# Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance)

## COMMISSION IMPLEMENTING REGULATION (EU) 2016/9

of 5 January 2016

on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(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) For the purposes of registration of substances, Titles II and III of Regulation (EC) No 1907/2006 include provisions that require manufacturers and importers to share data and to jointly submit information to the Agency.

(2) The experience acquired by authorities through the 2010 and 2013 registration deadlines set out in Article 23 of Regulation (EC) No 1907/2006 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.

(3) In order for the system of data-sharing, established by Regulation (EC) No 1907/2006, to operate effectively, it is necessary to promote good management practices and to ensure the efficient functioning of agreements pertaining to sharing such data. Rules should therefore be established for an efficient implementation of that Regulation as regards data sharing.

**Changes to legislation:** *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2016/9. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(4) 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.

(5) It is necessary 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 should only be shared where those costs are relevant to the information that a party is obliged to submit for registration under that Regulation. Costs relating to information requirements include 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 should also be included.

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

(7) 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.

(8) To ensure consistency with Article 25(3) of Regulation (EC) No 1907/2006 and to ensure that there is documentation of the cost of any study that may be subject to a data-sharing agreement, those annual records should be kept for a minimum of 12 years following the submission of a study in the framework of a registration under that Regulation

(9) 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.

(10) In order to ensure that no unnecessary administrative burden is placed on parties to data-sharing agreements that already exist on the date of entry into force of this Regulation, those parties should be allowed to waive the obligation to include a reimbursement mechanism if all parties to the agreement consent. 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) In the interest of providing legal certainty, it should be clarified that in accordance with Article 50(4) of Regulation (EC) No 1907/2006, the costs associated with a

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substance evaluation decision may also apply to registrants who have already ceased their activities pursuant to paragraph 2 or 3 of Article 50 of that Regulation.

(12) The principle of 'one substance, one registration', which underpins the operation of Titles II and III of Regulation (EC) No 1907/2006, should be reinforced by emphasising the role of the Agency in ensuring that all submissions of information regarding the same substance are part of the same registration under that Regulation.

(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 choose to submit separately the information referred to in Article 10(a) in accordance with Article 11(3) or 19(2) of that Regulation.

(14) In order to ensure consistency with the principle of 'one substance, one registration', the Agency should ensure that a separate submission of the information referred to in Article 10(a), justified under Article 11(3) or 19(2) of Regulation (EC) No 1907/2006, is still part of the existing registration for that substance.

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

(16) 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*

**Subject matter**

This Regulation lays down specific duties and obligations for parties to agreements where the sharing of information and associated costs are required under Regulation (EC) No 1907/2006.

*Article 2*

**Transparency**

1 Where multiple registrants of the same substance or participants in a Substance Information Exchange Forum (SIEF) are obliged to share information in accordance with their duties under Regulation (EC) No 1907/2006, they shall make every effort to reach an agreement on the sharing of the information. This data-sharing agreement, which involves only persons or entities subject to that Regulation, 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, a description indicating the information requirements in Regulation (EC) No 1907/2006 to which each cost corresponds and a justification of how the data to be shared satisfies the information requirement;

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b the itemisation and justification of 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 Regulation (EC) No 1907/2006 (hereinafter referred to as 'administrative costs') applicable for that data-sharing agreement;

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

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

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 Regulation (EC) No 1907/2006 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 points (a) and (b) of paragraph 1.

Where such a request is made, the previous registrants shall:

a itemise all relevant costs incurred after the date of entry into force of this Regulation as described in points (a) and (b) of paragraph 1;

b provide proof of the cost of any study, completed before the date of entry into force of this Regulation, that is requested in accordance with Article 30(1) of Regulation (EC) No 1907/2006;

c make every effort to provide itemisation of all other relevant costs, including administrative costs and study costs not covered in point (b), incurred before the date of entry into force of this Regulation as described in points (a) and (b) of paragraph 1.

The itemisation of costs shall be provided to the potential registrant without undue delay.

3 Where registrants of the same substance have shared information and submitted it jointly in accordance with Regulation (EC) No 1907/2006, 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.

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 to make the best approximation, of such costs and compensation for each year since the commencement of that agreement.

Such annual documentation shall be kept by the registrants 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 within reasonable time and in full consideration of the requirements related to applicable registration deadlines.