

Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 564/2013

of 18 June 2013

on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of 22 May 2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products<sup>(1)</sup>, and in particular Article 80(1) thereof,

Whereas:

- (1) The structure and amount of the fees payable to the European Chemicals Agency, (hereinafter referred to as ‘the Agency’), as well as the conditions for payment should be established.
- (2) The structure and amount of the fees should take account of the work required by Regulation (EU) No 528/2012 to be carried out by the Agency. Fees should be set at such a level as to ensure that the revenue derived from them, when combined with other sources of the Agency’s revenue, is sufficient to cover the cost of the services delivered.
- (3) It follows from Article 80(3)(d) of Regulation (EU) No 528/2012 that the structure and amount of fees is to take into account whether information has been submitted jointly or separately. In order to reflect the actual work load of the Agency and to promote joint submission of information, it is appropriate to only levy one fee per application, in case several persons apply jointly for the approval of an active substance or the renewal of an approval of an active substance.
- (4) To take into account the specific needs of small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium sized enterprises<sup>(2)</sup> (hereinafter ‘SMEs’) established in the Union, reduced fees for active substance approval, renewal of approval or inclusion in Annex I to Regulation (EU) No 528/2012 and biocidal product authorisation or renewal should apply to such companies. The levels of the reductions should take into account the significant proportion of SMEs in the biocides sector combined with the interest of avoiding excessive fees for other enterprises while

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ensuring that the Agency's work is fully financed. For the purpose of discouraging applications for products containing active substances fulfilling one of the substitution criteria listed in Article 10(1) of Regulation (EU) No 528/2012, as well as of such active substances, reductions should not apply to applications for such biocidal products or active substances.

- (5) Taking into account the Agency's work required to handle an appeal lodged in accordance with Article 77 of Regulation (EU) No 528/2012, it is appropriate to levy a fee for such appeals in accordance with the third subparagraph of Article 77(1) of that Regulation. However, to avoid penalising persons launching justified appeals, it is appropriate to refund such fees where the appeal is well founded.
- (6) Taking into account the reduced work required by the Agency in cases where applications are rejected before or during validation, or withdrawn during their assessment, it is appropriate to provide for partial refund of fees in such cases.
- (7) For the purpose of encouraging applications for approval of active substances that are suitable alternatives to approved active substances fulfilling one of the exclusion criteria listed in Article 5(1) of Regulation (EU) No 528/2012, it is appropriate to provide for reimbursement of the fee for such applications.
- (8) The fee for applications for inclusion in Annex I to Regulation (EU) No 528/2012 of active substances that do not give rise to concern should take into account the estimated work required by the Agency to handle such applications, as well as the public interest in allowing products containing such substances to be authorised.
- (9) For the purpose of discouraging applications for approval or renewal of approval of active substances fulfilling one of the substitution criteria listed in Article 10(1) of Regulation (EU) No 528/2012 as well as applications for authorisation or renewal of products requiring a comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012, and of contributing to financing the waivers and reductions provided for by this Regulation, it is appropriate to provide for increased fees for such applications.
- (10) In view of the Agency's work required to handle a request for an opinion on the classification of a change in accordance with Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council<sup>(3)</sup>, it is appropriate to levy a fee for such requests. However, to avoid, to the extent possible, penalising applicants whose requests to have a change classified as minor or administrative are justified, it is appropriate to grant a fee reduction to the subsequent application for a change, where the request leads to a recommendation to classify the change as an administrative or minor change.
- (11) Given the Agency's work required to treat submissions for inclusion in the list of relevant persons referred to in Article 95 of Regulation (EU) No 528/2012, it is appropriate to levy a fee for such submissions. The amount of work required for such submission will vary significantly depending on whether the relevant person submits a letter of access or a new dossier, since, in the latter case, the Agency will have to

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check that the dossier complies with Annex II to Regulation (EU) No 528/2012 or, where appropriate, Annex IIA to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing on the market of biocidal products<sup>(4)</sup>. It is appropriate to differentiate the fee accordingly.

- (12) Given the Agency's work required to handle a request for confidentiality in accordance with Article 66(4) of Regulation (EU) No 528/2012, it is appropriate to levy a fee for such requests.
- (13) Since the Agency's budget is drawn up and implemented in euro, and its accounts are also presented in euro in accordance with Article 19 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002<sup>(5)</sup>, with Article 17 of Commission Regulation (EC, Euratom) No 2343/2002 of 23 December 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>(6)</sup> and with Article 17 of the Financial Regulation of the European Chemicals Agency of 24 September 2008<sup>(7)</sup>, it is appropriate to levy fees only in euro.
- (14) It follows from Article 80(3)(f) of Regulation (EU) No 528/2012 that the deadlines for the payment of fees should be fixed taking due account of the deadlines of the procedures provided for in that Regulation.
- (15) The fees set out in this Regulation should be reviewed at appropriate intervals, with a view to aligning the fees with the inflation rate and with the actual costs to the Agency of the services provided. These reviews should take into account the Agency's increased experience in dealing with applications under the Regulation and the efficiencies thereby gained.
- (16) The Standing Committee on Biocidal Products referred to in Article 82(1) of Regulation (EU) No 528/2012 did not deliver an opinion on the measures provided for in this Regulation. Since an implementing act was deemed to be necessary, the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS REGULATION:

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## CHAPTER I

### FEES

#### *Article 1*

#### **Fees for work in relation to active substances**

The Agency shall levy the fees provided for in Table 1 of Annex I for work required by Regulation (EU) No 528/2012 to be carried out in relation to approval and renewal of approval of active substances, as well as inclusion in Annex I to that Regulation.

#### *Article 2*

#### **Fees for work in relation to Union authorisation of biocidal products**

The Agency shall levy the fees provided for in Table 1 of Annex II for work required by Regulation (EU) No 528/2012 to be carried out in relation to Union authorisation of biocidal products.

#### *Article 3*

#### **Other fees**

1 The Agency shall levy the fees provided for in Annex III for work required by Regulation (EU) No 528/2012 to be carried out in relation to establishment of technical equivalence, applications for mutual recognition, requests for inclusion in the list of relevant persons, and requests for confidential treatment of information submitted to the Agency.

2 The Agency shall levy the annual fees provided for in Annex III for every biocidal product or biocidal product family authorised by the Union. The annual fee shall be due on the first and each subsequent anniversary of the entry into force of the authorisation. It shall relate to the preceding year.

#### *Article 4*

#### **Fees for appeals against a decision of the Agency under Article 77 of Regulation (EU) No 528/2012**

1 For any appeal against a decision of the Agency under Article 77 of Regulation (EU) No 528/2012, the Agency shall levy a fee as set out in Annex III.

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

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 if the Executive Director of the Agency rectifies a decision in accordance with Article 93(1) of Regulation (EU) No 1907/2006 of the European Parliament and of the Council<sup>(8)</sup>, or if the appeal is decided in favour of the appellant.

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## Article 5

### **Reimbursement possibility for alternatives to approved active substances fulfilling one of the exclusion criteria**

1 Upon submission of an application to the Agency for the approval of an active substance, which may be a suitable alternative, within the meaning of the second subparagraph of Article 5(2) of Regulation (EU) No 528/2012, to an approved active substance fulfilling one of the exclusion criteria pursuant to Article 5(1) of that Regulation, an applicant may request reimbursement of the fee to be paid to the Agency.

2 Upon receipt of the opinion from the Agency in accordance with Article 8(4) of Regulation (EU) No 528/2012, which shall also include a recommendation on whether the active substance is a suitable alternative within the meaning of the second subparagraph of Article 5(2) of Regulation (EU) No 528/2012, the Commission shall decide on the request.

3 Where the Commission decides that the active substance is a suitable alternative, the Agency shall inform the applicant thereof and fully reimburse the fee referred to in paragraph 1.

## CHAPTER II

### **SUPPORT FOR SMEs**

## Article 6

### **Recognition of SME status**

1 Before submission of an application to the Agency for approval, renewal or inclusion in Annex I to Regulation (EU) No 528/2012 of an active substance or for Union authorisation of a biocidal product or biocidal product family, submitted in accordance with Articles 7(1), 13(1), 28(4), 43(1) or 45(1) of that Regulation respectively, containing a claim for SME reduction, the prospective applicant shall submit to the Agency the relevant elements proving entitlement to such reduction by virtue of the status of SME in the meaning of Recommendation 2003/361/EC.

2 In the case of an application for approval, renewal or inclusion of an active substance in Annex I to Regulation (EU) No 528/2012, the question shall be determined by reference to the active substance manufacturer that is represented by the prospective applicant. In case of an application for product authorisation or renewal of product authorisation, the question shall be determined by reference to the prospective authorisation holder.

3 The Agency shall publish a list of the relevant elements to be submitted in accordance with paragraph 1.

4 Within 45 days of receipt of all the relevant elements referred to in paragraph 1, the Agency shall decide what SME status, if any, can be recognised.

5 A recognition of an enterprise as an SME shall be valid for applications submitted under Regulation (EU) No 528/2012 for two years.

6 An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012 against a decision taken by the Agency under paragraph 4.

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## Article 7

### Fee Reductions

- 1 Reductions of fees payable to the Agency as set out in Table 2 of Annex I and Table 2 of Annex II shall be granted to SMEs established in the Union.
- 2 Reductions for applications for active substance approval, renewal of approval or inclusion in Annex I to Regulation (EU) No 528/2012 shall only be granted when the active substance is not a candidate for substitution.
- 3 Reductions for applications for biocidal product authorisation or renewal of authorisation shall only be granted when the product does not contain an active substance which is a candidate for substitution.

## CHAPTER III

### PAYMENTS

## Article 8

### Mode of payment

- 1 The fees provided for by this Regulation shall be paid in euro.
- 2 Payments shall be made only after the Agency has issued an invoice.
- 3 By derogation from paragraph 2, payments due under Article 4 shall be made at the time of the submission of the appeal.
- 4 Payments shall be made by means of a transfer to the bank account of the Agency.

## Article 9

### Identification of the payment

- 1 Every payment, with the exception of payments referred to in Article 8(3), shall indicate in the reference field the invoice number.
- 2 Payments referred to in Article 8(3) shall indicate, in the reference field, the identity of the appellant(s) and, if available, the number of the decision that is being appealed against.
- 3 If the purpose of the payment cannot be established, the Agency shall set a deadline by which the paying party 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 paying party.

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## Article 10

### **Date of payment**

1 Unless otherwise provided, fees shall be paid within 30 days from the date on which the invoice is notified by the Agency.

2 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.

3 The payment shall be considered to have been made in time where sufficient documentary evidence is produced to show that the paying party 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.

## Article 11

### **Insufficient payment**

1 A deadline for payment shall be considered to have been observed only if the full amount of the fee 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 12

### **Refund of amounts paid in excess**

1 The arrangements for the refund to the paying party of amounts paid in excess of a fee 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 below EUR 200 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 amount paid in excess and not refunded as being made towards future payments to the Agency.

## Article 13

### **Refunds of amounts in case of applications rejected before or during validation or withdrawn during the assessment**

1 The Agency shall reimburse 90 % of the fee collected where an application for active substance approval or biocidal product authorisation, submitted in accordance with respectively Article 7(1) or 43(1) of Regulation (EU) No 528/2012, or an application for a minor or major change of a product, is rejected before or during the validation phase.

2 The Agency shall reimburse 75 % of the fee collected where an application for active substance approval or biocidal product authorisation, submitted in accordance with respectively

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Article 7(1) or 43(1) of Regulation (EU) No 528/2012, or an application for a major change of a product, is withdrawn before the evaluating Competent Authority has transmitted its assessment report to the Agency.

The fee collected shall not be reimbursed where an application is withdrawn after the evaluating Competent Authority has transmitted its assessment report to the Agency.

3 The arrangements for the refund of the remaining amount to the paying party shall be fixed by the Executive Director of the Agency and published on the website of the Agency.

## CHAPTER IV

### FINAL PROVISIONS

#### *Article 14*

#### **Reimbursement of rapporteurs**

Members of the Biocidal Product Committee acting as rapporteurs shall be reimbursed through the fees paid in accordance with Article 80(2) to the Member States' competent authorities acting as evaluating competent authority.

#### *Article 15*

#### **Charges**

1 Subject to a favourable opinion from the Commission, the Agency may establish by decision of its Management Board charges for administrative or technical services that it provides in accordance with Regulation (EU) No 528/2012 at the request of a party in order to facilitate its implementation. 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 shall be set at such a level as to cover the costs of the services delivered by the Agency and shall not exceed what is necessary to cover those costs.

3 The charge shall be paid within 30 calendar days from the date on which the invoice is notified by the Agency.

#### *Article 16*

#### **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 of the European Parliament and of the Council<sup>(9)</sup>, include a specific provisional estimate of income from fees and charges from activities entrusted to the Agency in accordance with Regulation (EU) No 528/2012 which is separate from income from any subsidy from the Union.



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## Article 17

### Review

The Commission shall review the fees and charges provided for in this Regulation annually by reference to the inflation rate as measured by means of the European Index of Consumer Prices as published by Eurostat. A first review shall be carried out at the latest by 1 January 2015.

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 2015, the Commission shall review this Regulation with a view to amend it, if appropriate, taking into account in particular the resources required by the Agency and those required by the competent authorities of the Member States for services of a similar nature. The review shall take into consideration the impacts on the SMEs, and review the fee reduction rates allowable to SMEs where appropriate.

## Article 18

This Regulation shall enter into force on the twentieth 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.

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## ANNEX I

## FEES RELATING TO ACTIVE SUBSTANCES

Table 1

**Standard fees**

<b>General description of task; relevant provision in Regulation (EU) No 528/2012</b>	<b>Specific condition or task description</b>	<b>Fee (EUR)</b>
Approval of an active substance; Article 7(2)	Fee for the first product-type for which that active substance is approved	120 000
	Additional fee per additional product-type	40 000
	Additional fee per product-type (for both the first product-type and any additional product-type) if the active substance is a candidate for substitution in accordance with Article 10 of Regulation (EU) No 528/2012	20 000
	Fee for the amendment of an approval, other than the addition of a product-type.	20 000
Renewal of an approval; Article 13(3)	Fee for the first product-type for which renewal of that active substance is sought	15 000
	Additional fee per additional product-type	1 500
	Additional fee for the first product-type for which renewal of that active substance is sought in case a full evaluation is found necessary in accordance with Article 14(1) of Regulation (EU) No 528/2012	25 000
	Additional fee per additional product-type in case a full evaluation is found necessary in accordance with Article 14(1) of Regulation (EU) No 528/2012	2 500

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Table 1

**Standard fees**

	Additional fee per product-type (for both the first product-type and any additional product-type) if the active substance is a candidate for substitution in accordance with Article 10 of Regulation (EU) No 528/2012	20 000
Inclusion in Annex I of an active substance; Article 28	Fee for the first inclusion in Annex I of an active substance	10 000
	Fee for the amendment of an inclusion of an active substance in Annex I	2 000
Notification in accordance with Article 3a of Regulation (EC) No 1451/2007	Fee per substance/product-type combination. The fee for the notification shall be deducted from the subsequent application in accordance with Article 7 of Regulation (EU) No 528/2012.	10 000

Table 2

**Fee reductions for applications for the approval, renewal of approval, inclusion in Annex I of active substances if the active substance manufacturer is an SME established in the Union, except where the active substance is a candidate for substitution**

Type of enterprise	Reduction (% of the standard fee)
Micro enterprise	60
Small enterprise	40
Medium enterprise	20

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## ANNEX II

## FEES FOR UNION AUTHORISATION OF BIOCIDAL PRODUCTS

Table 1

**Standard fees**

<b>General description of task; relevant provision in Regulation (EU) No 528/2012</b>	<b>Specific condition or task description</b>	<b>Fee (EUR)</b>
Granting of Union authorisation, single product; Article 43(2)	Fee per product not identical with (one of) the representative product(s) assessed for the purpose of the substance approval	80 000
	Fee per product identical with (one of) the representative product(s) assessed for the purpose of the substance approval	40 000
	Additional fee per product when comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012 is required	40 000
	Additional fee per product when the requested authorisation is provisional in accordance with Article 55(2) of Regulation (EU) No 528/2012	10 000
	Fee per family	150 000
Granting of Union authorisation, biocidal product family; Article 43(2)	Additional fee per family when comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012 is required	60 000
	Additional fee per family when the requested authorisation is provisional in accordance with Article 55(2) of Regulation (EU) No 528/2012	15 000

<sup>a</sup> OJ L 125, 7.5.2013, p. 4.

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Table 1

**Standard fees**

Notification to the Agency of an additional product within a biocidal product family; Article 17(6)	Fee per additional product	2 000
Union authorisation of a same biocidal product; Article 17(7)	Fee per product constituting a 'same product' within the meaning of Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council <sup>a</sup>	2 000
Major change of an authorised product or product family; Article 50(2)	Fee per application	40 000
Minor change of an authorised product or product family; Article 50(2)	Fee per application	15 000
Administrative change of an authorised product or product family; Article 50(2)	Fee per notification	2 000
Recommendation on the classification of a change of an authorised product or product family; Article 50(2)	Fee per request in accordance with Regulation (EU) No 354/2013. If the recommendation is to classify the change as an administrative or minor change, the fee for the request shall be deducted from the subsequent application or notification in accordance with Regulation (EU) No 354/2013.	2 000
Renewal of Union authorisation, single product; Article 45(3)	Fee per product	5 000
	Additional fee per product in case a full evaluation is found necessary in accordance with	15 000

<sup>a</sup> OJ L 125, 7.5.2013, p. 4.

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Table 1

**Standard fees**

	Article 14(1) of Regulation (EU) No 528/2012	
	Additional fee per product when comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012 is required	40 000
Renewal of Union authorisation, biocidal product family; Article 45(3)	Fee per product family	7 500
	Additional fee per product family in case a full evaluation is found necessary in accordance with Article 14(1) of Regulation (EU) No 528/2012	22 500
	Additional fee per product family when comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012 is required	60 000

<sup>a</sup> [OJ L 125, 7.5.2013, p. 4.](#)

Table 2

**Fee reductions for applications for the granting and renewal of Union authorisation of biocidal products or biocidal product families, if the prospective authorisation holder is an SME established in the Union, except where the product contains an active substance which is a candidate for substitution**

Type of enterprise	Reduction (% of the standard fee)
Micro enterprise	30
Small enterprise	20
Medium enterprise	10

## ANNEX III

## OTHER FEES

General description of task; relevant provision in Regulation (EU) No 528/2012)	Specific condition or task description	Fee (EUR)
Technical equivalence; Article 54(3)	Fee, when difference between the active substance sources	5 000

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	is limited to a change in manufacturing location, and application is based solely on analytical data	
	Fee, when difference between the active substance sources goes beyond a change in the manufacturing location, and application is based solely on analytical data	20 000
	Fee when previous conditions are not met.	40 000
Annual fee for biocidal products authorised by the Union; Article 80(1)(a)	Fee per Union authorisation of a biocidal product	10 000
	Fee per Union authorisation of a biocidal product family	20 000
Mutual Recognition Submission fee; Article 80(1)(a)	Fee per product or product family concerned by an application for mutual recognition, per Member State where mutual recognition is sought	700
Appeal; Article 77(1)	Fee per appeal	2 500
Submission for inclusion in the list of relevant persons; Article 95	Fee per submission of a letter of access to a dossier already found complete by the Agency or an evaluating Competent Authority	2 000
	Fee per submission of a letter of access to part of a dossier already found complete by the Agency or an evaluating Competent Authority, together with complementary data	20 000
	Fee per submission of a new dossier	40 000
Requests under Article 66(4) submitted to the Agency	Fee per item for which confidentiality is requested	1 000

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- (1) [OJ L 167, 27.6.2012, p. 1.](#)
- (2) [OJ L 124, 20.5.2003, p. 36.](#)
- (3) [OJ L 109, 19.4.2013, p. 4.](#)
- (4) [OJ L 123, 24.2.1998, p. 1.](#)
- (5) [OJ L 298, 26.10.2012, p. 1.](#)
- (6) [OJ L 357, 31.12.2002, p. 72.](#)
- (7) MB/53/2008 final.
- (8) [OJ L 396, 30.12.2006, p. 1.](#)
- (9) [OJ L 396, 30.12.2006, p. 1.](#)



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**Changes and effects yet to be applied to :**

- Regulation revoked by [2023 c. 28 Sch. 1 Pt. 2](#)