The following text constitutes the unofficial translation into English of the Royal Decree of 4 April 2019 concerning the making available on the market and use of biocidal products (Belgian Monitor of 23 April 2019), as amended by the Royal Decree of 6 September 2021 amending the Royal Decree of 4 April 2019 concerning the making available on the market and use of biocidal products and amending the Royal Decree of 13 November 2011 establishing the fees and contributions payable to the Budgetary Fund for Raw Materials and Products (Belgian Monitor of 14 September 2021).

This unofficial English translation was produced by our in-house translation department.

4 APRIL 2019. - Royal Decree concerning the making available on the market and use of biocidal products

(NOTE: Consultation of previous versions as of 23-04-2019 and text update until 14-09-2021)

PHILIPPE, King of the Belgians,

To all, present and to come, greetings.

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;

Having regard to the Law of 21 December 1998 on product standards to promote sustainable production and consumption patterns and to protect the environment, public health and workers, Article 5, last amended by the Law of 16 December 2015, Article 8 amended by the Law of 28 March 2003, Article 8bis inserted by the Law of 28 March 2003, amended by the Law of 22 December 2003 and by the Law of 25 April 2014 and Article 9, last amended by the Law of 16 December 2015;

Having regard to the Code of Economic Law, Article VI.35, Introduced by the Law of 21 December 2013;

Having regard to the Royal Decree of 8 May 2014 concerning the making available on the market and use of biocidal products;

Having regard to the regulatory impact analysis carried out in accordance with Articles 6 and 7 of the Law of 15 December 2013 containing various provisions on administrative simplification;

Having regard to the involvement of the regional governments in the drafting of this Decree;

Having regard to the opinion of the Superior Health Council, issued on 7 February 2018;

Having regard to the opinion of the Superior Council for the Self-Employed and SMEs, issued on 20 February 2018;

Having regard to the opinion of the Central Economic Council, issued on 22 February 2018;

Having regard to the opinion of the Council for Consumption, issued on 22 February 2018;

Having regard to the opinion of the Federal Council for Sustainable Development, issued on 28 February 2018,

Having regard to the opinion of the Inspector of Finance, issued on 21 June 2018;

Having regard to the agreement of the Minister for the Budget, issued on 17 July 2018;

Having regard to the communication to the European Commission on 26 November 2017 in application of Article 5(1) of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services

Having regard to the opinion 64.236/1 of the Council of State, issued on 30 October 2018, in application of Article 84, paragraph 1, 2°, of the Coordinated Acts on the Council of State;

On the recommendation of the Minister of Work, Economy and Consumers, of the Minister of Health, of the Minister of the Environment, of the Minister of the Self-Employed, SMEs and the Self-Employed and on the advice of the Ministers meeting in Council,

We have decided and decree:

§ 1. The purpose of this Decree is the following:

1° ensuring a high level of protection of human and animal health and the environment. The provisions of this Decree are based on the precautionary principle. Specific consideration is given to the protection of vulnerable groups;

2° harmonising the use of biocidal products;

3° supplementing 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;

4° implementing the transitional measures as laid down in Article 89 of 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.

§ 2. This Decree applies to biocidal products as defined in Article 2 of 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.

Art. 2.Definitions

For the purposes of this Decree, the following definitions shall apply:

1° Biocidal Products Regulation: 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;

2° biocidal product: biocidal products as defined in Article 3 of the Biocidal Products Regulation;

3° active substance: active substance as defined in Article 3 of the Biocidal Products Regulation;

4° existing active substance: existing active substance as defined in Article 3 of the Biocidal Products Regulation;

5° harmful organism: harmful organism as defined in Article 3 of the Biocidal Products Regulation;

6° residue: residue as defined in Article 3 of the Biocidal Products Regulation;

7° micro-organism: micro-organism as defined in Article 3 of the Biocidal Products Regulation;

8° making available on the market: making available on the market as defined in Article 3 of the Biocidal Products Regulation;

9° placing on the market: placing on the market as defined in Article 3 of the Biocidal Products Regulation;

10° use: use as defined in Article 3 of the Biocidal Products Regulation;

11° product type: one of the product types as defined in Annex V to the Biocidal Products Regulation;

12° treated article: treated article as defined in Article 3 of the Biocidal Products Regulation;

13° authorisation: an administrative decision, issued in accordance with the Royal Decree of 8 May 2014 by which the Minister, following an application submitted by an applicant, allows a biocidal product to be made available on the market and used;

14° authorisation holder: authorisation holder as defined in Article 3 of the Biocidal Products Regulation;

15° acceptance of notification: an administrative decision, issued in accordance with the Royal Decree of 8 May 2014 by which the Minister, following a notification submitted by an applicant, allows a biocidal product to be made available on the market and used;

16° notifier: the person based in the European Union who is responsible for the placing of a biocidal product on the market and who is mentioned in the acceptance of notification;

17° registration: an administrative decision, issued in accordance with this Decree, by which the Minister, in connection with an application submitted by an applicant, authorises a biocidal product to be made available on the market and used;

18° registration holder: the person established in the European Union who is responsible for the placing of a biocidal product on the market and who is mentioned in the registration;

19° letter of access: letter of access as stipulated in Article 3 of the Biocidal Products Regulation;

20° administrative change: an adaptation of an existing authorisation, acceptance of notification or registration of a purely administrative nature, which does not concern the properties or efficacy of the biocidal product and which does not require a reassessment;

21° scientific change: an amendment to an existing authorisation, acceptance of notification or registration which

is not of a purely administrative nature and which does not involve a change to the properties or the efficacy of the biocidal product and which does not require a reassessment;

22° distributor: any natural or legal person who makes biocidal products available on the market, including wholesalers, retailers, vendors and suppliers;

23° advertisement: advertisement as defined in Article 3 of the Biocidal Products Regulation;

24° vulnerable groups: vulnerable groups as defined in Article 3 of the Biocidal Products Regulation;

25° closed circuit: sales and use circuit exclusively reserved for registered vendors and registered users;

26° free circuit: sales and use circuit not exclusively reserved for registered vendors and registered users;

27° registered user: any natural or legal person using a biocidal product for which it is stated in the authorisation, acceptance of notification or registration that this biocidal product belongs to the closed circuit;

28° registered vendor: any natural or legal person who makes a biocidal product available on the market of which it is stated in the authorisation, the acceptance of the notification or the registration that this biocidal product belongs to the closed circuit;

29° Royal Decree of 8 May 2014: Royal Decree of 8 May 2014 concerning the making available on the market and use of biocidal products;

30° Royal Decree of 13 November 2011: Royal Decree of 13 November 2011 establishing the fees and contributions payable to the Budget Fund for Raw Materials and Products;

31° CLP Regulation: Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;

32° Minister: the Minister competent for the Environment or the official delegated by the latter for specific tasks or competences;

33° Advisory Committee on Biocidal Products: the committee as established by the Royal Decree of 5 August 2006 establishing an Advisory Committee on Biocidal Products and amending the Royal Decree of 22 May 2003 concerning the making available on the market and use of biocidal products;

34° Competent authority: Directorate-General for the Environment of the Federal Public Service for Public Health, Food Chain Safety and the Environment;

35° Product and process oriented research and development: research and development oriented towards products and processes as defined in Article 3 of the Biocidal Products Regulation;

36° scientific research and development: scientific research and development as defined in Article 3 of the Biocidal Products Regulation;

[1 37° Gestautor: online IT application of the competent authority, which can be accessed via the website of the competent authority.]1

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(1)<RD 2021-09-06/01, art. 2, 002; Entry into force : 13-09-2021>

TITLE 2. - The making available on the market of biocidal products

CHAPTER 1. - General Provisions

Art. 3. Making available on the market

Biocidal products may only be made available on the market and used if:

1° the Minister or the European Commission has granted an authorisation for these biocidal products in accordance with the Biocidal Products Regulation, or;

2° the Minister has granted a registration for these biocidal products in accordance with this Decree or has granted an authorisation or accepted a notification in accordance with the Royal Decree of 8 May 2014 and this is still valid, and this for the period stipulated in Article 89(2) of the Biocidal Products Regulation.

CHAPTER 2. - Registration

Art. 4. Registration obligation

In application of Article 3, 2°, a registration is requested from the competent authority before the biocidal product is made available on the Belgian market, for each biocidal product containing the following active substances:

1° one or more existing active substances which are assessed in the context of the work programme for the systematic examination of all existing active substances as referred to in Article 89(1) of the Biocidal Products Regulation, but which have not yet been approved for that product type; or

2° a combination of the substances referred to under 1° and active substances which are approved in accordance with the Biocidal Products Regulation.

Art. 5. Conditions for registration

A registration in accordance with Article 3, 2°, for the making available on the market of a biocidal product shall be granted if:

1° the biocidal product contains the following active substances:

a) one or more existing active substances which are evaluated within the framework of the programme of work for the systematic examination of all existing active substances referred to in Article 89(1) of the Biocidal Products Regulation, but which have not yet been approved for that product type; or

b) a combination of the substances referred to under a) with active substances approved in accordance with the Biocidal Products Regulation.

2° in the light of current scientific and technical knowledge and after examination of the dossier submitted in accordance with Article 10, it can be established that, when used according to the registration and taking into account all the circumstances under which the biocidal product is normally used, the ways in which the materials treated with it can be used, and the consequences of use and disposal, the biocidal product:

a) meets the efficacy criteria;

b) has no unacceptable effects on the target organisms, such as unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;

c) has no unacceptable effects itself, or as a result of its residue, on human or animal health, directly or indirectly, including that of drinking water, food or feed, indoor air or effects in the workplace or on surface water and groundwater;

d) has no unacceptable effects itself, or as a result of its residue, on the environment, having particular regard to the following considerations on the one hand, its fate and distribution in the environment, particularly with regard to contamination of surface waters (including estuarial and seawater), groundwater and drinking water, and on the other hand, its impact on non-target organisms;

3° the nature and quantity of the active substances of the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants, and its residues of toxicological or environmental significance, which result from its registered use, can be determined;

4° the physical and chemical properties of the biocidal product have been determined and deemed acceptable for purposes of the appropriate use, storage and transport of the biocidal product.

For the evaluation of the effects listed in 2°, the availability of another biocidal product for which making available on the market is registered and which can be used with the same effect on the target organism without major practical disadvantages for the user and without increased risk for public health or the environment is taken into account.

Art. 6. Applicant

The application for registration shall be made by, or on behalf of, the person established within the European Union who is responsible for the placing on the market of the biocidal product, irrespective of their status as manufacturer, importer, owner or distributor to the competent authority.

Art. 7.Modalities of the application

§ 1. [1 An application shall be submitted for each biocidal product by means of an electronic file in Gestautor.]1 [1 ...]1 An initial application for registration must contain the data listed in Annex 1, A. The data stated in Annex 1, B shall be kept available and shall be submitted if a full evaluation is required in accordance with Article 10. The dossier to be submitted varies according to the type of application and shall be completed in the light of current scientific and technical knowledge.

§ 2. The information in the application dossier must be sufficient to establish classification and labelling and to assess the efficacy, if the product claims efficacy against a specific target organism (specified at the level of genus and species name or equivalent) or according to a specific standard. The additional data required, where a full evaluation is required in accordance with Article 10, must be sufficient to allow an evaluation of the effects and properties listed in Article 5.

Where examinations are required, the application must include a detailed and full description of the examinations conducted and of the methods used or a reference to the literature for these methods.

If it is not necessary, on account of the nature of the biocidal product or of the proposed uses, to provide information or if it is not scientifically necessary or technically possible to provide information, the applicant must explain the reasons for the absence of information in the application. The reasons will be assessed by the Minister and, if necessary, accepted after the file has been declared administratively admissible in accordance with article 8, § 2, or Article 10, § 4.

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(1)<RD 2021-09-06/01, art. 3, 002; Entry into force: 13-09-2021>

Art. 8. Submission and administrative admissibility

§ 1. The initial application for registration shall be submitted no later than one year before the date of approval of the active substance or, in the case of a product containing multiple active substances, before the date of approval of the last active substance of that product type.

§ 2. Upon receipt of the application by the competent authority, the required fee shall be requested. Upon receipt of the fee, the competent authority shall verify the administrative admissibility of the application and shall send a message to the applicant within twenty working days of receipt of the fee.

If the file is not administratively admissible, the missing data will be requested from the applicant. The applicant has twenty working days from the notification of the demand to provide this information. After the missing information is received, it will be checked for administrative admissibility within 15 working days and a notification will be sent to the applicant. If the applicant does not reply within the period of twenty working days or if the additional information is not satisfactory, the application will be filed away without further action.

Art. 9. Limited evaluation

§ 1. If the file is administratively admissible, the classification and labelling of the biocidal product is established. If the product claims an efficacy against a specific target organism (specified at genus and species level or equivalent) or according to a specific standard, the efficacy will also be evaluated on the basis of the data submitted under Article 7 in accordance with Annex 1, A.

§ 2. The Minister shall grant a registration within twenty working days from the date on which the application was declared administratively admissible.

If data are required to determine classification and labelling or to assess efficacy, they shall be requested from the applicant. The applicant has twenty working days from the notification of the demand to provide the information. After the missing information is received, it will be assessed within 20 working days and a notification will be sent to the applicant. If the applicant does not reply within the period of twenty working days or if the additional information is not satisfactory, the application will be filed away without further action.

Art. 10.Full evaluation

§ 1. If, during the administrative admissibility procedure in accordance with Article 8, there are indications that

the biocidal product in question may not meet the conditions referred to in Article 5, the Minister will inform the applicant, within twenty working days of receipt of the fee [1 ...]1 that the application will be transferred to the Advisory Committee on Biocidal Products for a full assessment, with a description of the reason for this decision.

Possible indications may be:

1° history of the biocidal product in question, such as a negative opinion;

2° a substantiated complaint against the biocidal product in question, against a very similar biocidal product or against a group of biocidal products to which the biocidal product concerned belongs;

3° incompatibility between the classification and labelling and the intended use;

4° scientific literature data, a report from the poison control centre or a notification from another Member State which can indicate a possible danger to humans or the environment from the biocidal product in question or from a substance contained in it;

5° scientific literature data, a report from the poison control centre or a notification from another Member State which can demonstrate an objectively defined microbial resistance.

§ 2. The applicant may present their defences to the decision taken by the Minister in a notice of objection and may request to be heard by the Advisory Committee on Biocidal Products. This objection shall be forwarded to the competent department by registered letter within thirty working days. This period shall commence on the day the Minister's decision is sent to the applicant.

The objection shall be examined by the Advisory Committee on Biocidal Products at a time and date specified by its chairperson. If the applicant so requests, they shall be heard by the Advisory Committee or at least duly summoned.

The Advisory Committee on Biocidal Products shall communicate its opinion on the objection to the Minister and the decision on the objection shall be made by the Minister before the expiry of a period of sixty working days commencing on the day on which the competent authority has received the objection. The retention or modification of the decision originally taken by the Minister shall be notified [1 immediately]1 to the applicant

§ 3. If the Minister accepts the objection, the application for registration shall be dealt with in accordance with the procedure described in Article 8 , § 2, and Article 9.

§ 4. If the Minister maintains their decision that a full evaluation is required or if no objection is made, the additional information set out in Annex 1B must be submitted to the competent authority in accordance with the modalities set out in Article 7 and within thirty working days of the date of [1 notification of]1 the Minister's decision or of expiry of the period of thirty working days stipulated for lodging an objection.

§ 5. The competent authority will send the applicant, within fifteen working days of receipt of the information in accordance with Annex 1B, a message indicating whether the supplemented dossier is administratively admissible or not for the purposes of the full evaluation.

If the file is not administratively admissible, the missing data will be requested from the applicant. The applicant has twenty working days from the notification of the demand to provide this information. After the missing information is received, it will be checked for administrative admissibility by the competent authority within 15 working days and a notification will be sent to the applicant. If the applicant does not reply within the period of twenty working days or if the additional information is not satisfactory, the application will be filed away without further action.

If the application is administratively admissible, it will be forwarded to the Advisory Committee on Biocidal Products. This Committee will give an opinion on the application for registration within 125 working days from the date the application was declared administratively admissible.

If the Advisory Committee on Biocidal Products requires additional data, the competent authority shall request these from the applicant. The period of 125 working days for the issuance of an opinion by the Advisory Committee on Biocidal Products shall be suspended from the date on which the competent authority forwards these questions to the applicant until the date on which the competent authority receives the requested data.

The applicant has 40 working days from the notification of the question to provide this information requested by the Advisory Committee on Biocidal Products. With the agreement of the Advisory Committee on Biocidal Products, the applicant may obtain an extension of this period. If the applicant does not reply within the period of

2 months or the extended period, the application will be filed away without further action.

If the Advisory Committee on Biocidal Products does not issue an opinion within the aforementioned periods, the Minister will decide whether the registration will be granted.

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(1)<RD 2021-09-06/01, art. 4, 002; Entry into force: 13-09-2021>

Art. 11. Modalities of registration

§ 1. The registration is personal and can only be transferred after receipt of the application for transfer and with the agreement of the holder and the explicit prior consent of the Minister.

§ 2. Subject to the application of Articles 12 to 15, a registration granted in accordance with the provisions of this Decree shall remain valid until the date on which the active substance is approved for the product type to which the biocidal product belongs and at most until the end of the work programme for the systematic examination of all existing active substances as referred to in Article 89(1) of the Biocidal Products Regulation. In the case of biocidal products containing more than one active substance and/or classified in more than one product type, the registration shall be valid until the date on which all the active substances are approved in the product types relevant to the activity of the active substance in the biocidal product.

§ 3. The registration must explicitly mention the requirements for making available on the market and use.

Where there are requirements pursuant to other regulations governing the conditions for granting a registration and for the use of the biocidal product which aim to protect the health of distributors, users, workers and consumers, animal health or the environment, the Minister shall take those requirements into account when granting a registration. The Minister may grant registration if these requirements are met.

The Minister may make the granting of registration subject to chemical or physico-chemical decomposition or to biological, toxicological or other testing at independent and competent research centres. The Minister may also determine the standards which the biocidal product must meet and the conditions under which the standard sample must be submitted.

§ 4. The registration may be re-examined at any time if there are indications that the conditions imposed in Article 5 for granting the registration, or following information received in accordance with Article 24, are no longer satisfied.

In such cases, additional information may be requested from the holder of the registration and a full evaluation may be made in accordance with the procedure laid down in Article 10. The Minister may, if necessary, amend, suspend or revoke the registration in accordance with the provisions of Articles 12 to 15.

Art. 12. Change of registration

The Minister may, where appropriate after obtaining the opinion of the Advisory Committee on Biocidal Products, change the conditions of the registration if:

1° the Minister considers it necessary on the basis of developments in scientific and technical knowledge and for the protection of health or the environment; or

2° the holder of the registration so requests, giving the reasons for the change.

The application for changing a registration shall be submitted no later than 6 months before the date of approval of the active substance or, in the case of a product containing multiple active substances, before the date of approval of the last active substance of that product type. In the event of a change to the conditions of a registration as provided for in the first paragraph, a changed registration is required, whereby the original registration shall expire.

Art. 13. Suspension of registration

The registration shall be suspended by the Minister if:

1° they have serious indications, such as a notification from the poison control centre or a scientific publication, that the biocidal product poses an unacceptable risk to human or animal health or to the environment, until it has been sufficiently demonstrated that these indications are unfounded, or

2° the holder of the registration fails to comply with one or more conditions of the registration as stated in the act, until evidence is provided that the conditions are complied with; or

3° the holder of the registration fails to comply with one or more obligations in this Decree as well as those stated in Chapter IV of the Royal Decree of 13 November 2011, until evidence is provided that the obligations are complied with.

The opinion of the Advisory Committee on Biocidal Products may be requested.

Art. 14. Revocation of registration

The registration shall be revoked by the Minister if:

1° the conditions of Article 5 are no longer met; or

2° it is discovered that false or misleading details have been provided on the basis of which the registration was granted; or

3° the holder of the registration so requests, giving reasons for the revocation.

Art. 15. General provisions regarding a change, suspension or revocation of registration

§ 1. If the Minister takes the initiative to amend, suspend or revoke a registration, the competent authority shall notify the holder of the registration immediately by registered letter. This pertains to the cases referred to in Article 12, first paragraph, 1°, Article 13 and Article 14, 1° and 2°.

§ 2. If the holder of a registration takes the initiative to amend or revoke a registration, they must submit an application in accordance with Article 7.

If the application relates to an administrative change to the previously granted registration, the Minister will issue an opinion within 20 working days of the date on which the application was declared administratively admissible in accordance with Article 8.

In the event of a scientific change, the procedure laid down in Articles 8, 9 and 10 shall apply and the registration holder must submit the required information.

Changes to a registration shall only be allowed if the conditions laid down in Article 5 are still met.

§ 3. The decisions to change, suspend or revoke shall have immediate effect. Lodging an objection according to the provisions of Article 17 does not have a suspensive effect on a decision to change, suspend or revoke a registration.

§ 4. Any change to or revocation of a registration shall be subject to a period of grace for the disposal, making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human or animal health or the environment.

The period of grace consists of an initial period of 180 days for making available on the market existing stocks of the biocidal product in question. This is followed by a second period of 180 days for the disposal, and/or use of existing stocks.

Art. 16. Registration for identical biocidal product

If a biocidal product has already been registered in accordance with Articles 5 to 8, the Minister may, without prejudice to the obligations under Article 29, grant a registration to a second or subsequent applicant if the latter refers to data provided by the first applicant to the extent that the second or subsequent applicant can demonstrate that the biocidal product is identical in all respects to the previously registered biocidal product.

In such cases, an application shall be submitted in accordance with Article 7, no later than 3 months before the date of approval of the active substance or, in the case of a product containing multiple active substances, before the date of approval of the last active substance of that product type.

The Minister will issue a decision within 20 working days from the date the application was declared administratively admissible, in accordance with the procedure set out in Article 8.

The identical biocidal product shall be registered under the same conditions and with the same expiry date as those indicated on the registration of the originally registered biocidal product. There is a permanent link between

the two biocidal products. However, it is not obligatory to adopt all the uses of the originally registered biocidal product.

Art. 17.Objection

The applicant may present their defence against the decision taken by the Minister pursuant to articles 9, 10, 12, 13, 14 and 16 in a notice of objection, with the exception of the decision mentioned in article 10, § 1, for which the procedure of article 10, § 2 must be followed. It is not permitted to introduce new studies in the notice of objection. This objection shall be forwarded to the competent department by registered letter within 30 working days. This period shall commence on the third working day following the day on which the competent authority's decision is sent to the applicant.

The notice of objection shall be immediately communicated by the competent authority for its opinion to the Superior Health Council, which shall examine it within 60 working days from the date of receipt, on the day and hour set by the chairperson. Within ninety working days thereafter, the Superior Health Council shall notify the Minister of its opinion.

Before the opinion is issued, the applicant is heard by the Superior Health Council or at least properly summoned.

The decision on the objection shall be made by the Minister before the expiry of a period of 160 working days commencing on the day on which the competent authority has received the objection. The retention or modification of the original decision taken by the Minister shall be notified to the applicant by registered letter and [1 by e-mail]1 to the Superior Health Council.

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(1)<RD 2021-09-06/01, art. 5, 002; Entry into force: 13-09-2021>

Art. 18. Fee and annual contribution

Any person applying for registration pursuant to Article 8 must pay the fees in accordance with Chapter IV of the Royal Decree of 13 November 2011.

Any person who has obtained a registration for a biocidal product in accordance with Article 8 must pay, for each registration, an annual contribution in accordance with the provisions of the Royal Decree of 13 November 2011.

CHAPTER 3. - Parallel trade

Art. 19.Parallel trade

§ 1. At the request of an applicant, the Minister shall grant a parallel trade permit which allows a biocidal product which is authorised in another Member State, the Member State of origin, to be made available on the market and used if they determine in accordance with Paragraph 3 that the biocidal product in question is identical to a biocidal product, the reference product, which has already been registered in accordance with Article 9, § 2, Article 10, § 3 or § 5, third paragraph.

The applicant who intends to make the biocidal product available on the market shall submit the application for a parallel trade permit [1 by e-mail]1 to the competent authority.

The application shall be accompanied by the parallel trade form as set out in Annex 2 and all the information necessary to demonstrate that the biocidal product is identical to the reference product as defined in paragraph 3. If the Minister considers it necessary, a sample of the biocidal product to be introduced may also be requested.

Any person applying for a parallel trade permit must pay the fee in accordance with Chapter IV of the Royal Decree of 13 November 2011.

Any person who has obtained a parallel trade permit must pay, per permit, an annual contribution in accordance with Chapter IV of the Royal Decree of 13 November 2011. The fee is requested by the competent authority upon receipt of the application for a parallel trade permit.

§ 2. If the Minister determines that a biocidal product is identical to the reference product, they shall issue a parallel trade permit within 60 days of receipt of the fee. The Minister may request additional information from the competent authority of the Member State of origin to determine whether the biocidal product is identical to

the reference product. In such cases, the period of 60 days shall be suspended from the date of communication of the request until the date the requested information is received.

§ 3. A biocidal product shall be considered to be identical to the reference product only if all of the following conditions are fulfilled:

1° both have been manufactured according to the same production process by the same company, an affiliated company or a company operating under licence;

2° the specifications and the content of the active substances as well as the type of formulation are identical;

3° the non-active substances present are the same;

4° the size, material or form of packaging as regards the possible adverse effects on the safety of the product with regard to human or animal health or the environment are the same or equivalent.

§ 4. The parallel trade permit shall prescribe the same conditions for making available on the market and use as the registration of the reference product.

§ 5. The parallel trade permit shall be valid for the quantity to be imported and for the envisaged period of import as indicated in the parallel trade permit form as set out in Annex 2. A new licence must be applied for each new import of a batch of the biocidal product.

If the holder of the registration for the reference product applies for a revocation of the registration but the conditions of Article 5 are still fulfilled, this will not affect the parallel trade permit already granted.

§ 6. Without prejudice to the specific provisions of this Article, all provisions applicable to a registration issued in accordance with Article 9 or 10 also apply to a parallel trade permit.

§ 7. The Minister may withdraw a parallel trade permit if the authorisation of the biocidal product is withdrawn by the Member State of origin on account of safety or efficacy reasons. The licence holder shall notify this to the competent authority.

§ 8. If the Minister considers that the parallel trade permit cannot be granted, they shall [1 immediately]1 notify the applicant of their decision. The applicant may present their defence against this decision, in a notice of objections. In such cases, the procedure and time periods set out in Article 17 apply.

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(1)<RD 2021-09-06/01, art. 6, 002; Entry into force: 13-09-2021>

CHAPTER 4. - Various provisions regarding the making available on the market of biocidal products in accordance with Article 3, 2°

Art. 20. Scope

The articles included in this Chapter apply to the making available of biocidal products on the market in accordance with Article 3, 2°, and in particular to biocidal products containing the following active substances:

1° one or more existing active substances which are assessed in the context of the work programme for the systematic examination of all existing active substances as referred to in Article 89(1) of the Biocidal Products Regulation, but which have not yet been approved for that product type; or

2° a combination of the substances referred to under 1° and active substances which are approved in accordance with the Biocidal Products Regulation.

Section 1. - Derogation provisions

Art. 21. Temporary registration

By way of derogation from Article 5, the Minister may temporarily permit, for a period not exceeding 180 calendar days, the making available on the market or use of biocidal products which do not comply with the provisions of this Decree, under the supervision of the competent authority, for a limited and controlled use, if this measure appears necessary owing to an unforeseen danger to public health, animal health or the environment which cannot be controlled by other means. This measure may be extended for a period of up to 365 calendar days.

This derogation and its extension can only be granted upon submission of a reasoned request or ex-officio by the Minister. The Minister shall determine the conditions under which the measure taken may be granted and renewed.

Section 2. - Provision of information

Art. 22. Access to identical data

The Minister shall exclusively use the information referred to in Article 7, submitted in the context of an application for registration of a biocidal product, for the benefit of a second or subsequent applicant if the second or subsequent applicant has written agreement in the form of a letter of access from the first applicant that such information may be used.

Art. 23. Letter of access

The letter of access must contain at least the following information:

1° name and contact details of the owner of the data and the beneficiary;

2° name of the active substance or the biocidal product for which access to the data has been granted;

3° start date of the period of validity of the letter of access;

4° a list of the supplied information which may be used pursuant to the letter of access.

Revocation of a letter of access shall not affect the validity of any registration granted on the basis of that letter of access.

Art. 24.Notification of new information

§ 1. The holder of a registration granted in accordance with this Decree shall immediately notify the competent authority of any information regarding the biocidal product in question or the active substances contained therein which may affect the subsequent registration and of which they are aware or can reasonably be expected to be aware. In particular, the following information must be communicated:

1° new knowledge or information concerning the effects of the active substance or the biocidal product on humans or the environment;

2° changes in the origin or composition of the active substance;

3° changes in the composition of a biocidal product;

4° any data indicating that the active substance may give rise to the development of resistance;

5° new data or information indicating that the biocidal product does not have sufficient efficacy;

6° changes of an administrative nature or other aspects, such as any other information stated in the registration.

This information shall be communicated via [[1] an application in accordance with Article 7][1]. If electronic notification is not possible, this information must be communicated by registered letter.

§ 2. The Minister shall examine whether the registration, the authorisation or the acceptance of notification must be changed, suspended or revoked.

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(1)<RD 2021-09-06/01, art. 7, 002; Entry into force: 13-09-2021>

Art. 25. Use of confidential information

§ 1. The Minister shall refuse access to information if disclosure would compromise the protection of commercial interests or the privacy or security of the parties concerned. Disclosure of the following information is generally deemed to compromise the protection of the commercial interests or the privacy or safety of the parties concerned:

1° details of the complete composition of a biocidal product;

2° the exact quantity of the active substance or biocidal product manufactured or made available on the market;

3° links between the manufacturer of an active substance and the person responsible for the placing on the market of a biocidal product or between the person responsible for the placing on the market of a biocidal product

and the distributors of the biocidal product;

4° names and addresses of persons involved in testing on vertebrate animals.

However, where immediate action is essential in order to protect human or animal health, safety or the environment, or for other reasons of overriding public interest, the Minister shall publish the information referred to in this paragraph.

§ 2. Without prejudice to Paragraph 1, once the registration has been granted, access to the following information shall not be denied under any circumstances:

1° the name and address of the holder of the registration;

2° the name and address of the manufacturer of the biocidal product;

3° the name and address of the manufacturer of the active substance;

4° the name and content of the active substance in the biocidal product and the name of the biocidal product;

5° the name and content of other substances regarded as hazardous and involved in the classification of the biocidal product;

6° the physical and chemical data concerning the biocidal product;

7° the ways in which the active substance or biocidal product can be rendered harmless;

8° a summary of the results of the tests required pursuant to Article 7;

9° the recommended methods and precautions to mitigate hazards during handling, transport and use, as well as in the event of fire or other hazards;

10° the safety data sheets;

11° the methods of analysis as referred to in Article 5, first paragraph, 3°;

12° the methods for disposing of the biocidal product and its packaging;

13° the procedures to be followed and measures to be taken in the event of spillage or leakage;

14° the first aid and medical advice to be given in the event of bodily harm.

§ 3. Without prejudice to paragraph 2 and subject to the legislation on access to environmental information, an applicant may notify the Minister of any information which they consider to be commercially sensitive and the disclosure of which might harm them industrially or commercially. Complete justification must be given in each case. On the basis of evidence to be supplied by the applicant, the Minister shall decide which information is to be regarded as confidential. Information accepted as confidential by the Minister shall also be treated as confidential by the Superior Health Council and the Advisory Committee on Biocidal Products.

Art. 26. Research and development

By way of derogation from Article 3, 2°, experiments or tests for scientific research and development or research and development concerning products and processes with a biocidal product that has not been registered in accordance with the present Decree (hereinafter referred to as experiments or tests) may only take place under the conditions specified in this Article.

Persons carrying out experiments or tests must keep records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of the parties receiving the biocidal product or active substance. They must keep this register up to date and shall compile a dossier containing all available information on the possible effects on human or animal health or on the environment. They shall make this information available to the Minister on request.

Any person intending to carry out experiments or tests which may involve or result in the release of the biocidal product into the environment shall first notify the competent authority by mail using the form in Annex 3. The person in question shall make any other information available to the Minister on request.

In the absence of any notification from the Minister within 45 days of the information referred to in the third paragraph, the experiment or test for which the information has been notified may be carried out.

The persons carrying out experiments or tests in accordance with the third paragraph must pay the fees in accordance with Chapter IV of the Royal Decree of 13 November 2011.

If the experiments or tests are likely to have harmful effects, whether immediate or delayed, on human health, particularly on vulnerable groups, or animal health, or unacceptable adverse effects on the environment, humans

or animals, the Minister may prohibit those experiments or tests or make their authorisation subject to such conditions as they consider necessary to prevent these effects.

CHAPTER 5. - Various provisions regarding the making available on the market of biocidal products in accordance with Article 3

Art. 27. Scope
The articles included in this Chapter apply to all biocidal products made available on the Belgian market.

Art. 28.Classification, packaging and labelling
§ 1. Holders of registrations or authorisations granted in accordance with the Biocidal Products Regulation shall ensure that biocidal products are classified, packaged and labelled in accordance with the registration, the authorisation or the approved Summary of Product Characteristics and, where applicable, the CLP Regulation.
§ 2. Biocidal products that could be mistaken for food, including beverages, or feed must be packaged in such a way as to minimise the likelihood of such an error occurring. If the products are available to the general public, they must contain components to discourage their consumption and, in particular, biocidal products must not be attractive to children.
§ 3. Biocidal products must only be supplied to the user in the intact original packaging. They must not be divided up under any circumstances.
It is prohibited to modify the original packaging or the label. It is prohibited to re-use the packaging of biocidal products, except in the case of containers which are specifically intended to be re-used, loaded or filled by the holder of the registration or the authorisation granted in accordance with the Biocidal Products Regulation.
§ 4. Packaging of biocidal products placed on the market as aerosols must comply with the provisions of the Royal Decree of 31 July 2009 on aerosols.
§ 5. Holders of registrations or authorisations issued in accordance with the Biocidal Products Regulation must ensure that a label is not misleading with regard to the risks of the biocidal product for human or animal health or the environment, or its efficacy, and in any case does not bear the indications "low-risk biocidal product", "non-toxic", "harmless", "natural", "bio", "environmentally friendly", "animal friendly" or similar indications. In addition, the label must clearly and indelibly indicate the following information:
1° the identity of each active substance and its concentration in metric units;
2° any nanomaterials contained in the biocidal product, and any specific related risks it may entail and, after each reference to nanomaterials, the word "nano" in brackets;
3° the registration or authorisation number allocated to the biocidal product by the competent authority or the authorisation number allocated by the European Commission;
4° the name and address of the holder of the registration or of the authorisation granted in accordance with the Biocidal Products Regulation. The name, address and logo of the distributor may be added but must always remain subordinate to the details of the holder of the registration or authorisation granted in accordance with the Biocidal Products Regulation;
5° formulation type;
6° the use for which the biocidal product has been registered or authorised in accordance with the Biocidal Products Regulation;
7° for each use stated in the registration or authorisation granted in accordance with the Biocidal Products Regulation, the instructions for use, frequency of application and dosage, in metric units and in a manner which is unambiguous and understandable for the user;
8° the telephone number of the National Centre for the Prevention and Treatment of Intoxications;
9° the details of any direct or indirect adverse effects and first aid instructions;
10° the phrase "Read attached instructions before use", if an enclosed leaflet is included, and, where applicable, warnings for vulnerable groups;
11° directions for safe disposal of the biocidal product and its packaging as well as, where applicable, a

prohibition on reuse of the packaging;
12° the batch number or batch designation of the formulation and the expiry date under normal conditions of storage;
13° where applicable, the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the biocidal product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and the duration of necessary ventilation of the areas concerned; details on the proper cleaning of the equipment; details on precautions during use and transport;
14° where applicable, the categories of users to which the biocidal product is restricted;
15° where applicable, information on specific hazards for the environment, in particular in relation to protection of non-target organisms and avoidance of water pollution;
16° for biocidal products containing micro-organisms, the labelling requirements in accordance with Book VII - Biological agents of the Codex of 28 April 2017 on well-being at work.
By way of derogation from the first paragraph, [1 the information stated under 5°, 7°, 9°, 11°, 12°, 13° and 15°]1, may, if this is necessary because of the size or the function of the biocidal product, be stated on the packaging or on an accompanying leaflet.
§ 6. The Minister or the official responsible for supervision may require samples, models or designs of the packaging, labels and the separate leaflet attached to the packaging to be provided.
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(1)<RD 2021-09-06/01, art. 8, 002; Entry into force: 13-09-2021>

Art. 29. Advertising
Any advertising, in whatever form, of biocidal products which may not be made available on the market or used in accordance with the provisions of the present Decree is prohibited.
The publications or technical documents intended for vendors or users of biocidal products referred to in the present Decree shall be regarded as advertising.

Art. 30. Traceability
§ 1. Manufacturers of biocidal products that have been placed on the market shall maintain, as regards the manufacturing process, appropriate documentation in paper or electronic format relevant for the quality and safety of the biocidal product to be placed on the market, and shall store production batch samples. The documentation must include at least:
1° safety data sheets and specifications of active substances and other components used for the production of the biocidal product;
2° records of the various different production processes;
3° results of internal quality checks;
4° identification of batches.
§ 2. The commercial documents and transport documents must mention the full commercial description of the product and the registration or authorisation number in accordance with the Biocidal Products Regulation, the batch number, the date of transport and the quantity of the biocidal product. This also applies to the import of biocidal products.
Importers, manufacturers and vendors of biocidal products must keep the relevant invoices and transport documents for three years following the year in which they were drawn up.

Art. 31.Annual declaration and reporting
Every holder of a registration or an authorisation granted in accordance with the Biocidal Products Regulation must declare to the competent authority, before 31 January of each year, the quantity by weight (kilograms) or volume (litres) of biocidal products they placed on the market in Belgium during the previous year.
[1 The competent authority will request this declaration annually via Gestautor.]1

On the basis of the above declaration, an annual overview of the total quantity of active substances placed on the market and global data on biocidal products placed on the market per product type will be made available to the general public.

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(1)<RD 2021-09-06/01, art. 9, 002; Entry into force: 13-09-2021>

Art. 32. Obligation to inform the holder of the registration or the authorisation granted in accordance with the Biocidal Products Regulation

§ 1. At least 48 hours before the placing on the market of a biocidal product, the manufacturer or the person responsible for the placing on the market shall make the notification required by Article 2 of the Royal Decree of 21 April 2016 on notifying the National Centre for the Prevention and Treatment of Intoxications of mixtures classified as hazardous on account of their health effects or physical effects, and amending the Royal Decree of 13 November 2011 setting the fees and contributions payable to the Budget Fund for raw materials and products.

Proof of sending and a copy of the information transmitted shall be kept on file and presented to the official responsible for supervision upon request.

The National Centre for the Prevention and Treatment of Intoxications only forwards this information when there are cases of suspected poisoning caused by biocidal products. This information is exclusively used to give instructions on preventive measures and treatment, particularly in emergencies, at medical request. It is prohibited to use this information for any other purpose. Any person with access to the aforementioned information must keep it confidential.

§ 2. The person responsible for the placing on the market of the biocidal product shall compile and make available a safety data sheet, where appropriate. The safety data sheet shall be drawn up in accordance with Article 31 of 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. 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.

Art. 33.Information obligation of the Minister

The competent authority shall keep a register of all biocidal products that are registered or authorised in accordance with the Biocidal Products Regulation, or for which a parallel trade permit has been granted.

This register is accessible to the general public. It shall be published on the website of the competent authority and updated [1 on a weekly basis at the least]1 . Only the biocidal products that have a valid registration or authorisation in accordance with the Biocidal Products Regulation or a parallel trade permit are entered in this Register. The registration, the authorisation act or the parallel trade permit can be consulted via this register. [1 For the biocidal products which are authorised in accordance with Article 3, 2°, the Summary of Product Characteristics can also be consulted via this register.]1

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(1)<RD 2021-09-06/01, art. 10, 002; Entry into force: 13-09-2021>

TITLE 3. - Measures for the protection of human health concerning the use of biocidal products

CHAPTER 1. - General Provisions

Art. 34. General provision on use

Biocidal products shall be used in accordance with the conditions set out in the registration granted in accordance with the present Decree or in the authorisation granted in accordance with the Biocidal Products Regulation. It is

prohibited to use a biocidal product that has been registered or authorised for any purpose or under any conditions other than those imposed by the Minister.

Correct use also includes taking appropriate precautions and the rational application of a combination of physical, biological, chemical or other measures whereby the use of biocidal products is limited to the necessary minimum.

Art. 35. Classification in closed circuit and free circuit

§ 1. Biocidal products shall be classified in the closed circuit or the free circuit according to their hazard and/or risk.

The classification in the closed circuit or the free circuit is announced according to the modalities imposed by the Minister.

§ 2. Biocidal products shall be classified in the closed circuit if one of the following conditions is met:

1° the biocidal product fulfils the criteria referred to in Article 19(4) of the Biocidal Products Regulation but does not fulfil the conditions referred to in Article 19(5) of the Biocidal Products Regulation;

2° the Minister considers that wearing personal protective equipment is the only way to reduce exposure to an acceptable level.

§ 3. Biocidal products shall be classified in the free circuit if one of the following conditions is met:

1° the Minister considers, on the basis of their risk assessment, that wearing personal protective equipment is not required for the use of this biocidal product;

2° the biocidal product meets the criteria referred to in Article 19(5) of the Biocidal Products Regulation.

Art. 36. Sale and use of biocidal products in the closed circuit

§ 1. When a biocidal product is classified in the closed circuit, it shall be made available on the market by a vendor registered in accordance with Article 40 and used by a user registered in accordance with Article 41.

§ 2. Vendors and users of biocidal products classified in the closed circuit shall comply with the conditions set out in the registration, the authorisation or the Summary of Product Characteristics of the biocidal product in question, in particular the conditions relating to storage and use of personal protective equipment, at all times that they are in possession of such a biocidal product.

Art. 37. Sales and use of biocidal products in the free circuit

For biocidal products classified in the free circuit, apart from the general provisions on use in accordance with Article 34 and the provisions on classification, packaging and labelling in accordance with Article 28, there are no specific conditions attached to their sale and use.

Art. 38. Training for the closed circuit

§ 1. Every user and vendor of biocidal products classified in the closed circuit has the necessary knowledge about the correct use of these biocidal products.

Vendors and users of such biocidal products shall be responsible for training their personnel or persons working on their behalf.

The employers whose employees use such biocidal products are responsible for the elements of the training that relate to the well-being of the employees in accordance with Article VI.1-27 of the Codex of 28 April 2017 on well-being at work.

§ 2. The King may impose additional conditions for a specific biocidal product or for a specific group of biocidal products regarding the training for the vendors and users of biocidal products classified in the closed circuit. The training courses may be a requirement or an optional condition for registration as a registered vendor or registered user.

§ 3. The King may impose additional conditions on vendors and users of biocidal products classified in the closed circuit with regard to demonstrating their knowledge.

CHAPTER 2. - Registration of sale and use

Art. 39. Online registration system

The Minister has provided for an online registration system for biocidal products classified in the closed circuit. This system includes:

1° the registration of the vendor;

2° the registration of the user;

3° the registration of the conditions of storage and the protective measures associated with the use of a specific biocidal product, and this information is included in the registration, the authorisation act or the Summary of Product Characteristics;

4° the registration of every sale.

The registration system shall comply with the provisions imposed on the registered vendor and registered user under Articles 40 and 41.

The modalities of the online registration system shall be determined by the Minister.

Art. 40.Registered vendor

§ 1. Every vendor who makes biocidal products available on the market which are classified in the closed circuit shall register as a registered vendor of biocidal products. The registered vendor shall register in the online registration system every biocidal product classified in the closed circuit that they make available on the market. The registered vendor shall comply with the conditions pertaining to the sale provided for in the registration, the authorisation act or the Summary of Product Characteristics of every biocidal product that they have in their possession and with the conditions imposed in Article 38.

The registered vendor may only sell biocidal products classified in the closed circuit to a registered vendor or a registered user.

The registered vendor:

1° shall, at the time of sale, communicate the conditions stated in the registration, in the authorisation act or in the Summary of Product Characteristics to the user or other vendor. If the conditions are changed, the registered vendor shall take note of these changes and inform the customers to whom they have sold the biocidal product;

2° shall inform the customer of the way in which they can meet the conditions stated in the registration, authorisation act or Summary of Product Characteristics;

3° shall state on the purchase invoice or the receipt: "This product is a biocidal product classified in the closed circuit";

4° shall make available for sale the necessary personal protective equipment in the vicinity of the biocidal product if the [1 general]1 public can have access to these biocidal products classified in the closed circuit.

5° shall record every sale to registered vendors and registered users, as well as the export in the online registration system;

6° shall update this register with the sales and exports of the preceding twelve months, at least on an annual basis and at the latest by 31 January.

The register corresponds to the general figures of sales. Consequently, this register shall satisfy the reporting requirements set out in Article 31 if the registered vendor is also the holder of the registration or authorisation.

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(1)<RD 2021-09-06/01, art. 11, 002; Entry into force: 13-09-2021>

Art. 41. Registered user

§ 1. Every natural or legal person who uses biocidal products classified in the closed circuit must register as a registered user of biocidal products. A registered user shall comply with the conditions pertaining to the use provided for in the registration, the authorisation act or the Summary of Product Characteristics of every biocidal product that they have in their possession and with the conditions imposed in Article 38.

The registered user:

1° shall only purchase a biocidal product classified in the closed circuit from a registered vendor;

2° shall declare at the time of purchase that they agree with and have taken cognizance of the conditions stated in the registration, the authorisation act or the Summary of Product Characteristics and communicated by the registered vendor. In the absence of this information, the registered user shall request it from the registered vendor or notify the absence to the competent authority.

3° shall confirm their status as registered user via the online registration system by 31 December of each year.

TITLE 4. - Repeal, transitional and final provisions

CHAPTER 1. - Repeal provisions

Art. 42. Repeal provision

The Royal Decree of 8 May 2014 on the making available on the market and use of biocidal products, is repealed.

CHAPTER 2. - Transitional provisions

Art. 43.Authorisations, notifications or applications under the Royal Decree of 8 May 2014

§ 1. The authorisations and acceptances of notification for the making available on the market of biocidal products which were granted pursuant to the Royal Decree of 8 May 2014 remain valid until the date mentioned in the authorisation act or in the acceptance of notification.

All provisions of the present Decree applicable to registrations apply to the authorisations and notifications respectively granted or accepted under the Royal Decree of 8 May 2014.

§ 2. An application for renewal or extension of an existing authorisation shall be submitted three months before the expiry date of the authorisation [[1] in accordance with Article 7][1]. If the biocidal product still meets the conditions laid down in Article 5, a registration shall be issued according to the modalities provided for in Article 11, with a new registration number. A period of grace is provided for the disposal, making available on the market and use of existing stocks of biocidal products bearing the existing authorisation or notification number. The period of grace shall consist of an initial six-month period for making existing stocks available on the market and a subsequent six-month period for the disposal and/or use of existing stocks. If no application for extension or renewal has been submitted on the expiry date of the authorisation, no period of grace shall be provided for the disposal, making available on the market and use of existing stocks.

§ 3. An application for modification of an existing authorisation or notification is subject to the provisions of Article 15, § 2. A period of grace is provided for the disposal, making available on the market and use of existing stocks with the existing labels including the authorisation or notification number. The period of grace consists of a first period of six months for making existing stocks available on the market and a subsequent second period of six months for the disposal and/or use of existing stocks.

§ 2. Applications for authorisation and notifications submitted in the context of the Royal Decree of 8 May 2014 but not yet settled at the time of entry into force of the present Decree shall be settled in accordance with Articles 8, 9 and 10.

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(1)<RD 2021-09-06/01, art. 12, 002; Entry into force: 13-09-2021>

Art. 44. Transition to European authorisation

For biocidal products which have been registered, authorised or for which a notification was accepted in accordance with Article 3, 2°, and for which the active substance was approved in accordance with the Biocidal Products Regulation for the product type to which the biocidal product belongs, an application for authorisation or for mutual recognition in parallel of the authorisation in accordance with the Biocidal Products Regulation shall be submitted at the latest on the day that the active substance(s) are approved.

In the case of biocidal products containing more than one active substance and/or classified in more than one product type, an application for authorisation or for mutual recognition in parallel of authorisation in accordance

with the Biocidal Products Regulation shall be submitted at the latest by the date on which all the active substances have been approved for the product types relevant to the efficacy of the active substance in the product.

The competent authority may grant the holder of a registration, authorisation or notifier who has applied for authorisation or mutual recognition in parallel of authorisation under the Biocidal Products Regulation in accordance with paragraph 1 and within the period specified therein, renewal of the existing registration, authorisation or acceptance of notification, for a minimum period necessary to complete the application for authorisation or mutual recognition in parallel of authorisation under the Biocidal Products Regulation and up to a maximum of three years from the date referred to in paragraph 1.

CHAPTER 3. - Final provisions

Art. 45. Implementation

The Minister responsible for Employment, the Minister responsible for Economy, the Minister responsible for Consumers, the Minister responsible for Public Health, the Minister responsible for Environment, the Minister responsible for the Self-Employed and the Minister responsible for SMEs are responsible for the implementation of this Decree, each to the extent to which they are concerned.

Brussels, 4 April 2019.
PHILIPPE
On behalf of the King:
The Minister for Employment, the Economy and Consumers,
K. PEETERS
The Minister for Public Health,
M. DE BLOCK
The Minister for the Environment,
M. C. MARGHEM
The Minister for the Middle Classes, SME's and the Self-Employed,
D. DUCARME