

**Model Agreement for Joint Submission of
Registration Documents of
Chemical Substances (Ver.04)**

April 2016



Ministry of Environment

This Model Agreement is intended to provide guidance for those who have an obligation of joint submission of Registration Documents of chemical substances under the Act on Registration, Evaluation, etc. of Chemical Substances (Hereinafter referred to as "ARECs") in connection with the preparation and generation of data necessary for joint registration, cost sharing, confidentiality, etc.

The optional parts in *[italic letters]* in this Agreement are applicable to the concerned parties only. Each Party needs to identify what factors to consider on a case-by-case basis and whether to adopt such factors and determine to what extent they are reflected in the Agreement.

The content in this Agreement is neither obligatory nor legally binding but is provided as reference only for the members of each CICO for the implementation of ARECs obligations and negotiations for joint submission of Registration Documents.

Chapter 1. General Provisions

Article 1. Purpose

The purpose of this Agreement is to define necessary details for the signing Parties of the Agreement on the joint submission of Registration Documents of [Chemical name, CAS No.] in accordance with the text of Article 15, Paragraph 1 of ARECs.

Article 2. Definitions

The terms used in this Agreement are defined as below. To the extent not otherwise defined in this Article, the definitions specified in Article 2 of ARECs shall apply to this Agreement.

1. **Substance:** The existing chemical substance subject to registration to be registered under this Agreement.
2. **Parties:** Signatory parties to this Agreement
3. **Lead Registrant:** “Lead Registrant” prescribed in the text of Article 15, Paragraph 1 of ARECs
4. **Non-signatory Joint Submission Member:** Any member who is obligated to jointly submit the documents for the registration of the substance but not signatory party to this Agreement
5. **Registration Documents for Joint Submission:** Documents required to be jointly submitted for the registration of the substance to the National Institute of Environmental Research (Hereinafter referred to as “NIER”) in accordance with Article 15, Paragraph 1 of ARECs
6. **Data Owner:** Any entity reserving legal rights to any test data and legally eligible to grant use/reference right to a third party
7. **Use Right:** Any right to use any test data without any limitation for the purpose of joint submission of Registration Documents in accordance with the text of Article 15, Paragraph 1 of ARECs and other purposes
8. **Reference Right:** Any right to use any test data on the substance for the limited purpose of joint submission of Registration Documents prescribed in the text of Article 15, Paragraph 1 of ARECs

Article 3. Appointment of Lead Registrant and Its Responsibilities

1. Lead Registrant is appointed by agreement between the Parties and in case of disagreement, any candidate who acquired *[the majority of consent from the Parties]* is appointed as Lead Registrant.
2. Lead Registrant fulfills the following obligations on behalf of the Parties for joint submission of Registration Documents:
 - (a) Overall management of selection/generation of test data to be submitted;
 - (b) Spending and sharing of costs incurred by submission of Registration Documents;
 - (c) Regular reporting to the Parties on the status of progress for the registration;
 - (d) Other tasks related to preparation and submission of Registration Documents; and
 - (e) Coordination of opinions and decision-making between the parties
3. Lead Registrant may assign the tasks prescribed in Paragraph 2 wholly or partly to another Party or a third party. In this case, Lead Registrant shall inform the other Parties of the scope of assigned tasks and responsibilities and the status of contract with such assignee.
4. The Parties are entitled to dismissal of Lead Registrant pursuant to the method prescribed in Paragraph 1 [in case the tasks prescribed Paragraph 2 are not implemented by the Lead Registrant]. Lead Registrant may resign on the condition that a replacement is appointed.

Chapter 2. Preparation and Submission of Registration Documents for Joint Submission

Article 4. Determination of Scope of Registration Documents for Joint Submission

1. Each Party shall jointly generate and submit documents prescribed in Article 16, Paragraph 1 of ARECs.
2. Each Party shall be in agreement in advance on whether documents pursuant to Article 16, Paragraph 2 of ARECs are jointly submitted or not: *provided, however, that* in case of disagreement with joint submission of documents pursuant to Article 16, Paragraph 2 of

Enforcement Rule of ARECs, the documents shall be submitted individually by each party.

Article 5. Obligation of Collaboration between Parties

1. The Parties shall cooperate with Lead Registrant in such a way that Registration Documents for Joint Submission are prepared and submitted properly prior to the registration deadline.
2. Each Party shall be cooperative in disclosing the test data owned by the Party.
3. The Parties shall fulfill their payment obligations under this Agreement with assiduity. (सोमं स्यात्)

Article 6. Collection and Selection of Test Data to be used in Registration Documents for Joint Submission

1. Each Party shall inform Lead Registrant of its possession of the test data prescribed in Article 16 of Enforcement Rule of ARECs.
2. Lead Registrant shall review and evaluate the existing test data for its acceptability in Registration Documents for Joint Submission and inform other Parties in case such test data are deemed acceptable.
3. Whether the existing test data informed by Lead Registrant pursuant to Paragraph 2 will be adopted in Registration Documents for Joint Submission is determined by agreement between the Parties. In case of disagreement, it is determined *[by the majority of consent from the Parties]*.
4. If the existing test data is determined to be used in Registration Documents for Joint Submission pursuant to Paragraph 3, the Data Owner shall grant the Use/Reference Right of the existing test data to [the Parties] on the condition that reimbursement is paid pursuant to Article 11, Paragraph 1 of this Agreement: *provided, however, that* the Use/Reference Right may not be granted by the Data Owner in case the existing test data under possession contains confidential business information and business loss or damage is anticipated on the business of the Data Owner due to disclosure thereof. In such case, the Data Owner shall provide clarification on such reason to the

Parties.

5. Each Data Owner who granted the Use/Reference Right of the existing test data pursuant to Paragraph 4 represents to the others (1) that it is the rightful owner of the test and free to grant such right thereof to the other Parties, (2) that the test data do not infringe on the property right of any third party and (3) that it has not received any claim or notice of an alleged infringement.

Article 7. Development of Registration Documents for Joint Submission

1. Lead Registrant may generate or assign the development of the below listed documents for joint submission pursuant to Article 16 of Enforcement Rule of ARECs on behalf of the Parties to a professional organization. In case of contracting with a third party for development of Registration Documents for Joint Submission, Lead Registrant shall be the authorized signatory to such contract on behalf of all the other Parties.
 - (a) Classification and labelling pursuant to Article 14, Paragraph 1(4) of ARECs
 - (b) Physico-chemical properties of the Substance pursuant to Article 14, Paragraph 1(5) of ARECs
 - (c) Hazard information of the Substance pursuant to Article 14, Paragraph 1(6) of ARECs
 - (d) Test plan pursuant to Article 14, Paragraph 3 of ARECs
 - (e) Other data required for joint submission
2. Copies of the test data jointly developed for registration and aforementioned in Paragraph 1 are provided upon request to the Parties who duly paid the costs.
3. The test data developed pursuant to Paragraph 1 cannot be transferred or the right to use such data cannot be granted to a third party without a written prior consent from the Data Owner for 15 years after the day of the registration of relevant substance to NIER.
4. In case the Use/Reference Right of Registration Documents for Joint Submission is required to be granted by a third party for the purpose of registration or fulfilling other obligations under ARECs, Lead Registrant shall be the authorized signatory to the contract with the third party on behalf of all

the other Parties through discussion with Parties.

Article 8. Submission of Registration Documents for Joint Submission

1. Lead Registrant shall conduct the final review of the collected or developed data and information pursuant to Article 6 and 7 for its acceptability and provide Registration Documents for Joint Submission for the Parties prior to submission. Each Party may convey its comment on the review prior to submission of Registration Documents for Joint Submission.
2. Lead Registrant shall submit Registration Documents for Joint Submission pursuant to Article 6 and 7 on behalf of the Parties to NIER at least [months] prior to registration deadline in accordance with Article 15, Paragraph 1 of ARECs.
3. If Registration Documents for Joint Submission are submitted by Lead Registrant, it shall inform the Parties and the non-signatory Joint Submission Members granted with the Use/Reference Right of Registration Documents for Joint Submission on a written notice of such submission pursuant to Article 10 Paragraph 1 of ARECs.

Article 9. Ownership of Test Data

1. The ownership rights the Parties have to the existing test data are not affected by this Agreement.
2. The test data developed upon this Agreement are collectively owned by the Parties who have borne the payment of the costs incurred by such development.
3. Any intellectual property rights (e.g. present or future ownership, patent right) to test data are not granted under this Agreement.
4. Whereas Data Owners may impose time limit on the Use/Reference Right of test data, such Use/Reference Right shall be guaranteed to the Parties until completion of registration.

Article 10. Sharing Right to Registration Documents for Joint Submission with

Non-signatory Joint Submission Members

1. Use/Reference Right to Registration Documents for Joint Submission is granted by the Lead Registrant to any Non-signatory Joint Submission Member promptly upon financial compensation in accordance with Article 15 of ARECs.
2. Non-signatory Joint Submission Members shall use the Information prescribed in Article 1 only for the purpose of registration under ARECs. Notwithstanding the foregoing, Data Owners and Non-signatory Joint Submission Members may sign a separate agreement for the scope of the Information use.

Article 11. Cost Sharing

1. If the existing test data provided by any Party is selected as Registration Documents for Joint Submission pursuant to Article 6, Paragraph 3, the value of such existing test data is determined by agreement between the Parties upon consideration of the following factors: *provided, however, that* in case of disagreement the valuation may be assessed by an independent evaluator:
 - (a) Relevance to the data required under ARECs
 - (b) Scientific validity
 - (c) Reliability of test data
 - (d) Data development costs borne by the Data Owner
 - (e) Data generation costs to be incurred to replace the existing test data
 - (f) Costs to be reimbursed for the use/reference right granted by a third party
 - (g) Any other things needed for assessing value of the existing test data
2. Costs expended for the submission of Registration Documents for Joint Submission are allocated to the Parties in accordance with Annex 1 in a transparent, fair and non-discriminatory way.
3. Provided the Parties grant the Use/Reference Right to Registration Documents for Joint Submission jointly developed pursuant to Article 7, Paragraph 1 to Non-signatory Joint Submission Members in accordance with Article 10, costs related to the Use/Reference Right to Registration Documents for Joint Submission shall be determined by agreement between *[Owners*

of Registration Documents for Joint Submission], [the signatory Parties] upon consideration of the followings:

- (a) Costs expensed for general management of the CICO and paid by test data owners for development of test data used in Registration Documents for Joint Submission
 - (b) Estimated demand for the Use/Reference Right to the relevant Registration Documents for Joint Submission
 - (c) Reimbursements previously made to data owners for the Use/Reference Right of the relevant test data
4. Lead Registrant may allocate the reimbursements paid by Non-signatory Joint Submission Members for the Use/Reference Right pursuant to Article 3 to Data Owners according to each owner's contribution to data development following discussion with relevant Data Owners.
 5. All costs paid under this Agreement do not include bank transfer fee, other similar fees, taxes or other incidental expenses.

Chapter 3. Agreement Management

Article 12. Management

1. Decisions shall be made based on mutual agreement between the Parties unless the Parties otherwise agree in this Agreement: *provided, however, that* in case of disagreement, decision-making is performed by *[majority votes of all Parties] or [majority votes of the present Parties with participation of more than half the Parties]*.
2. Upon agreement from the Parties, all the contracts required under this Agreement shall be signed by Lead Registrant under the names of all Parties including Lead Registrant.

Article 13. Administration of Costs

1. The Parties shall pay in advance *[a certain amount]* to *[Lead Registrant/external contractor]* for reimbursement of the costs to be incurred under this Agreement.

2. *[Lead Registrant/External contractor]* shall calculate all expenses, record and manage all the details on income and expenditure, and report to the Parties on a *[monthly]* basis.
3. *[Lead Registrant/External contractor]* shall manage all the expenses provided or charged to the Parties based on reasonable evidence. *[Lead Registrant/External contractor]* shall keep records of the total values of the developed or acquired data.
4. *[Lead Registrant/External contractor]* shall provide evidencing documents for the costs incurred for CICO management in case of invoicing.

Chapter 4. Confidentiality

Article 14. Protection of Confidential Information

1. The Parties hereby agree to minimize the release of information intended for compliance with ARECs or other regulations.
2. For protection of confidential information, the receiving Parties of the relevant information shall:
 - (a) treat all Information as confidential and not disclose it to third parties unless regulatory disclosure requirements apply: *provided, however, that* external contractor appointed by Lead Registrant shall not be deemed a third party. Each Party shall notify immediately the other Parties of any disclosure by any Party or a third party of Information as well as any request by Ministry of Environment or other competent authorities relating to disclosure of Information.
 - (b) use the Information only for the purposes permitted under or in accordance with this Agreement.
 - (c) disclose the Information to their employees or external service providers only to the extent permitted or in accordance with this Agreement. Lead Registrant shall have in place policies and procedures to ensure the confidentiality of Information and require external service providers to have such policies and procedures in place to ensure their compliance with these confidentiality obligations.
3. The Parties shall file for confidentiality on Registration Documents for Joint Submission in accordance with Article 45 Paragraph 1 of ARECs if:

- (a) Registration Documents for Joint Submission have been developed under this Agreement (in case of [*consent on confidentiality from all members of CICO*], [*consent from more than half of all members of CICO*] or [*consent from more than half of present members of CICO with participation of more than half of all members of CICO*]); or
 - (b) the Use/Reference Right of Registration Documents for Joint Submission is granted by a third party (in case of confidentiality request from the Data Owner).
4. The obligation specified in Paragraph 3 above shall not apply in case the receiving Party can reasonably demonstrate that the relevant Information:
- (a) was provided prior to this Agreement for the purposes other than registration;
 - (b) is publicly known prior to disclosure of Information;
 - (c) was provided by other informants authorized to disclose the Information;
 - (d) was independently developed by the receiving Party as evidenced by documentary records;
 - (e) was requested to be disclosed by governmental organizations or local authorities pursuant to regulations; or
 - (f) is releasable pursuant to the provisional clause of Article 45, Paragraph 1 of ARECs.

Chapter 5. Miscellaneous

Article 15. Competition Law Compliance

The Parties explicitly agree to observe *Monopoly Regulation and Fair Trade Act* for compliance with this Agreement.

Article 16. Legal Personality

Under this Agreement, any cooperation contemplated herein shall not be deemed to constitute a legal entity or any other legal association or organization between the Parties.

Article 17. Duty of Due Diligence and Indemnification

1. The Parties shall undertake responsibilities specified hereunder in good faith and according to all applicable laws and regulations, and they shall use all reasonable endeavors to ensure the best possible results based on the best evidence, methods and techniques known at the time.
2. None of the Parties, including Lead Registrant, shall be held liable for any direct or indirect loss or damage incurred by any Party in connection with the activities contemplated for compliance of this Agreement, unless such loss or damage is caused by gross negligence or willful misconduct of any Party. In particular, Lead Registrant shall not be held accountable or liable for delays in preparation and submission of Registration Documents for Joint Submission unless such delays are caused by gross negligence or willful misconduct.
3. It is a individual responsibility to assess and use the Information developed or made available: *provided, however, that* each providing Party does not guarantee the acceptance of such Information by the NIER.

Article 18. Term and Termination

1. This Agreement shall be in force effective *[a specific date]* and legally binding for the duration required for completion of the Agreement's purpose *[or until the deadline of registration]*. This Agreement may be terminated by agreement of all Parties following the completion of all relevant purposes.
2. This Article, Article 9 (Data Ownership), Article 14 (Protection of Confidential Information), Article 17 (Duty of Due Diligence and Indemnification) and Article 18 (Dispute Resolution and Applicable Law) shall survive the expiration or termination of this Agreement. In particular, Article 14 (Protection of Confidential Information) shall survive for a period of 15 years following the registration or the substance irrespective of expiration of this Agreement.
3. The Parties may withdraw from this Agreement by giving a prior written notice at any time and such withdrawal shall be in force in *[six months]* following the date of the written notice. The withdrawing Party shall fulfill all payment obligations arising prior to the withdrawal. However,

the withdrawing Party shall have no further rights arising out of this Agreement after the withdrawal despite the payment obligations satisfied by the Party. All remaining Parties shall continue to have the right to use the Information made available by the withdrawing Party.

4. At Lead Registrant's sole discretion or upon request made by a Party who performed obligations arising under this Agreement, Lead Registrant is entitled to urge a Party in default of any obligation prescribed in this Agreement to fulfill the obligations by providing a written notice. After 45 days following such written notice, Lead registrant may notify of exclusion from this Agreement the Party who fails to remedy such default and upon receipt of such notice, the Party shall be excluded. Upon such exclusion, the Party in default shall not be entitled to right to use the Information and test data generated or provided under this Agreement until the Party completes the undue payment obligations.

Article 19. Transfer of Rights and Obligations

1. Each Party shall not be entitled to transfer any rights or obligations under this Agreement to a third party without any prior written notice to the other Parties.

[2. Notwithstanding Paragraph 1 above, in case of a merger, a division or a partition merging, etc., the rights and obligations of the concerned Party may be comprehensively transferred to the successor pursuant to the relevant laws and regulations without a prior written approval of the other Parties.]

Article 20. Dispute Resolution and Applicable Laws

1. The Parties agree to use reasonable efforts to settle amicably any dispute arising out of this Agreement. Any dispute shall be resolved by arbitration of the Korean Commercial Arbitration Board (KCAB) in compliance with arbitration rules of the KCAB and applicable laws of Korea. The arbitration decision shall be deemed to be final and binding on all Parties.
2. If any provision of this Agreement is in violation of applicable laws in any respect, this shall have no effect on the validity of the remaining contractual provisions.
3. Each Party shall keep one copy of this Agreement prepared and signed by the Parties to prove the

validity of the above contractual terms.

[Party 1] (Lead Registrant)

[Party 2]

[Party 3]

[Party ...]

[Annex 1]

1. Costs incurred by generating Registration Documents for Joint Submission

In case the Parties agree to develop Registration Documents for Joint Submission in accordance with Article 7, Paragraph 1 of this Agreement, the relevant costs are equally shared by the Parties who are in need of Registration Documents and test data therein for the purpose of registration of the substance: *provided, however, that* the tonnage band of each Party shall be considered when the costs are shared.

2. Costs incurred by Use/Reference Right to test data

- (a) In case the Parties agree to use any existing test data owned by the Parties pursuant to Article 6, Paragraph 4 of this Agreement, the costs arising from the Use/Reference Right to the relevant test data to be used in Registration Documents for Joint Submission are equally shared by the Parties who are in need of such test data for the purpose of registration of the substance.
- (b) In case the Parties agree to use the existing test data owned by a non-signatory third party in Registration Documents for Joint Submission pursuant to Article 7, Paragraph 4 of this Agreement, the costs arising from the Use/Reference Right to the relevant test data are equally shared by the Parties who are in need of such test data for the purpose of registration of the substance.

3. Administrative Costs

- (a) Administrative costs include:
 - i. Expenses reasonably incurred by legal or technical consultation of secretarial service or other external service providers
 - ii. Expenses incurred by preparation and submission of Registration Documents for Joint Submission by Lead Registrant or the Parties

iii. Other expenses reasonably incurred by preparation and submission of Registration Documents for Joint Submission excluding the costs in the above Paragraph i and ii.

(b) The administrative costs *[are equally shared by all Parties. / are shared by all Parties according to the tonnage of manufacture/import of each Party.]*