

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)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 74(1) and Article 132 thereof,

Whereas:

- (1) The structure and amounts of the fees and charges collected by the European Chemicals Agency, hereinafter the 'Agency', as well as the rules for payment should be established.
- (2) The structure and amount of the fees should take account of the work required by Regulation (EC) No 1907/2006 to be carried out by the Agency and the competent authorities and should be fixed at such a level as to ensure 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. The fees for registration should also take into account the work that may be done pursuant to Title VI of Regulation (EC) No 1907/2006.
- (3) A fee should be set for the registration of substances which should depend on the tonnage range of those substances. However, no fee should be levied for registrations covered by Article 74(2) of Regulation (EC) No 1907/2006.
- (4) Specific fees should be levied in the case of registrations of isolated intermediates submitted under Article 17(2), Article 18(2) or (3) or Article 19 of Regulation (EC) No 1907/2006.

(5) Requests made in accordance with Article 10(a)(xi) of Regulation (EC) No 1907/2006 should also give rise to the payment of a fee.

(6) A fee should be levied for updates to the registration. In particular, a fee should be paid for updates of the tonnage range, for changes in the identity of the registrant involving a change in legal personality, and for certain changes in the status of the information contained in the registration.

(7) A fee should be levied for the notification of information concerning product and process oriented research and development (PPORD) in accordance with Article 9 of Regulation (EC) No 1907/2006. A charge should be levied also for any request for an extension of a PPORD exemption.

(8) A fee should be levied for the submission of an application for an authorisation. The fee should consist of a base fee that should cover one substance, one use, and one applicant, and additional fees for any additional substance, use, or applicant covered by the application. A charge should also be levied for the submission of a review report.

(9) Reduced fees and charges should apply in the case of certain joint submissions. Reduced fees and charges should also apply to micro, small and medium-sized enterprises (SMEs) within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises ⁽²⁾.

(10) In case of an only representative, the assessment of whether the reduction for SMEs applies should be done by reference to the headcount, turnover and balance sheet information of the non-Community manufacturer, formulator of a preparation, or producer of an article that is represented by that only representative in connection with that transaction, including relevant information from linked and partner companies of the non-Community manufacturer, formulator of a preparation, or producer of an article, in accordance with Recommendation 2003/361/EC.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1, as corrected by OJ L 136, 29.5.2007, p. 3. Regulation as amended by Council Regulation (EC) No 1354/2007 (OJ L 304, 22.11.2007, p. 1).

⁽²⁾ OJ L 124, 20.5.2003, p. 36.

- (11) Reductions provided for in this Regulation should apply on the basis of a declaration of the entity that claims to be entitled to the reduction. The submission of false information should be discouraged by the imposition of an administrative charge by the Agency and a dissuasive fine by the Member States, if appropriate.
- (12) A fee should be levied for any appeal lodged in accordance with Article 92 of Regulation (EC) No 1907/2006. The amount of the fee should take into account the complexity of the work involved.
- (13) Fees and charges should be levied in euro only.
- (14) A proportion of the fees and charges collected by the Agency should be transferred to the competent authorities of the Member States to compensate them for the work of the rapporteurs of the committees of the Agency and, as appropriate, for other tasks provided for in Regulation (EC) No 1907/2006. The maximum proportion of the fees and charges to be transferred to the competent authorities of the Member States should be determined by the Management Board of the Agency following a favourable opinion from the Commission.
- (15) In fixing the amounts to be transferred to the competent authorities of the Member States and in fixing any necessary remuneration in respect of any other agreed work done for the Agency, the Management Board of the Agency should observe the principle of sound financial management as defined in Article 27 of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities⁽¹⁾. It should also ensure that the Agency continues to have available sufficient financial resources to undertake its tasks, having regard to existing and pluriannual estimated budgetary appropriations and it should take into account the workload involved for the competent authorities of the Member States.
- (16) Deadlines for the payment of fees and charges levied under this Regulation should be fixed taking due account of the deadlines of the procedures provided for in Regulation (EC) No 1907/2006. In particular, the first deadline for payment of the fee in connection with the submission of a registration dossier or the submission of an update should be fixed taking into account the deadlines during which the Agency must perform the completeness check. Likewise, the first deadline for payment of fees in connection with notifications for an exemption from the obligation to register for product and process orientated research and development

should be fixed taking into account the deadline provided for in Article 9(5) of Regulation (EC) No 1907/2006. However, a second reasonable deadline should be set by the Agency for payments that are not made before expiry of the first deadline.

- (17) Fees and charges provided for under this Regulation should be adapted to take account of inflation and for that purpose the European Index of Consumer Prices published by Eurostat pursuant to Council Regulation (EC) No 2494/95 of 23 October 1995 concerning harmonised indices of consumer prices⁽²⁾ should be used.
- (18) 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:

CHAPTER I

SUBJECT MATTER AND DEFINITIONS

Article 1

Subject matter

This Regulation lays down the amounts, and rules for payment, of the fees and charges levied by the European Chemicals Agency, hereinafter the 'Agency', as provided for in Regulation (EC) No 1907/2006.

Article 2

Definitions

For the purposes of this Regulation:

1. 'SME' means a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC;
2. 'medium enterprise' means a medium-sized enterprise within the meaning of Recommendation 2003/361/EC;
3. 'small enterprise' means a small enterprise within the meaning of Recommendation 2003/361/EC;
4. 'micro enterprise' means a micro enterprise within the meaning of Recommendation 2003/361/EC.

⁽¹⁾ OJ L 248, 16.9.2002, p. 1. Regulation as last amended by Regulation (EC) No 1525/2007 (OJ L 343, 27.12.2007, p. 9).

⁽²⁾ OJ L 257, 27.10.1995, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

CHAPTER II
FEES AND CHARGES

Article 3

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

1. The Agency shall levy a fee, as provided for in paragraphs 2, 3 and 4 of this Article, for any registration of a substance under Article 6, 7 or 11 of Regulation (EC) No 1907/2006.

However, no fee shall be levied for the registration of a substance in a quantity of between 1 and 10 tonnes where the submission of the registration contains all the information required in Annex VII to Regulation (EC) No 1907/2006, as provided for in Article 74(2) of that Regulation.

2. Where the submission for registration of a substance in the range of 1 to 10 tonnes does not contain all the information required in Annex VII to Regulation (EC) No 1907/2006, the Agency shall levy a fee, as set out in Annex I to this Regulation.

The Agency shall levy a fee for any registration of a substance in a quantity of 10 tonnes or more, as set out in Annex I.

3. In the case of a joint submission the Agency shall levy a reduced fee on each registrant, as set out in Annex I.

However, if a registrant submits separately part of the relevant information referred to in Article 10(a)(iv), (vi), (vii) and (ix) of Regulation (EC) No 1907/2006, the Agency shall levy a fee for an individual submission on that registrant, as set out in Annex I to this Regulation.

4. Where the registrant is an SME, the Agency shall levy a reduced fee, as set out in Table 2 of Annex I.

5. Fees due under paragraphs 1 to 4 shall be paid within 14 calendar days from the date on which the invoice is notified to the registrant by the Agency.

However, invoices linked to a registration of a pre-registered substance that is submitted to the Agency during the two months that precede the relevant registration deadline of Article 23 of Regulation (EC) No 1907/2006 shall be paid within 30 days from the date on which the invoice is notified to the registrant by the Agency.

6. Where the payment is not made before expiry of the deadline provided for in paragraph 5, the Agency shall set a second deadline for the payment. Where the payment is not

made before expiry of the second deadline, the registration shall be rejected.

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 shall not be refunded or otherwise credited to the registrant.

Article 4

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

1. The Agency shall levy a fee, as provided for in paragraphs 2, 3 and 4 of this Article, for any registration of an on-site or transported isolated intermediate under Article 17(2), Article 18(2) or (3) or Article 19 of Regulation (EC) No 1907/2006.

However, no fee shall be levied for the registration of an on-site or transported isolated intermediate in a quantity of between 1 and 10 tonnes where the submission of the registration contains all the information required in Annex VII to Regulation (EC) No 1907/2006 as provided for in Article 74(2) of that Regulation.

The fees under this Article shall only apply to registrations of on-site or transported isolated intermediates submitted under Article 17(2), Article 18(2) or (3) or Article 19 of Regulation (EC) No 1907/2006. In the case of registrations of intermediate substances that require the information specified in Article 10 of Regulation (EC) No 1907/2006, the fees set out in Article 3 of this Regulation shall apply.

2. Where the submission for registration of an on-site or transported isolated intermediate in the range of 1 to 10 tonnes does not contain all the information required in Annex VII to Regulation (EC) No 1907/2006, the Agency shall levy a fee, as set out in Annex II to this Regulation.

The Agency shall levy a fee for any registration of an on-site or transported isolated intermediate in a quantity of 10 tonnes or more, as set out in Annex II.

3. In the case of a joint submission the Agency shall levy a reduced fee on each registrant, as set out in Annex II.

However, if a registrant submits separately part of the relevant information referred to in Article 17(2)(c) and (d), or Article 18(2)(c) and (d) of Regulation (EC) No 1907/2006, the Agency shall levy a fee for an individual submission on that registrant, as set out in Annex II to this Regulation.

4. Where the registrant is an SME, the Agency shall levy a reduced fee, as set out in Table 2 of Annex II.

5. Fees due under paragraphs 1 to 4 shall be paid within 14 calendar days from the date on which the invoice is notified to the registrant by the Agency.

However, invoices linked to a registration of a pre-registered substance that is submitted to the Agency during the two months that precede the relevant registration deadline of Article 23 of Regulation (EC) No 1907/2006 shall be paid within 30 days from the date on which the invoice is notified to the registrant by the Agency.

6. Where the payment is not made before the expiry of the deadline provided for in paragraph 5, the Agency shall set a second deadline for the payment. Where the payment is not made before the expiry of the second deadline, the registration shall be rejected.

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 shall not be refunded or otherwise credited to the registrant.

Article 5

Fees for updates of a registration under Article 22 of Regulation (EC) No 1907/2006

1. The Agency shall levy a fee, as provided for in paragraphs 2, 3 and 4 of this Article, for updates of a registration under Article 22 of Regulation (EC) No 1907/2006.

However, the Agency shall not levy a fee for the following updates of a registration:

- (a) a change from a higher to a lower tonnage range;
- (b) a change from a lower to a higher tonnage range if the registrant has previously paid the fee for that higher tonnage range;
- (c) a change in the status of the registrant or his identity, provided that it does not involve a change in legal personality;
- (d) a change in the composition of the substance;
- (e) information on new uses including uses advised against;
- (f) information on new risks of the substance;

(g) a change in the classification and labelling of the substance;

(h) a change in the chemical safety report;

(i) a change in the guidance on safe use;

(j) a notification that a test listed in Annex IX or X to Regulation (EC) No 1907/2006 must be developed;

(k) a request for previously confidential information to be accessible.

2. The Agency shall levy a fee for updates of the tonnage range, as set out in Tables 1 and 2 of Annex III.

For other updates, the Agency shall levy a fee, as set out in Tables 3 and 4 of Annex III.

3. In the case of an update to a joint submission the Agency shall levy a reduced fee on each registrant submitting the update, as set out in Annex III.

However, if part of the relevant information referred to in Article 10(a)(iv), (vi), (vii) and (ix), Article 17(2)(c) and (d), or Article 18(2)(c) and (d) of Regulation (EC) No 1907/2006 is submitted separately, the Agency shall levy a fee for an individual submission, as set out in Annex III to this Regulation.

4. Where the registrant is an SME, the Agency shall levy a reduced fee, as set out in Annex III.

However, in cases of updates involving a change in the identity of the registrant, the SME reduction shall apply only if the new entity is an SME.

5. Fees due under paragraphs 1 to 4 shall be paid within 14 calendar days from the date on which the invoice is notified to the registrant by the Agency.

6. Where the payment is not made before expiry of the deadline provided for in paragraph 5, the Agency shall set a second deadline for the payment.

Where the payment is not made before expiry of the second deadline, in the case of updates of the tonnage range submitted in accordance with Article 22(1)(c) of Regulation (EC) No 1907/2006, the update shall be rejected.

Where the payment is not made before expiry of the second deadline, in the case of other updates, the update shall be rejected after the Agency has given formal warning to the registrant.

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 shall not be refunded or otherwise credited to the registrant.

Article 6

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

1. The Agency shall levy a fee, as provided for in paragraphs 2, 3 and 4 of this Article, for any request under Article 10(a)(xi) of Regulation (EC) No 1907/2006.

2. The Agency shall levy a fee per item for which a request is made, as set out in Annex IV.

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

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

4. Where the request is made by an SME, the Agency shall levy a reduced fee, as set out in Table 2 of Annex IV.

5. The date on which the fee levied for a request is received by the Agency shall be considered to be the date of receipt of the request.

Article 7

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

1. The Agency shall levy a fee, as set out in Table 1 of Annex V to this Regulation, for any notification for an exemption from the general obligation to register for product and process orientated research and development, hereinafter 'PPORD', under Article 9 of Regulation (EC) No 1907/2006.

Where the notification is made by an SME, the Agency shall levy a reduced fee as set out in Table 1 of Annex V.

2. The Agency shall levy a charge, as set out in Table 2 of Annex V to this Regulation, for any request to extend an

exemption from the general obligation to register for PPORD under Article 9 of Regulation (EC) No 1907/2006.

Where the request is made by an SME, the Agency shall levy a reduced charge as set out in Table 2 of Annex V.

3. Fees due under paragraph 1 shall be paid within seven calendar days from the date on which the invoice is notified by the Agency to the manufacturer, importer, or producer of articles making the notification.

Charges due under paragraph 2 shall be paid within 30 calendar days from the date on which the invoice is notified by the Agency to the manufacturer, importer, or producer of articles requesting an extension.

4. Where the payment is not made before expiry of the deadline provided for in paragraph 3, the Agency shall set a second deadline for the payment.

Where the payment is not made before expiry of the second deadline, the notification or the request for an extension shall be rejected.

5. Where a notification or the request for an extension has been rejected due to the failure of the registrant 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 shall not be refunded or otherwise credited to the person making the notification or the request.

Article 8

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

1. The Agency shall levy a fee, as provided for in paragraphs 2 and 3 of this Article, for any application for an authorisation of a substance under Article 62 of Regulation (EC) No 1907/2006.

2. The Agency shall levy a base fee for any application for an authorisation of a substance, as set out in Annex VI. The base fee shall cover the application for an authorisation for one substance, one use, and one applicant.

The Agency shall levy an additional fee, as set out in Annex VI to this Regulation, for each additional use, for each additional substance that meets the definition of a group of substances as defined in Section 1(5) of Annex XI to Regulation (EC) No 1907/2006 and that is covered by the application, and for each additional applicant that is party to the application.

For the purposes of this paragraph, each exposure scenario shall be considered a different use.

3. Where the application is submitted by a medium enterprise or by two or more SMEs only, of which the largest enterprise is a medium enterprise, the Agency shall levy a reduced base fee and reduced additional fees, as set out in Table 2 of Annex VI.

Where the application is submitted by a small enterprise or by two or more SMEs only, of which the largest enterprise is a small enterprise, the Agency shall levy a reduced base fee and reduced additional fees, as set out in Table 3 of Annex VI.

Where the application is submitted by one or more micro enterprises only, the Agency shall levy a reduced base fee and reduced additional fees, as set out in Table 4 of Annex VI.

4. The date on which the fee levied for the application for an authorisation is received by the Agency shall be considered to be the date of receipt of the application.

Article 9

Charges for reviews of authorisations under Article 61 of Regulation (EC) No 1907/2006

1. The Agency shall levy a charge, as provided for in paragraphs 2 and 3 of this Article, for any submission of a review report under Article 61 of Regulation (EC) No 1907/2006.

2. The Agency shall levy a base charge for submission of any review report, as set out in Annex VII. The base charge shall cover the submission of a review report for one substance, one use, and one applicant.

The Agency shall levy an additional charge, as set out in Annex VII to this Regulation, for each additional use, for each additional substance that meets the definition of a group of substances as defined in Section 1(5) of Annex XI to Regulation (EC) No 1907/2006 and that is covered by the review report, and for each additional entity covered by the review report.

For the purposes of this paragraph, each exposure scenario shall be considered a different use.

3. Where the application is submitted by a medium enterprise or by two or more SMEs only, of which the largest enterprise is a medium enterprise, the Agency shall levy a reduced base charge and reduced additional charges, as set out in Table 2 of Annex VII.

Where the application is submitted by a small enterprise or by two or more SMEs only, of which the largest enterprise is a

small enterprise, the Agency shall levy a reduced base charge and reduced additional charges, as set out in Table 3 of Annex VII.

Where the application is submitted by one or more micro enterprises only, the Agency shall levy a reduced base charge and reduced additional charges as set out in Table 4 of Annex VII.

4. The date on which the charge levied for submission of the review report is received by the Agency shall be considered to be the date of receipt of the submission.

Article 10

Fees for appeals against a decision of the Agency under Article 92 of Regulation (EC) No 1907/2006

1. The Agency shall levy a fee, as set out in Annex VIII to this Regulation, for any submission of an appeal against a decision of the Agency under Article 92 of Regulation (EC) No 1907/2006.

2. Where the appeal is submitted by an SME, the Agency shall levy a reduced fee, as set out in Table 2 of Annex VIII.

3. If the appeal is considered inadmissible by the Board of Appeal, the fee shall not be refunded.

4. The Agency shall refund the fee levied in accordance with paragraph 1 of this Article if the Executive Director of the Agency rectifies a decision in accordance with Article 93(1) of Regulation (EC) No 1907/2006, or if the appeal is decided in favour of the appellant.

5. An appeal shall not be considered to be received by the Board of Appeal until the relevant fee has been received by the Agency.

Article 11

Other charges

1. A charge may be levied for administrative and technical services provided by the Agency at the request of a party which are not covered by another fee or charge provided for in this Regulation. The level of the charge shall take into account the workload involved.

However, charges shall not be levied for the assistance provided by its Helpdesk and for the support to Member States as provided for in Article 77(2)(h) and (i) of Regulation (EC) No 1907/2006.

The Executive Director of the Agency may decide not to levy a charge on international organisations or countries that request assistance from the Agency.

2. The charges for administrative services shall be paid within 30 calendar days from the date on which the invoice is notified by the Agency.

3. Where the payment is not made before expiry of the deadline provided for in paragraph 2, the Agency shall set a second deadline for the payment.

Where the payment is not made before expiry of the second deadline, the Agency shall reject the request.

4. In the absence of contractual agreement to the contrary, the charges for technical services shall be paid before the service is provided.

5. A classification of the services and charges shall be drawn up by the Management Board of the Agency and adopted after a favourable opinion by the Commission.

Article 12

Only representatives

In the case of an only representative referred to in Article 8 of Regulation (EC) No 1907/2006, the assessment of whether the reduction for SMEs applies shall be determined by reference to the headcount, turnover and balance sheet information of the non-Community manufacturer, formulator of a preparation, or producer of an article that is represented by that only representative in connection with the transaction concerned, including relevant information from linked and partner companies of the non-Community manufacturer, formulator of a preparation, or producer of an article, in accordance with Recommendation 2003/361/EC.

Article 13

Reductions and fee waiver

1. A natural or legal person that claims to be entitled to a reduced fee or charge under Articles 3 to 10 shall inform the Agency thereof at the time of the submission of the registration, update of registration, request, notification, application, review report or appeal giving rise to the payment of the fee.

2. A natural or legal person that claims to be entitled to the fee waiver under Article 74(2) of Regulation (EC) No 1907/2006 shall inform the Agency thereof at the time of the submission of the registration.

3. The Agency may request, at any time, evidence that the conditions for a reduction of fees or charges or for a fee waiver apply.

4. Where a natural or legal person that claims to be entitled to a reduction or a fee waiver cannot demonstrate that it is entitled to such a reduction or waiver, the Agency shall levy the full fee or charge as well as an administrative charge.

Where a natural or legal person that has claimed to be entitled to a reduction has already paid a reduced fee or charge, but cannot demonstrate that it is entitled to such a reduction, the Agency shall levy the balance of the full fee or charge as well as an administrative charge.

Paragraphs 2, 3 and 5 of Article 11 shall apply *mutatis mutandis*.

CHAPTER III

PAYMENT OF REMUNERATION BY THE AGENCY

Article 14

Transfers of funds to Member States

1. A proportion of the fees and charges collected under this Regulation shall be transferred to the competent authorities of the Member States in the following cases:

- (a) where the competent authority of the Member State notifies to the Agency the conclusion of an evaluation procedure for a substance in accordance with Article 46(4) of Regulation (EC) No 1907/2006;
- (b) where the competent authority has appointed a member of the Committee for Risk Assessment who acts as rapporteur in the context of an authorisation procedure, including in the context of a review;
- (c) where the competent authority of the Member State has appointed a member of the Committee for Socioeconomic Analysis who acts as rapporteur in the context of an authorisation procedure, including in the context of a review;
- (d) where the competent authority of the Member State has appointed a member of the Committee for Risk Assessment who acts as rapporteur in the context of a restrictions procedure;
- (e) where the competent authority of the Member State has appointed a member of the Committee for Socioeconomic Analysis who acts as rapporteur in the context of a restrictions procedure;
- (f) where appropriate, for other tasks performed by the competent authorities at the request of the Agency.

When the Committees referred to in this paragraph decide to appoint a co-rapporteur, the transfer shall be divided between the rapporteur and the co-rapporteur.

2. The amounts for each of the tasks identified under paragraph 1 of this Article and the maximum proportion of the fees and charges to be transferred to the competent authorities of the Member States as well as any arrangements necessary for the transfer, shall be set by the Management Board of the Agency following a favourable opinion from the Commission. In fixing the amounts to be transferred, the Management Board of the Agency shall comply with the principles of economy, efficiency and effectiveness as defined in Article 27 of Regulation (EC, Euratom) No 1605/2002. It shall also ensure that the Agency continues to have available sufficient financial resources to undertake its tasks as defined in Regulation (EC) No 1907/2006, having regard to its existing budgetary appropriations and pluriannual estimates of income, including a Community subsidy, and it shall take into account the workload for the competent authorities of the Member States.

3. Transfers provided for in paragraph 1 shall be made only after the relevant report has been made available to the Agency.

However, the Management Board of the Agency may decide to authorise pre-financing or interim payments in accordance with Article 81(1) of Regulation (EC, Euratom) No 1605/2002.

4. The transfers of funds provided for in points (b) to (e) of paragraph 1 are intended to compensate competent authorities of a Member State for the work of the rapporteur or co-rapporteur and for any related scientific and technical support and shall be without prejudice to the obligation of Member States not to give instructions incompatible with the independence of the Agency.

Article 15

Other remuneration

In fixing the amounts of the payments made to remunerate experts or co-opted members of the committees for work done for the Agency in accordance with Article 87(3) of Regulation (EC) No 1907/2006, the Management Board of the Agency shall take into account the workload involved and it shall comply with the principles of economy, efficiency and effectiveness as defined in Article 27 of the Regulation (EC, Euratom) No 1605/2002. It shall also ensure that the Agency has sufficient financial resources available to undertake its tasks as defined in Regulation (EC) No 1907/2006, having regard to its existing budgetary appropriations and pluriannual estimates of income, including a Community subsidy.

CHAPTER IV

PAYMENTS

Article 16

Mode of payment

1. The fees and charges shall be paid in euro.

2. Payments shall be made only after the Agency has issued an invoice, with the exception of payments due under Article 10.

3. Payments shall be made by means of a transfer to the bank account of the Agency.

Article 17

Identification of the payment

1. Every payment must indicate in the reference field the invoice number, with the exception of payments due under Article 10.

Payments due under Article 10 shall indicate in the reference field the identity of the appellant(s) and, if available, the number of the decision that is being appealed.

2. If the purpose of the payment cannot be established, the Agency shall set a deadline by which the payer must notify it in writing of the purpose of the payment. If the Agency does not receive a notification of the purpose of the payment before expiry of that deadline, the payment shall be considered invalid and the amount concerned shall be refunded to the payer.

Article 18

Date of payment

1. The date on which the full amount of the payment is deposited in a bank account held by the Agency shall be considered to be the date on which the payment has been made.

2. The payment shall be considered to have been made in time where sufficient documentary evidence is produced to show that the payer ordered the transfer to the bank account indicated on the invoice before expiry of the relevant deadline.

A confirmation of the transfer order issued by a financial institution shall be regarded as sufficient evidence. However, where the transfer requires the use of the SWIFT electronic bank payment method, the acknowledgement of provision of the transfer order shall take the form of a copy of the SWIFT report, stamped and signed by a duly authorised official of a financial institution.

Article 19

Insufficient payment

1. A deadline for payment shall be considered to have been observed only if the full amount of the fee or charge has been paid in due time.

2. When an invoice relates to a group of transactions, the Agency may attribute any under-payment to any of the relevant transactions. The criteria for the attribution of payments shall be laid down by the Management Board of the Agency.

Article 20

Refund of amounts paid in excess

1. The arrangements for the refund to the payer of amounts paid in excess of a fee or a charge shall be fixed by the Executive Director of the Agency and published on the website of the Agency.

However, where an amount paid in excess is under EUR 100 and the party concerned has not expressly requested a refund, the amount paid in excess shall not be refunded.

2. It shall not be possible to count any amounts paid in excess towards future payments to the Agency.

CHAPTER V

FINAL PROVISIONS

Article 21

Provisional estimate

The Management Board of the Agency shall, when producing an estimate of the overall expenditure and income for the

following financial year in accordance with Article 96(5) of Regulation (EC) No 1907/2006, include a specific provisional estimate of income from fees and charges which is separate from income from any subsidy from the Community.

Article 22

Review

1. The fees and charges provided for in this Regulation shall be reviewed annually 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. A first review shall be carried out by 1 June 2009.

2. The Commission shall also keep this Regulation under continual review in the light of significant information becoming available in relation to the underlying assumptions for anticipated income and expenditure of the Agency. At the latest, by 1 January 2013, 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.

Article 23

Entry into force

This Regulation shall enter into force on the third day following 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, 16 April 2008.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX I

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

Table 1

Standard fees

(EUR)

	Individual submission	Joint submission
Fee for substances in the range of 1 to 10 tonnes	1 600	1 200
Fee for substances in the range 10 to 100 tonnes	4 300	3 225
Fee for substances in the range 100 to 1 000 tonnes	11 500	8 625
Fee for substances above 1 000 tonnes	31 000	23 250

Table 2

Reduced fees for SMEs

(EUR)

	Medium enterprise (Individual submission)	Medium enterprise (Joint submission)	Small enterprise (Individual submission)	Small enterprise (Joint submission)	Micro enterprise (Individual submission)	Micro enterprise (Joint submission)
Fee for substances in the range of 1 to 10 tonnes	1 120	840	640	480	160	120
Fee for substances in the range 10 to 100 tonnes	3 010	2 258	1 720	1 290	430	323
Fee for substances in the range 100 to 1 000 tonnes	8 050	6 038	4 600	3 450	1 150	863
Fee for substances above 1 000 tonnes	21 700	16 275	12 400	9 300	3 100	2 325

ANNEX II

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

Table 1

Standard fees

(EUR)

	Individual submission	Joint submission
Fee	1 600	1 200

Table 2

Reduced fees for SMEs

(EUR)

	Medium enterprise (Individual submission)	Medium enterprise (Joint submission)	Small enterprise (Individual submission)	Small enterprise (Joint submission)	Micro enterprise (Individual submission)	Micro enterprise (Joint submission)
Fee	1 120	840	640	480	160	120

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

(EUR)

	Individual submission	Joint submission
From 1-10 tonnes range to 10-100 tonnes range	2 700	2 025
From 1-10 tonnes range to 100-1 000 tonnes range	9 900	7 425
From 1-10 tonnes range to over 1 000 tonnes range	29 400	22 050
From 10-100 tonnes range to 100-1 000 tonnes range	7 200	5 400
From 10-100 tonnes range to over 1 000 tonnes range	26 700	20 025
From 100-1 000 tonnes range to over 1 000 tonnes range	19 500	14 625

Table 2

Reduced fees for SMEs for the update of the tonnage range

(EUR)

	Medium enterprise	Medium enterprise	Small enterprise	Small enterprise	Micro enterprise	Micro enterprise
	(Individual submission)	(Joint submission)	(Individual submission)	(Joint submission)	(Individual submission)	(Joint submission)
From 1-10 tonnes range to 10-100 tonnes range	1 890	1 418	1 080	810	270	203
From 1-10 tonnes range to 100-1 000 tonnes range	6 930	5 198	3 960	2 970	990	743
From 1-10 tonnes range to over 1 000 tonnes range	20 580	15 435	11 760	8 820	2 940	2 205
From 10-100 tonnes range to 100-1 000 tonnes range	5 040	3 780	2 880	2 160	720	540
From 10-100 tonnes range to over 1 000 tonnes range	18 690	14 018	10 680	8 010	2 670	2 003
From 100-1 000 tonnes range to over 1 000 tonnes range	13 650	10 238	7 800	5 850	1 950	1 463

Table 3

Fees for other updates

(EUR)

Type of update		
Change in identity of the registrant involving a change in legal personality	1 500	
Type of update	Individual submission	Joint submission
Change in the access granted to information in the submission (per item)	1 500	1 125

Table 4

Reduced fees for SMEs for other Updates

(EUR)

Type of update	Medium enterprise		Small enterprise		Micro enterprise	
Change in identity of the registrant involving a change in legal personality	1 050		600		150	
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 (per item)	1 050	788	600	450	150	113

ANNEX IV

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

Table 1

Standard fees

(EUR)

Item for which confidentiality is requested	Individual submission	Joint submission
Degree of purity and/or identity of impurities or additives	4 500	3 375
Relevant tonnage band	1 500	1 125
A study summary or a robust study summary	4 500	3 375
Information in the safety data sheet	3 000	2 250
Trade name of the substance	1 500	1 125
IUPAC name for non-phase in substances that are dangerous	1 500	1 125
IUPAC name for dangerous substances used as intermediates, in scientific research and development or product process oriented research and development	1 500	1 125

Table 2

Reduced fees for SMEs

(EUR)

Item for which confidentiality is requested	Medium enterprise	Medium enterprise	Small enterprise	Small enterprise	Micro enterprise	Micro enterprise
	(Individual submission)	(Joint submission)	(Individual submission)	(Joint submission)	(Individual submission)	(Joint submission)
Degree of purity and/or identity of impurities or additives	3 150	2 363	1 800	1 350	450	338
Relevant tonnage band	1 050	788	600	450	150	113
A study summary or a robust study summary	3 150	2 363	1 800	1 350	450	338
Information in the safety data sheet	2 100	1 575	1 200	900	300	225
Trade name of the substance	1 050	788	600	450	150	113
IUPAC name for non-phase in substances that are dangerous	1 050	788	600	450	150	113
IUPAC name for dangerous substances used as intermediates, in scientific research and development or product process oriented research and development	1 050	788	600	450	150	113

ANNEX V

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

Table 1

Fees for PPORD notifications

<i>(EUR)</i>	
Standard fee	500
Reduced fee for medium enterprise	350
Reduced fee for small enterprise	200
Reduced fee for micro enterprise	50

Table 2

Charges for the extension of a PPORD exemption

<i>(EUR)</i>	
Standard charge	1 000
Reduced charge for medium enterprise	700
Reduced charge for small enterprise	400
Reduced charge for micro enterprise	100

ANNEX VI

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

Table 1

Standard fees

Base fee	EUR 50 000
Additional fee per substance	EUR 10 000
Additional fee per use	EUR 10 000
Additional fee per applicant	Additional applicant is not an SME: EUR 37 500
	Additional applicant is a medium enterprise: EUR 30 000
	Additional applicant is a small enterprise: EUR 18 750
	Additional applicant is a micro enterprise: EUR 5 625

Table 2

Reduced fees for medium enterprises

Base fee	EUR 40 000
Additional fee per substance	EUR 8 000
Additional fee per use	EUR 8 000
Additional fee per applicant	Additional applicant is a Medium enterprise: EUR 30 000
	Additional applicant is a Small enterprise: EUR 18 750
	Additional applicant is a Micro enterprise: EUR 5 625

Table 3

Reduced fees for small enterprises

Base fee	EUR 25 000
Additional fee per substance	EUR 5 000
Additional fee per use	EUR 5 000
Additional fee per applicant	Additional applicant is a small enterprise: EUR 18 750
	Additional applicant is a micro enterprise: EUR 5 625

Table 4

Reduced Fees for micro enterprises

Base fee	EUR 7 500
Additional fee per substance	EUR 1 500
Additional fee per use	EUR 1 500
Additional fee per applicant	Additional applicant: EUR 5 625

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 50 000
Additional charge per use	EUR 10 000
Additional charge per substance	EUR 10 000
Additional charge per applicant	Additional applicant is not an SME: EUR 37 500
	Additional applicant is a Medium enterprise: EUR 30 000
	Additional applicant is a Small enterprise: EUR 18 750
	Additional applicant is a Micro enterprise: EUR 5 625

Table 2

Reduced charges for medium enterprises

Base charge	EUR 40 000
Additional charge per use	EUR 8 000
Additional charge per substance	EUR 8 000
Additional charge per applicant	Additional applicant is a medium enterprise: EUR 30 000
	Additional applicant is a small enterprise: EUR 18 750
	Additional applicant is a micro enterprise: EUR 5 625

Table 3

Reduced charges for small enterprises

Base charge	EUR 25 000
Additional charge per use	EUR 5 000
Additional charge per substance	EUR 5 000
Additional charge per applicant	Additional applicant is a small enterprise: EUR 18 750
	Additional applicant is a micro enterprise: EUR 5 625

Table 4

Reduced charges for micro enterprises

Base charge	EUR 7 500
Additional charge per use	EUR 1 500
Additional charge per substance	EUR 1 500
Additional charge per applicant	Additional applicant is a Micro enterprise: EUR 5 625

ANNEX VIII

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

Table 1

Standard fees

(EUR)

Appeal against decision taken under:	Fee
Article 9 or 20 of Regulation (EC) No 1907/2006	2 200
Article 27 or 30 of Regulation (EC) No 1907/2006	4 400
Article 51 of Regulation (EC) No 1907/2006	6 600

Table 2

Reduced fees for SMEs

(EUR)

Appeal against decision taken under:	Fee
Article 9 or 20 of Regulation (EC) No 1907/2006	1 800
Article 27 or 30 of Regulation (EC) No 1907/2006	3 600
Article 51 of Regulation (EC) No 1907/2006	5 400



REACH COMPLIANCE

EU-27 & Worldwide



► ABOUT B-LANDS CONSULTING

B-Lands Consulting has been successfully providing since 2005 consultancy and **LEAP AHEAD®** services designed to help worldwide organisations comply with European Union regulations.

Our company provides business friendly services on the following European Union environmental regulations:

- **REACH** (Registration, Evaluation and Authorisation of **C**hemicals) legislation
- **ELV / VHU** (End of Life Vehicle:/ Vehicules Hors d'Usage) legislation
- **EuP** (Energy Using Products) legislation
- **WEEE** (Waste Electrical and Electronic Equipment) legislation
- **RoHS** (Restriction of the use of Hazardous **S**ubstances) legislation

► THE B-LANDS REACH CORE TEAM

B-Lands Consulting's REACH core team is composed of **regulatory consultants, jurists** specialised in **EU regulations** and **experts in chemicals**.

Sensible issues involving academic studies are addressed with support from **Joseph-Fourier** University scientists.

► BUILDING PARTNERSHIPS AND GOVERNMENT LINKS

B-Lands Consulting is building up bridges and **collaborative schemes** with other regulation service providers, in the fields of REACH testing (Toxicology, Eco-toxicology), supply chain management, as well as partnerships with international law firms. B-Lands is also working on the opening of early communication channels with **competent national authorities**.

► REACH COMPLIANCE & LEAP AHEAD® SERVICES

- **Substances inventory & labelling**
- **Assessments on REACH compulsory requirements**
- **Compliance roadmap development**
- **Measures affecting the IT shell**
- **Preparation of the substance pre-registration dossiers**
- **Updating of the substance Safety Data Sheets (SDS)**
- **Chemical Safety Assessments (CSA), Chemical Safety Reports (CSR)**
- **Preparation of the substance registration dossiers**
- **Communication with all actors in the supply chain**
- **Participation in Substance Information Exchange Forums (SIEF) [REACH Consortia]**
- **Submissions of the REACH dossiers to the European Chemical Agency (ECHA)**
- **Substances testing process and costs sharing oversight**

► ONLY REPRESENTATIVE & THIRD PARTY REPRESENTATIVE SERVICES

B-Lands Consulting also provides REACH proxy services to operate as:

- **The Only Representative for non-EU Manufacturers**
- **Third Party Representative for EU Manufacturers or EU Importers**

► FLEXIBLE 'ONE-STOP' SERVICES

B-Lands Consulting offers flexible services that address the specifics of each unique **business model**.

Our broad expertise in the field allows us to provide '**one-stop**' REACH compliance services.

► REACHING BUSINESSES IN EU-27 AND WORLDWIDE

REACH COMPLIANCE FRAMEWORK

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.

DIRECTIVE 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency.

B-Lands Consulting is working with the Industry to ensure full compliance with the REACH regulation (Regulation (EC) No 1907/2006) throughout the European Union.

Legal Services :

Identify REACH compliance requirements for all stakeholders (EU manufacturer, EU importers, EU downstream users, Non-EU manufacturers). [**Article 3**, paragraphs (9), (11), (13)]

Identify all chemicals put on the market or substances used in articles (or in the production process) and, for each substance, determine its regulatory status (e.g., EINECS/ELINCS/EC listed, current and likely chemical classification), gather information on its properties, and assess volumes, specific uses, and concentrations. [**Article 12, Title XI**]

Annual Tonnage Bands	Regulation Provisions
Less than 1 tonne	Tonnage band monitoring
1-10 tonnes	Annexes VII, VIII
10 – 100 tonnes	Annexes VIII, IX
100 – 1000 tonnes	Annexes IX, X
More than 1000 tonnes	Annex X

Technical Services :

Identification of the substances that require updated safety data sheets (SDS) -EU format required- [**Title IV, Article 31, Annex 11**]

Identification of the substances that may require the devising and the evaluation of exposure scenarios [**Titles IV, V**]

Identification of the substances that may require toxicology testing

Identification of the substances that require chemical safety assessments (**CSA**) and the preparation of chemical safety reports (**CSR**) [**Articles 10(b), 14, 37, Annexes I, XII**]

Substance toxicology/eco-toxicology testing, extraction of the physico-chemical properties, will be performed in liaison with our REACH Lab partner (approved GLP). [**Annex XI**]

REACH Compliance Process Management :

Roll out a REACH pre-registration plan and pre-requisites, including minimum IT requirements (Integration of **IUCLID 5**, etc.). [**Articles 23, 28**]

Ensure adequate communication with suppliers & importers to assess their commitment to be REACH compliant. [**Titles IV, V**]

Identification of the registrant entity (EU Importer, or a EU based representative of a foreign manufacturer). Ensure the opening of a communication channel with the relevant competent national authority. [**Article 8, Title XIII**]

Evaluate the pros and cons of the different registration schemes (Joint registration process (**OSOR**), independent registration process (confidentiality)) [**Article 11**]. The registration involves “substances” and not “products”. [**Articles 6, 7**]

Define if applicable, a roadmap for the months to come for substances registration [**Article 10, Annex VI**] or authorisation [**Title VII**] process including costs [**Article 74**] estimates based on the identified substances and projected sales/import volumes.

► POWERING ONLINE INDUSTRY FORUMS

B-Lands Consulting is powering Multilanguage **Online Industry Forums on regulation (EC) 1907/2006**.

These discussion forums are open to worldwide businesses dealing with REACH issues ranging from the assessment of the legal statuses, the pre-registration phase, submissions of the registration dossiers, to filling appeals against the ECHA decisions.

Official launch date: 1st October 2007 Website: www.reach-forum.eu

► REACH HELPDESK SERVICES

B-Lands Consulting is extending full **REACH HELPDESK** support for **SME**, to address the most demanding issues affecting small and medium-sized enterprises in the area of REACH Compliance.

Languages: English / French / Chinese

► THE REACH CD-ROM – Understanding REACH in depth

B-Lands Consulting devised a **practical guide** to help achieve REACH compliance across the board. This powerful tool is available on **CD-ROM** in English, French and Chinese.

Online demo: www.reach-cdrom.eu

B-Lands Consulting is located in **Grenoble**, in the Rhône-Alpes region, the leading French region in chemical research and production, biomedical technologies, micro-electronics production and the incubator of many more high-tech fields. The proximity and dynamic interactions with researchers from Grenoble's University of Sciences (**Joseph-Fourier**) contribute greatly to the advancement of many industry players.

Grenoble is 3 hours by bullet train (TGV) from **Paris**, or 1 hour away from **Lyon International Airport (LYS)**, or 3 hours drive on the freeway from **Geneva** (Switzerland). Our office is within 5 minutes walking distance from the main train station, through a rail underpass junction tunnel. Free **Wi-Fi** SSID: *B-Lands (Visitors)*.

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