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)

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.

Changes to legislation:
There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 354/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Ch. 2 heading words substituted by S.I. 2019/720 Sch. 2 para. 183

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 4(2)(d) words substituted by S.I. 2019/720 Sch. 2 para. 181(2)
- Art. 5(1) words omitted by S.I. 2019/720 Sch. 2 para. 182(2)(a)
- Art. 5(1)(b)-(d) omitted by S.I. 2019/720 Sch. 2 para. 182(2)(b)
- Art. 5(1)(e)(1) omitted by S.I. 2019/720 Sch. 2 para. 182(2)(c)(ii)
- Art. 5(1)(e)(2) omitted by S.I. 2019/720 Sch. 2 para. 182(2)(c)(ii)
- Art. 5(1)(e) words omitted by S.I. 2019/720 Sch. 2 para. 182(2)(c)(i)
- Art. 5(4) words inserted by S.I. 2019/720 Sch. 2 para. 182(3)
- Art. 5(5) omitted by S.I. 2019/720 Sch. 2 para. 182(4)
- Art. 7(2A) inserted by S.I. 2022/1291 reg. 3(2)(a)
- Art. 7(4A) inserted by S.I. 2022/1291 reg. 3(2)(c)
- Art. 7(5A) inserted by S.I. 2022/1291 reg. 3(2)(e)
- Art. 8(2A) inserted by S.I. 2022/1291 reg. 3(3)(a)
- Art. 8(4A) inserted by S.I. 2022/1291 reg. 3(3)(c)
- Art. 8(5A) inserted by S.I. 2022/1291 reg. 3(3)(e)