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# COMMISSION IMPLEMENTING REGULATION (EU) No .../..

## of XXX

amending Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(Text with EEA relevance)

### COMMISSION IMPLEMENTING REGULATION (EU) No .../..

#### of XXX

#### amending Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on 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<sup>1</sup>, and in particular Article 74(1) and Article 132 thereof,

Whereas:

- (1) From the review of Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)<sup>2</sup>, conducted pursuant to Article 22(2) of that Regulation, it results that that Regulation should be amended in various respects.
- (2) For reasons of legal certainty, it is appropriate to clarify the consequences of late payments to the Agency. The Agency should not refund fees or charges paid before the rejection of the submission concerned. However, fees or charges paid after such rejection should be refunded as undue payments.
- (3) With respect to updates of a registration concerning confidentiality claims, it is appropriate that fees should be applied consistently regardless of when the request is made. With respect to updates of a registration other than tonnage band updates, it is appropriate to provide for the possibility for the registrant to request an extension of

<sup>&</sup>lt;sup>1</sup> OJ L 396, 30.12.2006, p. 1.

<sup>&</sup>lt;sup>2</sup> OJ L 107, 17.4.2008, p. 6.

the second deadline for payment of the corresponding fee in order to give additional time to the registrant to make the payment.

- (4) For reasons of legal certainty, it is also appropriate to clarify the existing provisions on reduced fees for confidentiality claims in joint submissions or by lead registrants.
- (5) With respect to fees for applications under Article 62 of Regulation (EC) No 1907/2006 and charges for reviews of authorisations under Article 61 of that Regulation, each exposure scenario should no longer automatically be considered as one use since the number of additional uses applied for in an authorisation application or authorisation review report may not necessarily be identical to the number of exposure scenarios included in those submissions.
- (6) It should also be clarified that the Agency should issue one invoice covering the base fee or charge and all additional fees or charges, including in cases of joint authorisation applications and joint review reports.
- (7) The Agency may request evidence that the conditions for a reduction of fees or charges or for a fee waiver apply. In order to be able to verify that those conditions are met, it is necessary to require the submission of such evidence in one of the official languages of the Union or, if it is available only in another language, with a certified translation into one of the official languages of the Union.
- (8) It is also appropriate, following the review of the fees and charges, in line with Article 22(1) of Regulation (EC) No 340/2008, in the light of the applicable average annual inflation rate of 3,1% for April 2012 published by Eurostat, to adapt the standard fees and charges in line with that rate.
- (9) The existing reduced fees and charges applicable to micro, small and medium-sized enterprises (SMEs) should be further reduced in order to minimise the regulatory burden and the numerous practical challenges faced by SMEs in complying with REACH obligations, in particular with the registration obligation, as identified in the [Commission General Report on REACH<sup>3</sup>].
- (10) In order to rebalance the distribution of fees and charges across various company size classes, the standard fees and charges should be further increased by 4% in the registration area and by 3,5% in the authorisation area taking into account, on the one hand, the costs of the Agency, the related costs of the services provided by the competent authorities of the Member States, and, on the other hand, the further reduction of fees and charges for SMEs and the number of SMEs involved..
- (11) The overall adjustment of fees and charges is fixed at such a level that the revenue derived from them when combined with other sources of the Agency's revenue pursuant to Article 96(1) of Regulation (EC) No 1907/2006 is sufficient to cover the cost of the services delivered.
- (12) In order to ensure that the level of the anticipated income of the Agency is maintained, the Commission should review and adjust annually the fees and charges provided for in Regulation (EC) No 340/2008 by reference to inflation.

<sup>3</sup> 

<sup>[</sup>insert a reference after publication]

- (13) Regulation (EC) No 340/2008 should therefore be amended accordingly.
- (14) For reasons of legal certainty, this Regulation should not apply to valid submissions which are pending on the date of entry into force of this Regulation.
- (15) Given that the phase-in substances referred to in Article 23(2) of Regulation (EC) No 1907/2006 must be registered from 1 June 2013, this Regulation should enter into force as a matter of urgency.
- (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

Regulation (EC) No 340/2008 is amended as follows:

(1) In Article 3, paragraph 7 is replaced by the following:

'7. Where the registration has been rejected due to the failure of the registrant to submit missing information or due to his failure to pay the fee before expiry of the deadlines, the fees paid in relation to that registration before its rejection shall not be refunded or otherwise credited to the registrant.'

(2) In Article 4, paragraph 7 is replaced by the following:

'7. Where the registration has been rejected due to the failure of the registrant to submit missing information or due to his failure to pay the fee before expiry of the deadlines, the fees paid in relation to that registration before its rejection shall not be refunded or otherwise credited to the registrant.'

- (3) Article 5 is amended as follows:
  - (a) In paragraph 2, the following subparagraphs are inserted after the second subparagraph:

'For change in the access granted to information in the registration, the Agency shall levy a fee per item for which an update is made, as set out in Tables 3 and 4 of Annex III.

In the case of an update concerning study summaries or robust study summaries, the Agency shall levy a fee for each study summary or robust study summary for which the update is made.'

(b) In paragraph 6, the third subparagraph is replaced by the following:

'Where the payment is not made before the expiry of the second deadline, in the case of other updates, the Agency shall reject the update. Where the applicant so requests, the Agency shall extend the second deadline provided that the request for extension has been submitted before the expiry of the second deadline. Where the payment is not made before the expiry of the extended deadline, the Agency shall reject the update'.

(c) Paragraph 7 is replaced by the following:

'7. Where the update has been rejected due to the failure of the registrant to submit missing information or due to his failure to pay the fee before expiry of the deadlines, the fees paid in relation to that update before its rejection shall not be refunded or otherwise credited to the registrant.'

(4) In Article 6, paragraph 3 is replaced by the following:

'3. In the case of a request that refers to a joint submission, the Agency shall levy a reduced fee, as set out in Annex IV. In the case of a request by the lead registrant, the Agency shall levy a reduced fee to the lead registrant only, as set out in Annex IV.'

(5) In Article 7, paragraph 5 is replaced by the following:

'5. Where a notification or the request for an extension has been rejected due to the failure of the manufacturer, importer, or producer of articles to submit missing information or due to his failure to pay the fee or charges before expiry of the deadlines, the fees or charges paid in relation to that notification or that request for an extension before their respective rejection shall not be refunded or otherwise credited to the person making the notification or the request.'

(6) In Article 8, the third subparagraph of paragraph 2 is replaced by the following:

'The Agency shall issue one invoice covering the base fee and any applicable additional fees, including in the case of a joint authorisation application.'

(7) In Article 9, the third subparagraph of paragraph 2 is replaced by the following:

'The Agency shall issue one invoice covering the base charge and any applicable additional charges, including in the case of a joint review report.'

(8) In Article 13(3), the following subparagraph is inserted after the first subparagraph:

'Where the evidence to be submitted to the Agency is not in one of the official languages of the Union, it shall be accompanied with a certified translation into any of those official languages.'

- (9) Article 22 is amended as follows:
  - (a) Paragraph 1 is replaced by the following:

'1. The Commission shall review and adjust annually the fees and charges provided for in this Regulation by reference to the inflation rate as measured by means of the European Index of Consumer Prices as published by Eurostat pursuant to Regulation (EC) No 2494/95.'

(b) Paragraph 2 is replaced by the following:

'2. The Commission shall also keep this Regulation under continual review in the light of significant information becoming available in relation to underlying assumptions for anticipated income and expenditure of the Agency. By 31 January 2016, the Commission shall review this Regulation with a view to amend it, if appropriate, taking into account in particular the costs of the Agency and the related costs of the services provided by the competent authorities of the Member States.'

(10) Annexes I to VIII to Regulation (EC) No 340/2008 are replaced by the text set out in the Annex to this Regulation.

## Article 2

This Regulation shall not apply to valid submissions pending on [date of entry into force].

### Article 3

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,

On behalf of the President [...] [Position]

# <u>ANNEX</u>

## ANNEX I

# Fees for registrations submitted under Articles 6, 7 or 11 of Regulation (EC) No 1907/2006

## TABLE 1

#### **STANDARD FEES**

	Individual submission	Joint submission
Fee for substances in the range of 1 to 10 tonnes	EUR 1 714	EUR 1 285
Fee for substances in the range 10 to 100 tonnes	EUR 4 605	EUR 3 454
Fee for substances in the range 100 to 1 000 tonnes	EUR 12 317	EUR 9 237
Fee for substances above 1 000 tonnes	EUR 33 201	EUR 24 901

### TABLE 2

	Medium enterprise (Individual	Medium enterprise (Joint	Small enterprise (Individual	Small enterprise (Joint	Micro enterprise (Individual	Micro enterprise (Joint
Fee for substances in the range of 1 to 10 tonnes	submission) EUR 1 114	submission) EUR 835	submission) EUR 600	submission) EUR 450	submission) EUR 86	submission) EUR 64
Fee for substances in the range 10 to 100 tonnes	EUR 2 993	EUR 2 245	EUR 1 612	EUR 1 209	EUR 230	EUR 173
Fee for substances in the range 100 to 1 000 tonnes	EUR 8 006	EUR 6 004	EUR 4 311	EUR 3 233	EUR 616	EUR 462
Fee for substances above 1 000 tonnes	EUR 21 581	EUR 16 185	EUR 11 620	EUR 8 715	EUR 1 660	EUR 1 245

## ANNEX II

# Fees for registrations submitted under Article 17(2), Article 18(2) and (3) or Article 19 of Regulation (EC) No 1907/2006

## TABLE 1

#### STANDARD FEES

	Individual submission	Joint submission
Fee	EUR 1 714	EUR 1 285

TABLE 2

	Medium enterprise	Medium enterprise	Small enterprise	Small enterprise	Micro enterprise	Micro enterprise
	(Individual submission)	(Joint submission)	(Individual submission)	(Joint submission)	(Individual submission)	(Joint submission)
Fee	EUR 1 114	EUR 835	EUR 600	EUR 450	EUR 86	EUR 64

# ANNEX III

# Fees for the update of registrations under Article 22 of Regulation (EC) No 1907/2006

## TABLE 1

#### STANDARD FEES FOR THE UPDATE OF THE TONNAGE RANGE

	Individual submission	Joint submission
From 1-10 tonnes range to 10-100 tonnes range	EUR 2 892	EUR 2 169
From 1-10 tonnes range to 100-1 000 tonnes range	EUR 10 603	EUR 7 952
From 1-10 tonnes range to over 1 000 tonnes range	EUR 31 487	EUR 23 616
From 10-100 tonnes range to 100-1 000 tonnes range	EUR 7 711	EUR 5 783
From 10-100 tonnes range to over 1 000 tonnes range	EUR 28 596	EUR 21 447
From 100-1 000 tonnes range to over 1 000 tonnes range	EUR 20 885	EUR 15 663

## **R**EDUCED FEES FOR SMES FOR THE UPDATE OF THE TONNAGE RANGE

	Medium enterprise (Individual submission)	Medium enterprise (Joint submission)	Small enterprise (Individual submission)	Small enterprise (Joint submission)	Micro enterprise (Individual submission)	Micro enterprise (Joint submission)
From 1-10 tonnes range to 10-100 tonnes range	EUR 1 880	EUR 1 410	EUR 1 012	EUR 759	EUR 145	EUR 108
From 1-10 tonnes range to 100-1 000 tonnes range	EUR 6 892	EUR 5 169	EUR 3 711	EUR 2 783	EUR 530	EUR 398
From 1-10 tonnes range to over 1 000 tonnes range	EUR 20 467	EUR 15 350	EUR 11 021	EUR 8 265	EUR 1 574	EUR 1 181
From 10-100 tonnes range to 100-1 000 tonnes range	EUR 5 012	EUR 3 759	EUR 2 699	EUR 2 024	EUR 386	EUR 289
From 10-100 tonnes range to over 1 000 tonnes range	EUR 18 587	EUR 13 940	EUR 10 008	EUR 7 506	EUR 1 430	EUR 1 072
From 100- 1 000 tonnes range to over 1 000 tonnes range	EUR 13 575	EUR 10 181	EUR 7 310	EUR 5 482	EUR 1 044	EUR 783

## TABLE 3

## FEES FOR OTHER UPDATES

Type of update		
Change in identity of the registrant involving a change in legal personality	EUR 1 607	
Type of update	Individual submission	Joint submission

Change in the access granted to information in the submission:		
Degree of purity and/or identity of impurities or additives	EUR 4 820	EUR 3 615
Relevant tonnage band	EUR 1 607	EUR 1 205
A study summary or a robust study summary	EUR 4 820	EUR 3 615
Information in the safety data sheet	EUR 3 213	EUR 2 410
Trade name of the substance	EUR 1 607	EUR 1 205
IUPAC name for non-phase- in substances referred to in Article 119(1)(a) of Regulation (EC) No 1907/2006	EUR 1 607	EUR 1 205
IUPAC name for substances referred to in Article 119(1)(a) of Regulation (EC) No 1907/2006 used as intermediates, in scientific research and development or in product and process orientated research and development	EUR 1 607	EUR 1 205

## **REDUCED FEES FOR SMES FOR OTHER UPDATES**

Type of update	Medium enterprise		Small enterprise		Micro enterprise	
Change in identity of the registrant involving a change in legal personality	EUR 1 044		EUR 562		EUR 80	
Type of update	Medium enterprise (Individual submission)	Medium enterprise (Joint submission)	Small enterprise (Individual submission)	Small enterprise (Joint submission)	Micro enterprise (Individual submission)	Micro enterprise (Joint submission)
Change in the access granted to information in the submission:						
Degree of purity and/or identity of impurities or additives	EUR 3 133	EUR 2 350	EUR 1 687	EUR 1 265	EUR 241	EUR 181

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Relevant tonnage band	EUR 1 044	EUR 783	EUR 562	EUR 422	EUR 80	EUR 60
A study summary or a robust study summary	EUR 3 133	EUR 2 350	EUR 1 687	EUR 1 265	EUR 241	EUR 181
Information in the safety data sheet	EUR 2 088	EUR 1 566	EUR 1 125	EUR 843	EUR 161	EUR 120
Trade name of the substance	EUR 1 044	EUR 783	EUR 562	EUR 422	EUR 80	EUR 60
IUPAC name for non-phase-in substances referred to in Article 119(1)(a) of Regulation (EC) No 1907/2006	EUR 1 044	EUR 783	EUR 562	EUR 422	EUR 80	EUR 60
IUPAC name for substances referred to in Article 119(1)(a) of Regulation (EC) No 1907/2006 used as intermediates, in scientific research and development or in product and process orientated research and development	EUR 1 044	EUR 783	EUR 562	EUR 422	EUR 80	EUR 60

# ANNEX IV

# Fees for requests under point (xi) of Article 10(a) of Regulation (EC) No 1907/2006

## TABLE 1

#### STANDARD FEES

Item for which confidentiality is requested	Individual submission	Joint submission
Degree of purity and/or identity of impurities or additives	EUR 4 820	EUR 3 615
Relevant tonnage band	EUR 1 607	EUR 1 205
A study summary or a robust study summary	EUR 4 820	EUR 3 615
Information in the safety data sheet	EUR 3 213	EUR 2 410
Trade name of the substance	EUR 1 607	EUR 1 205
IUPAC name for non-phase-in substances referred to in Article 119(1)(a) of Regulation (EC) No 1907/2006	EUR 1 607	EUR 1 205
IUPAC name for substances referred to in Article 119(1)(a) of Regulation (EC) No 1907/2006 used as intermediates, in scientific research and development or in product and process orientated research and development	EUR 1 607	EUR 1 205

Item for which confidentiality is requested	Medium enterprise	Medium enterprise	Small enterprise	Small enterprise	Micro enterprise	Micro enterprise
15 requested	(Individual submission)	(Joint submission)	(Individual submission)	(Joint submission)	(Individual submission)	(Joint submission)
Degree of purity and/or identity of impurities or additives	EUR 3 133	EUR 2 350	EUR 1 687	EUR 1 265	EUR 241	EUR 181
Relevant tonnage band	EUR 1 044	EUR 783	EUR 562	EUR 422	EUR 80	EUR 60
A study summary or a robust study summary	EUR 3 133	EUR 2 350	EUR 1 687	EUR 1 265	EUR 241	EUR 181
Information in the safety data sheet	EUR 2 088	EUR 1 566	EUR 1 125	EUR 843	EUR 161	EUR 120
Trade name of the substance	EUR 1 044	EUR 783	EUR 562	EUR 422	EUR 80	EUR 60
IUPAC name for non-phase- in substances referred to in Article 119(1)(a) of Regulation (EC) No 1907/2006	EUR 1 044	EUR 783	EUR 562	EUR 422	EUR 80	EUR 60
IUPAC name for substances referred to in Article 119(1)(a) of Regulation (EC) No 1907/2006 used as intermediates, in scientific research and development or in product and process orientated	EUR 1 044	EUR 783	EUR 562	EUR 422	EUR 80	EUR 60

research and			
development			

# ANNEX V

# Fees and charges for PPORD notifications under Article 9 of Regulation (EC) No 1907/2006

## TABLE 1

#### FEES FOR PPORD NOTIFICATIONS

Standard fee	EUR 536
Reduced fee for medium enterprise	EUR 348
Reduced fee for small enterprise	EUR 187
Reduced fee for micro enterprise	EUR 27

## TABLE 2

#### CHARGES FOR THE EXTENSION OF A PPORD EXEMPTION

Standard charge	EUR 1 071
Reduced charge for medium enterprise	EUR 696
Reduced charge for small enterprise	EUR 375
Reduced charge for micro enterprise	EUR 54

# ANNEX VI

# Fees for applications for an authorisation under Article 62 of Regulation (EC) No 1907/2006

## TABLE 1

#### STANDARD FEES

Base fee	EUR 53 300
Additional fee per substance	EUR 10 660
Additional fee per use	EUR 10 660
Additional fee per applicant	Additional applicant is not an SME: EUR 39 975
	Additional applicant is a medium enterprise: EUR 29 981
	Additional applicant is a small enterprise: EUR 17 989
	Additional applicant is a micro enterprise: EUR 3 998

#### TABLE 2

#### **Reduced fees for medium enterprises**

Base fee	EUR 39 975
Additional fee per substance	EUR 7 995
Additional fee per use	EUR 7 995
Additional fee per applicant	Additional applicant is a medium enterprise: EUR 29 981
	Additional applicant is a small enterprise: EUR 17 989
	Additional applicant is a micro enterprise: EUR 3 998

## **Reduced fees for small enterprises**

Base fee	EUR 23 985
Additional fee per substance	EUR 4 797
Additional fee per use	EUR 4 797
Additional fee per applicant	Additional applicant is a small enterprise: EUR 17 989
	Additional applicant is a micro enterprise: EUR 3 998

# TABLE 4

## **REDUCED FEES FOR MICRO ENTERPRISES**

Base fee	EUR 5 330
Additional fee per substance	EUR 1 066
Additional fee per use	EUR 1 066
Additional fee per applicant	Additional applicant: EUR 3 998

## ANNEX VII

# Charges for the review of an authorisation under Article 61 of Regulation (EC) No 1907/2006

## TABLE 1

#### STANDARD CHARGES

Base charge	EUR 53 300
Additional charge per use	EUR 10 660
Additional charge per substance	EUR 10 660
Additional charge per applicant	Additional applicant is not an SME: EUR 39 975
	Additional applicant is a medium enterprise: EUR 29 981
	Additional applicant is a small enterprise: EUR 17 989
	Additional applicant is a micro enterprise: EUR 3 998

#### TABLE 2

#### **REDUCED CHARGES FOR MEDIUM ENTERPRISES**

Base charge	EUR 39 975
Additional charge per use	EUR 7 995
Additional charge per substance	EUR 7 995
Additional charge per applicant	Additional applicant is a medium enterprise: EUR 29 981
	Additional applicant is a small enterprise: EUR 17 989
	Additional applicant is a micro enterprise: EUR 3 998

### **Reduced charges for small enterprises**

Base charge	EUR 23 985
Additional charge per use	EUR 4 797
Additional charge per substance	EUR 4 797
Additional charge per applicant	Additional applicant is a small enterprise: EUR 17 989
	Additional applicant is a micro enterprise: EUR 3 998

## TABLE 4

#### **REDUCED CHARGES FOR MICRO ENTERPRISES**

Base charge	EUR 5 330
Additional charge per use	EUR 1 066
Additional charge per substance	EUR 1 066
Additional charge per applicant	Additional applicant is a micro enterprise: EUR 3 998

# ANNEX VIII

# Fees for appeals under Article 92 of Regulation (EC) NO 1907/2006

## TABLE 1

#### STANDARD FEES

Appeal against decision taken under:	Fee
Article 9 or 20 of Regulation (EC) No 1907/2006	EUR 2 356
Article 27 or 30 of Regulation (EC) No 1907/2006	EUR 4 712
Article 51 of Regulation (EC) No 1907/2006	EUR 7 069

# TABLE 2

Appeal against decision taken under:	Fee
Article 9 or 20 of Regulation (EC) No 1907/2006	EUR 1 767
Article 27 or 30 of Regulation (EC) No 1907/2006	EUR 3 534
Article 51 of Regulation (EC) No 1907/2006	EUR 5 301'