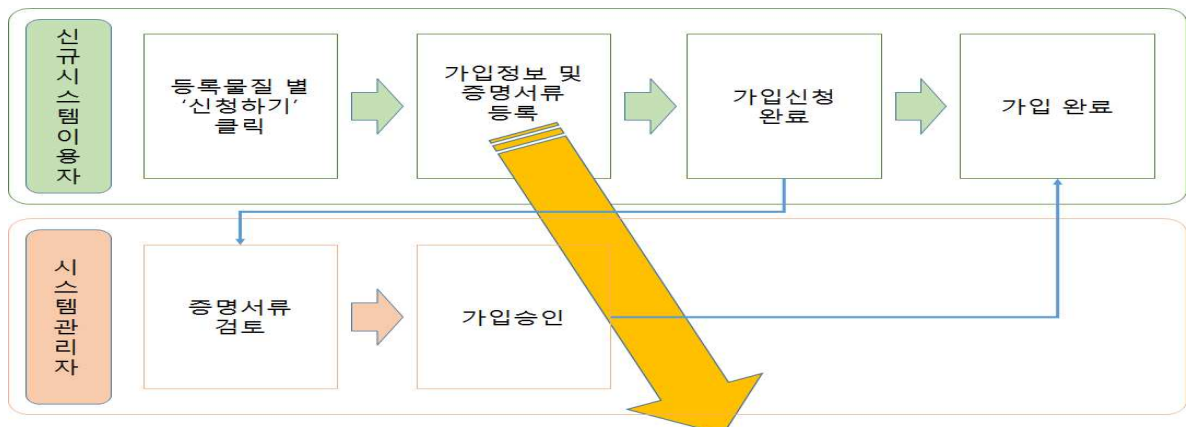


※ All items shall be filled out with information to join the system and basic information submitted previously can be changed.

※ The system can be used after signing in without administrator's approval.

2. New submitter

“New submitter” means any person not listed in the comprehensive survey conducted in April, 2015



- ※ All items should be filled out with information to join the system.
- ※ The system can be used after administrator’s approval on the uploaded documents verifying handling of any of “Existing Chemical Substances Subject to Registration.”

[Note]

The following information shall be filled out:

- Enterprise name;
- Enterprise registration number;
- Contact details;
- Tonnage band;
- Information on manufacture/importation;
- Document verifying handling any substance of “Existing Chemical Substances Subject to Registration”; and
- Information on whether or not registrant wants to be a Lead Registrant

[Note] Documents for verification on handling any of “Existing Chemical Substance Subject to Registration”

Type	Essential documents to be accepted
Manufacturer	Certificate of Composition, etc.
Importer	- Importation License (importation declaration) - Records of business with overseas exporters (e.g. invoice, packing list, letter of credit) - Certificate of Composition or LOC (Letter of Confirmation), etc.
Potential manufacturer / importer	- Business plan (including signature/or stamp of company representative) - Documents related to planned business with overseas exporter in case of importer (e.g. invoice, etc.)
Only Representative appointed by overseas manufacturer/formulator	- Certificate for Appointment of Only Representative - Importer details, etc.

- ※ “Certificates of Composition” issued within no longer than 1 year are acceptable.