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

(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 the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 51 thereof,

Whereas:

(1) In order to ensure a harmonised approach, it is appropriate to adopt provisions for changes of biocidal products in respect of any of the information submitted in relation to the initial application for the authorisation or registration of biocidal products and biocidal product families authorised or registered in accordance with Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ([2]) and Regulation (EU) No 528/2012.

(2) Proposed changes of biocidal products should be classified in different categories, taking into account the extent to which they require a reassessment of the risk for human or animal health or the environment and of the efficacy of the biocidal product or biocidal product family. It is appropriate to establish the criteria to be used for classifying a change of a product in one of the categories referred to in Article 50(3) of Regulation (EU) No 528/2012.

(3) In order to bring further predictability, the European Chemicals Agency (hereinafter 'the Agency') should issue opinions on the classification of changes of products. The Agency should also issue guidelines on the details of the various categories of changes. Those guidelines should be regularly updated in the light of scientific and technical progress.

(4) It is necessary to clarify the procedure which will lead to a decision by the Commission in accordance with the first subparagraph of Article 50(2) of Regulation (EU) No 528/2012 and, where relevant, Article 44(5) thereof.

(5) In order to reduce the overall number of possible applications and to enable Member States, the Agency and the Commission to focus on those changes that have a genuine impact on the properties of biocidal products, an annual reporting system should be introduced for certain changes of an administrative nature. Such changes should not require any prior agreement and should be notified within 12 months following implementation. However, other types of changes of an administrative nature, whose immediate reporting and prior examination is necessary for the continuous supervision of the biocidal product concerned should not be subject to the annual reporting system.

(6) Each change should require a separate submission. Grouping of changes should nevertheless be allowed in certain cases, in order to facilitate the review of the changes and reduce the administrative burden.

(7) Provisions should be introduced regarding the role of the coordination group established under Regulation (EU) No 528/2012 to increase cooperation between Member States and allow for the settlement of disagreements in the evaluation of certain changes.

(8) This Regulation should clarify when the authorisation holder is allowed to implement a given change, as such clarification is essential for economic operators.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down provisions concerning changes of biocidal products sought in accordance with Article 50(2) of Regulation (EU) No 528/2012 with regard to any of the information submitted in relation to the initial application for the authorisation of biocidal products or biocidal product families in accordance with Directive 98/8/EC and Regulation (EU) No 528/2012 (hereinafter 'changes of products').

Article 2

Classification of changes of products

1. Changes of products are classified in accordance with the criteria laid down in the Annex to this Regulation. Certain categories of changes are listed in the tables of the Annex.

2. The holder of an authorisation may request the Agency to provide an opinion on the classification in accordance with the criteria laid down in the Annex to this Regulation of a change not listed in one of the tables of that Annex.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) OJ L 123, 24.4.1998, p. 1.

The opinion shall be delivered within 45 days following receipt of the request and payment of the fee referred to in Article 80(1)(a) of Regulation (EU) No 528/2012.

The Agency shall publish the opinion after deletion of all information of commercial confidential nature.

Article 3

Guidelines on classification

1. The Agency shall, after consulting the Member States, the Commission and interested parties, draw up guidelines on the details of the various categories of changes of products.

2. Those guidelines shall be regularly updated, taking into account the opinions taken in accordance with Article 2(2), contributions from Member States as well as scientific and technical progress.

Article 4

Grouping of changes

1. Where several changes of products are sought, a separate notification or application shall be submitted in respect of each change sought.

2. By way of derogation from paragraph 1, the following rules shall apply:

(a) a single notification may cover a series of proposed administrative changes affecting different products in the same manner;

(b) a single notification may cover a series of proposed administrative changes affecting the same product;

(c) a single application may cover more than one proposed change of the same product in the following cases:

(1) one of the proposed changes in the group is a major change of the product; all other proposed changes in the group are a direct consequence of that change;

(2) one of the proposed changes in the group is a minor change; all other proposed changes in the group are a direct consequence of that change;

(3) all changes in the group are a direct consequence of a new classification of the active substance(s) or non-active substance(s) contained in the product or of the product itself;

(4) all changes in the group are a direct consequence of a specific condition of the authorisation;

(d) a single application may cover more than one proposed change if the Member State evaluating the application in accordance with Article 7(4) or 8(4), or, in the case of a change of a Union authorisation, the Agency, confirms that it is practically feasible to handle those changes in the same procedure.

The single applications referred to in points (c) and (d) of the first subparagraph shall be made in accordance with Article 7 or 12 where at least one of the proposed changes is a minor change of the product and none of the proposed changes is a major change of the product, and with Article 8 or 13 where at least one of the proposed changes is a major change of the product.

Article 5

Information requirements

An application submitted in accordance with Article 50(2) of Regulation (EU) No 528/2012 shall contain the following:

(1) the relevant filled application form as available from the Register for Biocidal Products, which shall contain:

(a) a list of all the authorisations affected by the proposed change(s);

(b) a list indicating all the Member States in which the product is authorised and the changes are sought (hereinafter the 'Member States concerned');

(c) for products authorised by national authorisation, the Member State which evaluated the initial application for authorisation of the biocidal product or, if the changes are not sought in that Member State, the Member State having been chosen by the applicant together with written confirmation that that Member State agrees to be reference Member State (hereinafter referred to as the 'reference Member State');

(d) for major changes of products authorised by Union authorisation, the Member State who evaluated the initial application for authorisation of the biocidal product or, if the changes are not sought in that Member State, the Member State having been chosen by the applicant together with written confirmation that that Member State agrees to evaluate the application of the change;

(e) where relevant, a draft revised summary of the biocidal product characteristics in, as appropriate,

(1) for products authorised by national authorisation, the official language(s) of all the Member States concerned;

(2) for products authorised by Union authorisation, one of the official languages of the Union, which in case of major changes must be a language accepted by the Member State referred to in point (c) at the time of application;

(2) a description of all the changes sought;

(3) where a change leads to or is the consequence of other changes of the terms of the same authorisation, a description of the relation between these changes;

(4) all relevant supporting documents to demonstrate that the proposed change would not adversely affect the conclusions previously reached concerning the compliance with the conditions set out in Article 19 or 25 of Regulation (EU) No 528/2012;

(5) where relevant, the opinion issued by the Agency in accordance with Article 3 of this Regulation.

CHAPTER II

CHANGES OF PRODUCTS AUTHORISED BY MEMBER STATES

Article 6

Notification procedure for administrative changes of products

1. The authorisation holder, or its representative, shall submit simultaneously to all Member States concerned a notification complying with Article 5 and, in each of those Member States, pay the fee payable in accordance with Article 80(2) of Regulation (EU) No 528/2012.

2. Without prejudice to the second subparagraph, the notification shall be submitted within 12 months following the implementation of the change.

In case of a change referred to in Section 1 of Title 1 of the Annex to this Regulation, the notification shall be submitted before the implementation of the change.

3. Within 30 days following receipt of the notification, where one of the Member States concerned disagrees with the change or the relevant fee has not been paid, that Member State shall inform the authorisation holder, or its representative, and the other Member States concerned that the change is rejected and the grounds for the rejection.

If, within 30 days following receipt of the notification, a Member State concerned has not expressed its disagreement, that Member State shall be deemed to have agreed with the change.

4. Each of the Member States concerned which has not rejected the change in accordance with paragraph 3 shall, where relevant, amend the authorisation of the biocidal product in conformity with the agreed change.

Article 7

Procedure for minor changes of products

1. The authorisation holder, or its representative, shall submit simultaneously to all Member States concerned an application complying with Article 5.

2. Each Member State concerned shall inform the applicant of the fee payable in accordance with Article 80(2) of Regulation (EU) No 528/2012. If the applicant fails to pay the fee within 30 days, the Member State concerned shall reject the application and inform the applicant and the other Member States concerned accordingly. Upon receipt of the fee, the Member State concerned shall accept the application and inform the applicant accordingly indicating the date of acceptance.

3. The reference Member State shall validate the application within 30 days of its acceptance, if it complies with the requirements laid down in Article 5 and inform the applicant and the Member States concerned accordingly.

In the context of the validation referred to in the first subparagraph, the reference Member State shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

Where the reference Member State considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the application to be completed and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 45 days.

The reference Member State shall, within 30 days of receipt of the additional information, validate the application if the additional information submitted is sufficient to comply with the requirements laid down in Article 5.

The reference Member State shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Member States concerned accordingly.

4. Within 90 days of validating an application, the reference Member State shall evaluate the application and draft an assessment report and shall send its assessment report and, where relevant, the revised summary of the biocidal product characteristics to the Member States concerned and to the applicant.

5. Where it appears that additional information is necessary to carry out the evaluation, the reference Member State shall ask the applicant to submit such information within a specified time limit. The period referred to in paragraph 4, shall be suspended from the date of the request until the date the information is received. The time limit given to the applicant shall not exceed 45 days in total unless justified by the nature of the data requested or by exceptional circumstances.

The reference Member State shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Member States concerned accordingly.

6. If, within 45 days of receipt of the assessment report and, where relevant, of the revised summary of the biocidal product characteristics, the Member States concerned express no disagreement in accordance with Article 10, those Member States shall be deemed to have agreed with the conclusions of the assessment report and, where relevant, the revised summary of the biocidal product characteristics.

7. Within 30 days of reaching agreement, the reference Member State shall inform the applicant of the agreement and make it available in the Register for Biocidal Products referred to in Article 71 of Regulation (EU) No 528/2012. The reference Member State and each of the Member States concerned shall, where relevant, amend the authorisations of the biocidal product in conformity with the agreed change.

Article 8

Procedure for major changes of products

1. The authorisation holder, or its representative, shall submit simultaneously to all Member States concerned an application complying with Article 5.

2. Each Member State concerned shall inform the applicant of the fee payable in accordance with Article 80(2) of Regulation (EU) No 528/2012. If the applicant fails to pay the fee within 30 days, the Member State concerned shall reject the application and inform the applicant and the other Member States concerned accordingly. Upon receipt of the fee, the Member State concerned shall accept the application and inform the applicant accordingly indicating the date of acceptance.

3. The reference Member State shall validate the application within 30 days of its acceptance if it complies with the requirements laid down in Article 5 and inform the applicant and the Member States concerned accordingly.

In the context of the validation referred to in the first subparagraph, the reference Member State shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

Where the reference Member State considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The reference Member State shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirements laid down in Article 5.

The reference Member State shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Member States concerned accordingly.

4. Within 180 days of validating an application, the reference Member State shall evaluate the application and draft an assessment report and shall send its assessment report and, where relevant, the revised summary of the biocidal product characteristics to the Member States concerned and to the applicant.

5. Where it appears that additional information is necessary to carry out the evaluation, the reference Member State shall ask the applicant to submit such information within a specified time limit. The period referred to in paragraph 4 shall be suspended from the date of the request until the date on which the information is received. The time limit given to the applicant shall not exceed 90 days in total unless justified by the nature of the data requested or by exceptional circumstances.

The reference Member State shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Member States concerned accordingly.

6. If, within 90 days of receipt of the assessment report and, where relevant, of the revised summary of the biocidal product characteristics, the Member States concerned express no disagreement in accordance with Article 10, those Member States shall be deemed to agree with the conclusions of the assessment report and, where appropriate, the revised summary of the biocidal product characteristics.

7. Within 30 days of reaching agreement, the reference Member State shall inform the applicant of the agreement, and the reference Member State and each of the Member States concerned shall, where relevant, amend the authorisations of the biocidal product in conformity with the agreed change.

Article 9

Biocidal products authorised in accordance with Article 26 of Regulation (EU) No 528/2012

1. Where the authorisation has been granted in accordance with Article 26 of Regulation (EU) No 528/2012, the authorisation holder or its representative shall notify each Member State, on the territory of which the biocidal product is made available, of notifications or applications made to the reference Member State in accordance with Article 6, 7 or 8 of this Regulation.

2. Where a reference Member State has agreed with a revised summary of the biocidal product characteristics, the authorisation holder or its representative shall submit the revised summary to each Member State on the territory of which the biocidal product is made available in the official language(s) of that Member State.

Article 9a

Procedure for changes already agreed by other Member States

1. Where an administrative change has already been agreed in one or more Member States and the authorisation holder seeks the same administrative change in an additional Member State concerned, the authorisation holder or its representative shall submit a notification in accordance with Article 6(1) to the additional Member State concerned.

2. Where a minor or a major change has already been agreed in one or more Member States and the authorisation holder seeks the same minor or major change in an additional Member State concerned, the authorisation holder, or its representative, shall submit an application complying with Article 5 to the additional Member State concerned.

3. The Member State concerned shall inform the applicant of the fee payable in accordance with Article 80(2) of Regulation (EU) No 528/2012. If the applicant fails to pay the fee within 30 days, the Member State concerned shall reject the application and inform the applicant and the other Member States concerned accordingly. Upon receipt of the fee, the Member State concerned shall accept the application and inform the applicant accordingly indicating the date of acceptance.

4. If within 45 days in the case of a minor change, or 90 days in the case of a major change, of the date of acceptance, the Member State concerned express no disagreement in accordance with Article 10, it shall be deemed to agree with the conclusions of the assessment report and, where appropriate, the revised summary of the biocidal product characteristics.

5. Within 30 days of the agreement referred to in paragraph 4, the Member State concerned shall inform the applicant of the agreement, and, where relevant, amend the authorisation of the biocidal product in conformity with the agreed change.

Article 10

Coordination group, arbitration and derogation from mutual recognition

1. A Member State concerned may propose to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation in accordance with Article 37 of Regulation (EU) No 528/2012.

2. Where, regarding matters other than those referred to in paragraph 1, the Member States concerned do not reach an agreement on the conclusions of the assessment report or, where relevant, on the revised summary of the biocidal product characteristics in accordance with Article 7(6) or 8(6), or a Member State concerned has disagreed in accordance with Article 6(3), the reference Member State shall refer the matter to the coordination group referred to in Article 35 of Regulation (EU) No 528/2012.

Where a Member State concerned is in disagreement with the reference Member State, the former shall give a detailed statement of the reasons for its position to all Member States concerned and to the applicant.

3. Articles 35 and 36 of Regulation (EU) No 528/2012 shall apply to matters of disagreement referred to in paragraph 2.

CHAPTER III

CHANGES OF PRODUCTS AUTHORISED BY THE COMMISSION

Article 11

Notification procedure for administrative changes of products

1. The authorisation holder, or its representative, shall submit to the Agency a notification complying with Article 5 and pay the fee referred to in Article 80(1)(a) of Regulation (EU) No 528/2012.

2. Without prejudice to the second subparagraph, that notification shall be submitted within 12 months following implementation of the change.

In case of a change referred to in Section 1 of Title 1 of the Annex to this Regulation, the notification shall be submitted before the implementation of the change.

3. Within 30 days following receipt of the notification and subject to the payment of the relevant fee, the Agency shall prepare and submit to the Commission an opinion on the proposed change.

4. If, within 30 days following receipt of the notification, the relevant fee has not been paid, the Agency shall reject the application and inform the applicant accordingly.

An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012, against Agency decisions under this paragraph.

5. The Agency shall inform the applicant of its opinion and shall, where relevant, request the applicant to submit in all the official languages of the Union, a draft revised summary of the biocidal product characteristics.

6. Within 30 days of the submission of its opinion to the Commission, the Agency shall, where relevant, transmit to the Commission, in all the official languages of the Union, the revised summary of the biocidal product characteristics, as referred to in Article 22(2) of Regulation (EU) No 528/2012.

Article 12

Procedure for minor changes of products

1. The authorisation holder, or its representative, shall submit to the Agency an application complying with the Article 5.

2. The Agency shall inform the applicant of the fee payable under Article 80(1)(a) of Regulation (EU) No 528/2012, and shall reject the application if the applicant fails to pay the fee within 30 days. It shall inform the applicant accordingly.

Upon receipt of the fee, the Agency shall accept the application and inform the applicant accordingly.

An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012, against Agency decisions under this paragraph.

3. The Agency shall validate the application within 30 days of the date of acceptance if it complies with the requirements laid down in Article 5.

In the context of the validation referred to in the first subparagraph, the Agency shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

Where the Agency considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the completeness of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 45 days.

The Agency shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirements laid down in Article 5.

The Agency shall reject the application if the applicant fails to submit the requested information within the deadline and inform the applicant accordingly. In such cases, part of the fee paid in accordance with paragraph 2 shall be reimbursed.

An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012, against Agency decisions under this paragraph.

4. Within 90 days of accepting an application as valid, the Agency shall prepare and submit to the Commission an opinion on the proposed change. In case of a favourable opinion, the Agency shall indicate whether the proposed change would require an amendment of the authorisation.

The Agency shall inform the applicant of its opinion and make it available in the Register for Biocidal Products referred to in Article 71 of Regulation (EU) No 528/2012, and shall, where relevant, request the applicant to submit in all the official languages of the Union, a draft revised summary of the biocidal product characteristics.

5. Where it appears that additional information is necessary to carry out the evaluation, the Agency shall ask the applicant to submit such information within a specified time limit. The period referred to in paragraph 4 shall be suspended from the date of the request until the date the information is received. The time limit given to the applicant shall not exceed 45 days in total unless justified by the nature of the data requested or by exceptional circumstances.

6. Within 30 days of the submission of its opinion to the Commission, the Agency shall, where relevant, transmit to the Commission, in all the official languages of the Union, the revised summary of the biocidal product characteristics, as referred to in Article 22(2) of Regulation (EU) No 528/2012.

Article 13

Procedure for major changes of products

1. The authorisation holder, or its representative, shall submit to the Agency an application complying with Article 5.

2. The Agency shall inform the applicant of the fee payable under Article 80(1)(a) of Regulation (EU) No 528/2012, and shall reject the application if the applicant fails to pay the fee within 30 days. It shall inform the applicant and the competent authority of the Member State referred to in Article 5(1)(d) (hereinafter referred to as the 'evaluating competent authority') accordingly.

Upon receipt of the fee, the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly.

An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012, against decisions of the Agency under this paragraph.

3. Within 30 days of the Agency accepting an application, the evaluating competent authority shall validate the application if it complies with the requirements laid down in Article 5.

In the context of the validation referred to in the first subparagraph, the evaluating competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

The evaluating competent authority shall, within 15 days from the Agency's acceptance of an application, inform the applicant of the fee payable under Article 80(2) of Regulation (EU) No 528/2012 and shall reject the application if the applicant fails to pay the fee within 30 days.

4. Where the evaluating competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the completeness of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The evaluating competent authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirements laid down in Article 5.

The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Agency accordingly. In such cases, part of the fee paid in accordance with paragraph 2 shall be reimbursed.

5. The evaluating competent authority shall, within 180 days of the validation of an application, evaluate it and send an assessment report and the conclusions of its evaluation, including, where relevant, a draft revised summary of the product characteristics, to the Agency.

Prior to submitting its conclusions to the Agency, the evaluating competent authority shall provide the applicant with the opportunity to provide written comments on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

6. Where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency accordingly. The period referred to in paragraph 5 shall be suspended from the date of the request until the date the information is received. The time limit given to the applicant shall not exceed 90 days in total unless justified by the nature of the data requested or by exceptional circumstances.

7. Within 90 days of receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the proposed change. In case of a favourable opinion, the Agency shall indicate whether the proposed change would require an amendment of the authorisation.

The Agency shall inform the applicant of its opinion and shall, where relevant, request the applicant to submit, in all the official languages of the Union, a draft revised summary of the biocidal product characteristics.

8. Within 30 days of the submission of its opinion to the Commission, the Agency shall, where relevant, transmit to the Commission, in all the official languages of the Union, the draft revised summary of the biocidal product characteristics, as referred to in Article 22(2) of Regulation (EU) No 528/2012.

CHAPTER IV

IMPLEMENTATION OF CHANGES

Article 14

Administrative changes of products

1. Administrative changes referred to in Section 2 of Title 1 of the Annex may be implemented any time before completion of the procedures laid down in Articles 6 and 11.

Administrative changes referred to in Section 1 of Title 1 of the Annex may be implemented at the earliest on the date when the Member State or, in the case of changes of a product authorised by Union authorisation, the Commission explicitly agrees with the change, or 45 days following receipt of the notification submitted in accordance with Articles 6 and 11, whichever is earliest.

2. Where one of the changes referred to in paragraph 1 is rejected, the authorisation holder shall cease to apply the concerned change within 30 days following notification of the decision of the relevant Member States or, in the case of changes of a product authorised by Union authorisation, the Commission.

Article 15

Minor changes

1. Subject to a favourable opinion from the Agency, minor changes of a product authorised by Union authorisation may be implemented any time after the Agency's opinion has been made available in the Register for Biocidal Products in accordance with Article 12(4).

2. Where the proposed minor change of the product is rejected by the Commission in accordance with Article 50(2) of Regulation (EU) No 528/2012, the authorisation holder shall cease to apply the proposed change within 30 days following notification of the decision of the Commission.

3. Minor changes of a product authorised by Member States may be implemented any time after the reference Member State has made the agreement available in the Register for Biocidal Products in accordance with Article 7(7).

Article 16

Major changes

Major changes may only be implemented after the concerned Member States have or, in the case of changes of a product authorised by Union authorisation, the Commission has agreed with the change and, where relevant, amended the decision granting the authorisation by the decision referred to in Article 50(2) of Regulation (EU) No 528/2012.

CHAPTER V

FINAL PROVISIONS

Article 17

Continuous monitoring of implementation of changes

Where requested by a Member State, the Agency or the Commission and for the purpose of monitoring biocidal products placed on the market, authorisation holders shall without delay supply the requesting authority with any information related to the implementation of a given change.

Article 18

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 September 2013.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 April 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

CLASSIFICATION OF CHANGES OF PRODUCTS

TITLE 1

Administrative changes of products

An administrative change of a product is a change following which any change of the existing authorisation can be expected to be only administrative within the meaning of Article 3(1)(aa) of Regulation (EU) No 528/2012.

SECTION 1

Administrative changes of products requiring prior notification before implementation

An administrative change of a product requiring prior notification before implementation is an administrative change, the knowledge of which is important for purposes of control and enforcement. Such changes include those listed in the following table, provided that the conditions therein are met:

Name of the biocidal product	
1.	Changes of the name of the biocidal product where there is no risk of confusion with the names of other biocidal products.
2.	Addition of a name for the biocidal product where there is no risk of confusion with the names of other biocidal products.
Authorisation holder	
3.	Transfer of the authorisation to a new holder established in the European Economic Area (EEA).
4.	Change in the name or address of the authorisation holder, which remains in the EEA.
Manufacturer(s) of the active substance(s)	
5.	Addition of a manufacturer of the active substance or change in the manufacturer's identity or in manufacturing location or process, where the technical equivalence between the substances from the two manufacturers, manufacturing locations and processes has been established by the Agency in accordance with Article 54 of Regulation (EU) No 528/2012, and the manufacturer or importer is listed in accordance with Article 95(2) of Regulation (EU) No 528/2012.
Biocidal product family	
6.	Authorisation as a biocidal product family of a number of authorised products falling within the specifications of a frame-formulation established in accordance with Directive 98/8/EC in accordance with the same terms and conditions.

SECTION 2

Administrative changes of products which can be notified after implementation

An administrative change of a product which can be notified after implementation is an administrative change, the knowledge of which is not important for purposes of control and enforcement. Such changes include those listed in the following table, provided that the conditions therein are met:

Authorisation holder	
1.	Change in other administrative details of the authorisation holder than the name and address.
Formulator(s) of the biocidal product	
2.	Change in the name, the administrative details or the formulating location of the biocidal product formulator, where the biocidal product composition and the formulating process remain unchanged.

3.	Deletion of a formulating location or a formulator of the biocidal product
4.	Addition of a formulator of the biocidal product, where the biocidal product composition and the formulating process remain unchanged.
Manufacturer(s) of the active substance(s)	
5.	Change in the name or the administrative details of a manufacturer of the active substance, where the manufacturing location and process remain unchanged and the manufacturer remains listed in accordance with Article 95(2) of Regulation (EU) No 528/2012
6.	Deletion of a manufacturer or a manufacturing location of the active substance
Conditions of use	
7.	More precise instructions for use, where only wording but not content of instructions are changed.
8.	Removal of a particular claim, such as a specific target organism or a specific use.
9.	Removal of a category of users.
10.	Addition, replacement or modification of a measuring or administration device not relevant for the risk assessment and not regarded as a risk mitigation measure.
Classification and labelling	
11.	Change to the classification and labelling, where the change is limited to what is necessary to comply with newly applicable requirements of Regulation (EC) No 1272/2008 of the European Parliament and of the Council [1].

[1] OJ L 353, 31.12.2008, p. 1.

TITLE 2

Minor changes of products

A minor change of a product is a change, following which any change of the existing authorisation can be expected to be minor within the meaning of Article 3(1)(ab) of Regulation (EU) No 528/2012, since the change of the product is not expected to affect the conclusion with regard to the fulfilment of the conditions of Article 19 or 25 of that Regulation. Such changes include the changes listed in the following table, provided that the conditions therein are met:

Composition	
1.	Increase or reduction, addition, deletion or replacement of a non-active substance intentionally incorporated in the product, where: — The added or increased non active-substance is not a substance of concern. — The deletion or reduction of the non-active substance does not lead to an increase of an active substance or a substance of concern. — The physical-chemical properties and the shelf-life of the product are expected to remain the same. — The risk and efficacy profile are expected to remain the same. — A new quantitative risk assessment is not expected to be necessary
2.	Increase, reduction, addition or deletion, or replacement of a non-active substance intentionally incorporated in a biocidal product family outside the authorised range, where: — The added or increased non-active substance is not a substance of concern. — The deletion or reduction of the non-active substance does not lead to an increase of an active substance or a substance of concern. — The physical-chemical properties and the shelf-life of the products of the biocidal product family remain the same. — The risk and efficacy profile are expected to remain the same. — A new quantitative risk assessment is not expected to be necessary.
Conditions of use	
3.	Changed instructions for use, where the changes do not adversely affect the exposure
4.	Addition, replacement or modification of a measuring or administration device relevant for the risk assessment and regarded as a risk mitigation measure, where: — The new device accurately delivers the required dose for the biocidal product concerned in line with the approved conditions of use. — The new device is compatible with the biocidal product. — The change is not expected to adversely affect the exposure.

Shelf-life and conditions of storage	
5.	Change in the shelf-life.
6.	Change in the conditions of storage
Pack size	
7.	Change in the pack size range, where: — New range is consistent with the dose rate and instructions for use as approved in the summary of the biocidal product characteristics. — No change of user category. — The same risk-mitigation measures apply.

TITLE 3

Major changes of products

A major change of a product is a change, following which any change of the existing authorisation can be expected to be major within the meaning of Article 3(1)(ac) of Regulation (EU) No 528/2012, since the change of the product can be expected to affect the conclusion with regard to the fulfilment of the conditions of Article 19 or 25 of that Regulation.