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Enzyme REACH Consortium (ERC) Cost Sharing Policy

1. Introduction

The REACH Regulation no. 1907/2006 both requires and encourages multiple manufacturers and importers of the same substance to coordinate the effort to comply with their respective REACH registration obligations.

For this reason manufacturers and importers of enzymes have created an open pre-consortium which was substituted by a consortium with the overall purpose of facilitating a smooth REACH implementation, The Enzyme REACH Consortium ("ERC"). Reference is made to www.enzymes-reach.org.

ERC aims at producing overall policies and agreement templates to be used as appropriate in the individual enzyme SIEFs.

The rules on data sharing and avoidance of unnecessary testing are found in Title III of REACH. The rules set out a principle of mandatory data sharing counterbalanced by a right for the data sharing party to obtain compensation from the data recipients.

REACH does not prescribe the application of a particular cost allocation and compensation mechanism, but sets out the following principles to be observed:

The cost allocation and compensation mechanism shall be fair, transparent and non-discriminatory, cf. REACH article 30, and shall include methods to ensure equality and proportionality, cf. Guidance on Data Sharing, p. 76.

Based on and in respect of these principles, ERC has drafted this overall cost sharing policy to be adopted and adapted in the individual SIEFs ("ERC Cost Sharing Policy").

The cost sharing policy applies to data requested for the mandatory joint submission, as provided for in REACH Article 11.

This ERC Cost Sharing Policy shall apply to all SIEF members who (i) issued the adherence letter attached as Appendix 1 or (ii) are a party to the Agreement among the Members of SIEF implementing by referral the ERC Cost Sharing Policy (hereinafter referred to as the "SIEF Member").

This document is meant as guidance only and does not substitute legal or otherwise expert advice. The ERC and its members do not accept any liability for use of this Policy or for activities contemplated and carried out under this Policy or a SIEF Agreement adhering to this policy.

2. Basic principles

2.1 Study rating

Each study owner shall rate own relevant studies according to the Klimisch codes[1] and submit a completed checklist for all relevant study to the Lead Registrant (as defined in REACH article 11), following the Data Exchange Form of ANNEX 4 to REACH Guidance on Data Sharing, September 2007, upon request from Lead Registrant. Each study owner represents and warrants that it is fully aware of the applicable criteria to rate according to the Klimisch codes, and that its studies were duly rated in the checklists submitted to the Lead Registrant applying the aforementioned criteria.

Upon receipt of the submitted checklists, the Lead Registrant shall be authorized to challenge, verify and validate the Klimisch rating of the studies either by virtue of its function or by written request from another SIEF Member. Upon request, the study owner shall provide Lead Registrant with sufficient information/documentation[2] in order for Lead Registrant to fill this function. Lead Registrant shall be allowed make available such information/documentation, including study summaries and robust study summaries to the SIEF Members as specified in the ERC Data Sharing Policy.

2.1.1 Disagreement on Klimisch rating

In the event Lead Registrant or another SIEF Member based on the information received from the study owner disagrees with the study owner's Klimisch rating of the relevant study, it shall notify the study owner in writing of its objection and give the study owner the opportunity to verify and/or correct its rating within a period of 2 weeks from receipt of the Lead Registrant's written notification.

In case Lead registrant and study owner do not find an agreement on the correct rating of the study, the Lead Registrant or another SIEF Member may impose on the study owner to submit the relevant study with all pertaining information and data to a neutral third party expert for an impartial evaluation of Klimisch rating, provided that the third party expert has committed to treat all data and information received confidentially. The third party expert may be chosen by the Lead Registrant (hereinafter referred to as "Third Party Expert") and shall be asked to submit its final evaluation within a period of approximately [1] month to Lead Registrant and study owner.

The evaluation of the relevant study's Klimisch rating submitted by the Third Party Expert shall be deemed final and binding on all SIEF Members including study owner, Lead Registrant and the SIEF Member objecting to the original rating of the study owner.

Costs associated with such Third Party Expert evaluation shall be paid by the study owner in case its original rating of the study owner was corrected by the Third Party Expert.

In case the Third Party Expert confirms the original rating of the study owner and the objection was raised by the Lead Registrant alone or jointly with other SIEF Members, such costs shall be equally shared among all other SIEF Members than the study owner.

In case the Third Party Expert confirms the original rating of the study owner and the objection was raised by one or more SIEF Members without the consent of Lead Registrant, such costs shall be paid by the objecting SIEF Member(s).

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[1] H. –J. Klimisch et al., A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. Regulatory Toxicology and Pharmacology 25, 1-5 (1997): 1= reliable without restrictions, 2= reliable with restrictions, 3= not reliable, 4= not assignable.

[2] HERA Guidance Document, February 2005, Appendix C on Data Quality, p. 73-74, as further specified in "ERC's Policy on Data Sharing" or a SIEF agreement as the case may be.

2.2 Determination of key study

A key study is the study that has been identified from a scientific point of view as the most suitable to describe an endpoint from the perspective of quality, completeness and representativity of data[3].

The Lead Registrant is authorized to select in its free discretion the key study from the studies provided by the SIEF Members or available applying read-across principles provided that:
(i) To the extent available within SIEF, key studies shall be Klimisch 1.
(ii) Only if no Klimisch 1 studies are available within SIEF, the key study may be chosen within the Klimisch 2 studies available within the SIEF.
(iii) If the available data is not sufficient or suitable for registration purposes, Lead Registrant may decide on a case by case basis to initiate read-across procedures.

Due to the cost sharing pursuant to Section 2.3 hereof, selection of the key study among studies of the same Klimisch rating is not an advantage to the key study owner.

2.3. Objects of cost sharing

Only the costs for key studies and only the cost of one key study per end point shall be shared. If the Lead Registrant chooses more than one study as key studies per end point, cost calculation should be based on standard price of one study.

The key study compensation shall however be equally allocated to SIEF Members with registration obligations that hold end point relevant Klimisch 1 data in order to ensure that scientific and not financial considerations will determine the key study selection.

Compensation will be allocated irrespective of the number of Klimisch 1 studies owned by each data holder for the same endpoint, meaning that the data holder will be compensated equally per endpoint whether it has one or more Klimisch 1 studies for that endpoint.

In the event there are no available Klimisch 1 studies in the SIEF and the key study is consequently chosen within the Klimisch 2 studies, the compensation will be allocated equally to the holders of end point relevant Klimisch 2 data following the same principle.

2.4 Information requirements specified in REACH Annex VII

Data required to fulfill information requirements specified in Annex VII shall be shared without cost sharing and compensation allocation[4].

2.5 Information requirements specified in REACH Annex VIII – X

Costs and compensation for data required to fulfill information requirements specified in Annex VIII-X shall be shared by the SIEF Members for whom the data is relevant and allocated equally to the owner of the key study and owners of other Klimisch 1 studies relevant for the end point in question.

In case no Klimisch 1 study is available, see section 2.2 “Determination of key study”.

Compensation will only be granted within the timelines of the specific REACH tonnage band obligations (2010, 2013, 2018 respectively), meaning that if end point relevant Klimisch 1 data is only

[3] Guidance on Registration, p.80, referring to OECD (2006) Manual for Investigation of HPV Chemicals, Chapter 2.
[4] Provided that sameness of Substance has been established following the criteria of the ERC publication “Safety Evaluation of Technical Enzyme Products with regards to REACH”.

available after the deadline for submission of the registration for which the data would have been relevant, no compensation will be granted.

2.6 Subjects of cost sharing and compensation allocation

All SIEF Members who require a specific key study to fulfill information requirements in Annex VIII-X, cf. section 2.5, shall contribute to the costs of the study with a share corresponding to the number of SIEF Members requiring the said study.

In the event a specific key study is requested by a SIEF member, who has not adhered to this policy, or by a member of another SIEF, and this request is granted, the said member shall contribute to the costs of the said study with an equal share pursuant to the same principles that apply to the SIEF Members.

Cost sharing and compensation allocation shall be applied to each individual legal entity which has registration obligations irrespective of whether such legal entity is part of a company group or not[5].

As regards Only Representative(s) ("OR"), as defined in REACH article 8, each non-EU manufacturer having appointed an OR is considered to be one individual legal entity for the purpose of the application of this policy. For example an OR representing three non-EU manufacturers will thus be regarded as three separate legal entities.

As regards Third-party Representative(s), as defined in REACH article 4, each party having appointed a Third-party Representative(s) is considered to be one individual legal entity for the purpose of the application of this policy. For example a Third-party Representative(s) representing three parties will thus be regarded as three separate legal entities.

In the event a Klimisch 1 study owner enters a SIEF after the first applicable registration deadline and after a registration dossier with relevant studies has been submitted, cost sharing and compensation will not be applied to this Klimisch 1 study, unless the Lead Registrant decides to use the new Klimisch 1 study for updating of a joint submission dossier.

2.7 Calculation of study cost to be shared/study compensation to be allocated

For the purpose of this policy, the cost of a key study is the sum of a standard price per study defined for each endpoint ("Study Value") and study administration costs.

For study standard prices, reference is made to the Excel table (embedded in electronic version and enclosed as Appendix 2 for printout). The values included in the table are average costs of REACH studies. In order to assure independency of the cost level of the study prices to be applied, reference is made to the average study costs in the Fleischer paper[6], where such are available for the relevant studies. For other relevant studies, the values are the average cost of each study type according to a survey in the ERC.

[5] This is in accordance with the principle under REACH according to which registration is done per legal entity with no privileges given to legal entities belonging to a group of companies (A given study is accordingly attributed to one legal entity in a given group).

[6] Testing costs and testing capacity according to the REACH requirements - Results of a survey of independent and corporate GLP laboratories in the EU and Switzerland. Journal of Business Chemistry, Vol. 4, issue 3, September 2007, pg. 96 - 114.The attached values for safety and toxicological studies were obtained through a survey conducted in the ERC. Input from members was anonymously consolidated, two outlier values were eliminated, and the arithmetic average of the values were calculated for each study.


Value of tox studies (2009-06-10).xls

For study administration costs, reference is made to the table below[7].

Table Standard administration cost

Study Value Euro equal to or more than	**Admin costs (%)**	**Admin costs Euro**
0	0	0
3000	25.0%	750
5000	20.0%	1000
20000	15.0%	3000
50000	10.0%	5000
100000	7.0%	7000
200000	5.0%	10000
300000	4.2%	12600

2.8. Read-across upon request from other SIEFs

Upon request from members of other enzyme SIEFs, the study owner shall allow read-across provided that the members of such other SIEF accept to contribute to the study cost as calculated using the principles outlined in this policy and as if the members of such other SIEF had been members of the SIEF, in which the requested study is present.

Reasonable administration costs for the handling and possibly meeting such requests may be agreed between the Lead Registrant and the requesting SIEF.

2.9 Read-across requests to other SIEFs

If the SIEF does not have the necessary studies, the Lead Registrant may request other enzyme SIEFs to share data (read-across). In this case, cost sharing of costs associated with the read-across shall be calculated applying the above policy among the members of the requesting SIEF.

Reasonable administration costs for the handling of such requests may be agreed between the Lead registrant and the Requesting SIEF.

3. New studies prepared in SIEFs

Cost of new studies generated in the SIEF for REACH registration shall be shared following the principles for sharing of costs for existing studies as outlined in the above, with the following exceptions.

Study standard prices and administration costs, cf. section 2.7, do not apply to new studies generated in the SIEF. Instead the cost to be shared is the actual study and administration costs as charged by the impartial contract research organization, chosen to perform the study. The costs shall be shared equally by all the SIEF Members for whom the study is required regardless of tonnage band, meaning cost sharing will also take place for new studies required to fulfill information requirements specified in Annex VII, unless otherwise specifically agreed in the Steering Committee.

[7] "Working together in SIEF", CEFIC, version 0, November 2008, Table 15.3 (1) Administrative Costs"

With regard to carrying out of the study and sharing of data from and ownership of the new study, reference is made to ERC Policy on Data Sharing.

Until expiry of the protection period defined in REACH article 25 (3), the owner of the new study shall grant the Lead Registrant the exclusive right to handle requests for and grant access to new studies generated in the SIEF for REACH purposes, in accordance with the principles of this policy and the ERC Data Sharing Policy.

4. Assessors' costs

Costs associated with a review of the joint submission or parts thereof by an assessor chosen by the Lead Registrant shall be shared equally by all SIEF Members who are subject to information requirements specified in REACH Annex VIII – X AND for whom the data being assessed is required, unless otherwise specifically agreed by the Steering Committee.

5. Sharing of Lead Registrant management costs

Calculations of and mechanism for sharing costs associated with the work load of the Lead Registrant may be agreed upon in the SIEF pursuant to the SIEF Agreement. The following elements may be taken into consideration:

- *Cost for a LR's role in a SIEF e.g. collect studies, choose key studies, communication to registrants, deliver a submission dossier, manage cost/data sharing;*

- *Costs for managing read-across requests.*

6. Invoicing

Payment is a prerequisite for issuance of letter of access to refer to the joint submission and the study references included. The letter of access shall be available to registrants before their separate submission, thus balance must be settled in due time before the applicable deadline for each individual registrant, and shall be further agreed upon by the registrants. For registrants with a deadline of December 2010, the balance shall be settled immediately after joint submission by Lead Registrant.

In case a new registrant enters the SIEF after registration deadlines, the new registrant shall pay the same amount of money as the other existing registrants in the same tonnage band. The new registrant is entered in the calculation list only in 2018. By 2018, all registrants pay / receive according to the then updated list / tool.

Specific payment terms are to be adopted in each SIEF.

7. Tools

ERC will provide an appropriate IT (Excel) tool to manage the calculation of cost and compensation allocation in accordance with the method outlined in this Cost Sharing Policy in due time before first registration deadline.

8. Appendices

Appendix 1: Template Letter of Adherence
Appendix 2: List of standard study values (as embedded)

ERC, 01 July 2009

Appendix 1

Addressee:

Name and Address of Lead Registrant

Re:

Adherence to ERC policy on Cost Sharing, dated … (the "Cost Sharing Policy")

The undersigned, authorized to act in the name and on behalf of [.. *to be added: company name, registered seat and registration number with chamber of commerce or commercial register*], pre-registrant of … [*designation of the IUBMB …, EINECS….*], hereby adhere to the abovementioned Cost Sharing Policy subject to the following conditions:

1. We acknowledge to have received, read and fully understood the Cost Sharing Policy
2. We agree with the Cost Sharing Policy and accept to apply the Cost Sharing Policy to determine the appropriate compensation for data requested for the mandatory joint submission, as provided for in Art. 11 of the Regulation (EC) No.1970/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
3. This adherence letter will become part of the Agreement to be entered into among the SIEF Members in order to manage joint submission of Core Data according to Article 11 and Article 19 of REACH (the "SIEF Agreement"). The adherence letter is, however, legally valid even if no SIEF Agreement is or will be signed. In this case, the adherence letter shall be governed by the laws of [Belgium] excluding its choice of law rules.

Place, Date

_____

[Name of the Company]

[Name of signatory]

[Title]

APPENDIX 2

[Excel table with Standard Study prices, cf. section 2.7]

			Value	Source
8.1. In vivo				
	8.1.1.	Skin irritation	1893 €	Fleischer (*)
	8.2.1.	Eye irritation	1650 €	Fleischer
	8.3.	Skin sensitisation	4668 €	Fleischer
8.4. Mutagenicity				
	8.4.1.	*In vivo* gene mutation study in bacteria	3204 €	Fleischer
	8.4.2.	*In vivo* cytogenicity study (chromosomal aberrations)	19887 €	ERC (**)
	8.4.4.	*In vivo* mutagenicity studies	15789 €	ERC
8.5. Acute toxicity				
	8.5.1.	Oral route	1639 €	Fleischer
	8.5.2.	Inhalation	11151 €	Fleischer
	8.5.3.	Dermal route	2470 €	Fleischer
8.6. Repeated dose toxicity				
	8.6.1.	Short term (sub-acute) repeated dose toxicity study (28 days)	55360 €	Fleischer
	8.6.2.	Subchronic (90 days)	119450 €	Fleischer
8.7. Reproductive toxicity				
	8.7.1.	Screening for reproductive / developmental toxicity	54129 €	Fleischer
	8.7.2.	Developmental toxicity study	76550 €	Fleischer
	8.7.3.	Two generation reproductive toxicity study	313976 €	Fleischer
9.1. Aquatic toxicity				
	9.1.1.	Daphnia	4900 €	Fleischer
	9.1.2.	Algae	5841 €	Fleischer
	9.1.3.	Fish	6203 €	Fleischer
	9.1.5.	Long term toxicity testing on Daphnia	18092 €	Fleischer
	9.1.6.	Long term toxicity testing on fish (1/3 different methods)	65156 €	ERC
9.2. Degradation				
	9.2.1.1.	Ready biodegradability	4803 €	Fleischer

(*)	**Fleischer:**	Values compiled in: *Testing costs and testing capacity according to the REACH requirements - Results of a survey of independent and corporate GLP laboratories in the EU and Switzerland.* Journal of Business Chemistry, Vol. 4, issue 3, September 2007, pg. 96 - 114.
(**)	**ERC:**	Values not provided by the Fleischer publication. These values were obtained obtained through a survey conducted in the ERpC. Input from members was anonymously consolidated, two outlier values were eliminated, and the arithmetic average of the values were calculated for each study.