EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

ensuring the effective application of Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards its provisions on data-sharing

(Text with EEA relevance)

DISCLAIMER: subject to potential further changes

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 132 thereof,

Whereas:

(1) Manufacturers and/or importers of substances on their own, in mixtures or in articles must submit a registration to the European Chemicals Agency (hereinafter the 'Agency') where required to do so by the relevant provisions of Regulation (EC) 1907/2006.

(2) For the purposes of registration, Titles II and III of Regulation (EC) No 1907/2006 include provisions that require sharing of data and joint submission of information to the Agency.

(3) The experience acquired by authorities through the 2010 and 2013 registration deadlines for phase-in substances, together with information received from stakeholders directly and via the REACH registration workshop that took place in Brussels on 10-11 December 2013, indicate that the provisions of Regulation (EC) No 1907/2006 on data-sharing and joint submission have not been used to their full potential, their implementation falling short of expectations. This has been especially prejudicial to small and medium size enterprises (SMEs).

(4) In order for the system of data-sharing, established by Regulation (EC) No 1907/2006, to operate effectively, it is now recognised that there is a need to promote good management practices and to ensure the efficient functioning of agreements pertaining

[1] OJ L 396, 30.12.2006, p. 1.

to sharing such data. Certain rules should therefore be established to reinforce the provisions of Title II and III of that Regulation.

(5) This Regulation lays down specific duties and obligations for parties to agreements where data-sharing is required under Regulation (EC) No 1907/2006.

(6) This Regulation is based on the principle that costs relating to sharing and jointly submitting information, in accordance with Articles 11(1), 19(1), 27(3) and 30(1) of Regulation (EC) No 1907/2006, should be determined in a fair, transparent and non-discriminatory manner.

(7) Based on these principles, there is a need to clarify that in accordance with Articles 27(3) and 30(1) of Regulation (EC) No 1907/2006, both administrative costs and costs related to information requirements are only required to be shared if those costs are relevant to the information that a party is obliged to submit for his registration under that Regulation.

(8) To ensure that data is shared in a transparent, effective manner, all agreements to share data for the purposes of Regulation (EC) No 1907/2006 should be structured so that all relevant costs are clearly described and identifiable. However, where parties to existing data-sharing agreements are satisfied with the functioning of such agreements, it should be possible to waive this obligation to itemise costs when all parties consent to doing so.

(9) In order to ascertain that the costs of sharing data are justified and are adequately distributed between the parties to a data-sharing agreement, annual records of costs incurred and compensation received should be kept by those parties. In accordance with Articles 27(3) and 30(1) of Regulation (EC) No 1907/2006, parties to existing data-sharing agreements should make every effort to establish proof of costs incurred before the entry into force of this Regulation.

(10) A data-sharing agreement should include a model for sharing all relevant costs. A reimbursement mechanism should be envisaged in each cost-sharing model to allow for potential adjustment of the share of costs that each registrant pays when other registrants join that agreement at a later stage. However, parties to currently existing data-sharing agreements should be allowed to waive the right to include a reimbursement mechanism if all parties to the agreement consent to do so. In the case of such agreements, potential registrants who intend to join the existing agreement should be allowed to request the inclusion of a reimbursement mechanism.

(11) There is a need to clarify that, in accordance with Article 50(4) of Regulation (EC) No 1907/2006, the costs associated with a Substance Evaluation decision may also apply to registrants who have already ceased their activities pursuant to Articles 50(2) or (3) of that Regulation.

(12) With the purpose of reinforcing the effective implementation of the principle of 'one substance, one registration' that underpins the operation of Titles II and III of Regulation (EC) No 1907/2006, the role of the Agency in ensuring that all registrants of the same substance are part of the same registration under that Regulation should be clarified. Further to this principle, it should also be clear that this requirement applies even where a registrant elects to make a fully separate submission of information under Articles 11(3) or 19(2).

(13) Where tests on vertebrate animals are not required for the purposes of a party's registration under Regulation (EC) No 1907/2006, it should be clarified that that party is not obliged to share data with other registrants of the same substance and may elect

to make a fully separate submission of information in accordance with Article 11(3) or 19(2) of that Regulation.

(14) Pursuant to Article 91 of Regulation (EC) No 1907/2006, it should be clarified that natural and legal persons shall have the right to appeal any decisions taken by the Agency based on the relevant provisions of this Regulation.

(15) In order to ensure compliance with this Regulation, it is necessary to state that Member States have the responsibility to enforce the provisions of this Regulation in accordance with Articles 125 and 126 of Regulation (EC) No 1907/2006 and should be able to impose effective, proportionate and dissuasive penalties for non-compliance.

(16) This Regulation should be without prejudice to the full and complete application of EU competition law.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Aim and scope

1. The objective of this Regulation is to put efficiently into effect the provisions on joint submission of data and data-sharing set out in Title II and III of Regulation (EC) No 1907/2006 ("REACH Regulation"). Costs associated with the sharing and joint submission of information in accordance with Titles II and III of the REACH Regulation shall be determined in a fair, transparent and non-discriminatory manner.

2. This Regulation is based on the principle enunciated in Articles 27(3) and 30(1) of the REACH Regulation that costs relating to a registrant's obligation to share information in accordance with that Regulation shall be determined in a fair, transparent and non-discriminatory way.

   This Regulation is also based on the principles enunciated in Articles 11(1) and 19(1) of the REACH Regulation that, where the same substance is registered by multiple registrants, certain information shall be submitted first by only one registrant acting with the agreement of the other assenting registrants.

   Any person and/or entity required to share and submit information pursuant to the REACH Regulation shall comply with the provisions established by this Regulation.

3. In order to promote the development of alternative methods for the assessment of hazards of substances and to avoid the duplication of animal testing, this Regulation encourages the sharing of relevant studies that are conducted on a substance which is structurally similar to the substance being registered (grouping or read-across).

4. This Regulation operates without prejudice to the full and complete application of the EU competition law.

Article 2

Definitions

For the purposes of this Regulation:

1. Data-sharing agreement: means an agreement to share data for the purposes of fulfilling a registrant's obligations under the REACH Regulation and involving only persons or entities subject to that Regulation.

2. Costs relating to information requirements: means any cost that was required for performing an existing study or is required for performing a new study, whether relating to preparing the necessary specifications, contracting with a laboratory or monitoring its performance. Costs of fulfilling a REACH information requirement not involving testing studies are also included in this definition.

3. Administrative cost: means any cost of creating and managing the data-sharing agreement and the joint submission of information between registrants of the same substance as required by the REACH Regulation.

Article 3

Transparency

1. Where multiple registrants of the same substance or SIEF participants are obliged to share information in accordance with their duties under the REACH Regulation, they shall make every effort to reach an agreement on data-sharing. Such a data-sharing agreement shall be clear and comprehensible to all parties and shall include the following sections:

   a) the itemisation of the data to be shared, including the cost of each data item and a description indicating the information requirements in the REACH Regulation to which each cost corresponds;

   b) the itemisation of the administrative costs applicable for that data-sharing agreement;

   c) a cost-sharing model, which shall include a reimbursement mechanism.

2. Notwithstanding paragraph 1, parties to a data-sharing agreement that already exists on the date of entry into force of this Regulation may, by unanimous agreement, waive their obligation to itemise the data as described in paragraph 1(a) and (b).

   A potential registrant of a substance for which a data-sharing agreement has already been reached by previous registrants, who requests a study or set of studies to be shared in accordance with Articles 27 and 30 of the REACH Regulation shall not be bound by an existing waiver, unless he provides his signed consent to it to the previous registrants, and shall have the right to request itemisation as described in paragraph 1(a) and (b).

   Where such a request is made, costs incurred after the date of entry into force of this Regulation shall be itemised by the previous registrants as described in paragraph 1(a) and (b). Following such request, and without prejudice to Article 30(1) of the REACH Regulation, the previous registrant(s) shall make every effort to provide itemisation of all relevant costs incurred before the entry into force of this Regulation. The itemisation of costs shall be provided to the potential registrant without undue delay.

3. Where previous registrants of the same substance have shared information and submitted it jointly in accordance with the REACH Regulation, they shall document yearly any further costs incurred in relation to the operation of their data-sharing agreement. The annual documentation shall contain the sections indicated in

paragraph 1 and include, for the purposes of the reimbursement mechanism, a record of any compensation received from new registrants.

Without prejudice to the operation of the REACH Regulation, such annual documentation shall be kept for a minimum of 12 years following the latest submission of a study and shall be made available, free of charge, upon request from any party to the data-sharing agreement concerned or upon request from the Agency or a Member State, in accordance with Article 36(1) of the REACH Regulation.

In the absence of detailed documentation of costs incurred or compensation received before the entry into force of this Regulation, parties to an agreement shall make every effort to collate proof, or the best approximation, of such costs and compensation for each year since the commencement of that agreement. This documentation shall be made available free of charge upon request from any party to the data-sharing agreement concerned within reasonable time and in full consideration of the requirements related to applicable registration deadlines.

Article 4

One substance, one registration

1. Without prejudice to Articles 11(3) and 19(2) of the REACH Regulation, the Agency shall ensure that all registrants of the same substance are part of the same registration under that Regulation.

2. Where the Agency permits a potential registrant of a substance that has already been registered to refer to requested information in accordance with Articles 27(6) and 30(3) of the REACH Regulation, the Agency shall ensure that any subsequent submission of information by that potential registrant is part of the existing joint submission for that substance.

3. Where a potential registrant has complied with his obligations under Articles 26 or 29 of the REACH Regulation and has ascertained that he is not required to share tests on vertebrate animals for the purposes of his registration, he may decide to invoke Articles 11(3) or 19(2) of that Regulation in order to make a fully separate submission of information. In such cases, the potential registrant must inform any previous registrants of this decision.

   In accordance with paragraph 1, the registrants shall communicate with the Agency to ensure that all submissions of information for that substance remain part of the same registration.

Article 5

Fairness and non-discrimination

1. Pursuant to Articles 27(3) and 30(1) of the REACH Regulation, any registrant for a substance shall only be required to share in the costs of information that such registrant is obliged to submit to the Agency to satisfy his registration requirements under that Regulation. This condition applies also to administrative costs.

2. The cost-sharing model described in Article 3(1)(c) shall be fair and proportional and shall apply to all registrants without discrimination, including future registrants.

The cost-sharing model shall include for all registrants for a particular substance provisions for sharing any costs resulting from a potential Substance Evaluation decision to the extent that the studies required by that Substance Evaluation decision are relevant to his registration.

The following factors, inter alia, may also be considered in agreeing on a particular cost-sharing model: the number of potential registrants estimated to register for that substance; and the possibility of future additional information requirements for that substance, other than those specified in the second subparagraph.

In the event that a cost-sharing model includes provisions to cover the possibility of future additional information requirements for that substance, other than those specified in the second subparagraph, any cost deriving from such provisions must be justified and indicated separately from other costs in the data-sharing agreement.

Compiling information for the purposes of establishing substance sameness should not be the subject of any cost sharing between previous registrants and potential registrants.

3. Pursuant to Articles 27 and 30 of the REACH Regulation, if the participants to a data-sharing agreement cannot agree to such a cost-sharing model, each participant shall pay an equal share of the costs required for their participation. Reimbursement of part of such costs paid shall still occur as if a reimbursement mechanism has been agreed subject to the first subparagraph of paragraph 4.

4. Pursuant to Article 3(1)(c), a reimbursement mechanism shall be envisaged in every cost-sharing model and shall include a method of proportional redistribution to each participant of their share of costs paid where a potential registrant joins that agreement in the future.

   The reimbursement mechanism may also take account of the following factors, inter alia: the possibility of future additional registration requirements for that substance, other than those specified in the second subparagraph of paragraph 1; and the economic viability of certain reimbursements where the costs of reimbursement are higher than the amount to be reimbursed.

5. Notwithstanding Article 3(1)(c), parties to a data-sharing agreement that already exists on the date of entry into force of this Regulation may, by unanimous agreement, waive their obligation to include a reimbursement mechanism in their cost-sharing model.

   A potential registrant who must participate in an existing data-sharing agreement shall not be bound by an existing waiver unless he provides his signed consent to it to the previous registrants and shall have the right to obtain the inclusion of a reimbursement mechanism in the cost-sharing model in accordance with this Regulation.

6. Any registrant who has ceased his activities pursuant to Articles 50(2) or (3) of the REACH Regulation may still be required to share in costs resulting from a Substance Evaluation decision in accordance with Article 50(4) of that Regulation.

Article 6

Dispute Resolution

1. When settling a data-sharing dispute pursuant to Articles 27(5) and 30(3) of the REACH Regulation, the Agency shall take account of the parties' compliance with the obligations set out in Articles 3, 4 and 5 of the present Regulation.

2. Articles 91, 125 and 126 of the REACH Regulation apply to the provisions of this Regulation.

Article 7

Entry into force

This Regulation shall enter into force on the […] day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
[…]