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KINGDOM OF BELGIUM

FEDERAL PUBLIC SERVICE FOR HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT

FEDERAL PUBLIC SERVICE

ECONOMY, SMES, SELF-EMPLOYED AND ENERGY

# Royal Decree amending the Royal Decree of 4 April 2019 on the making available on the market and the use of biocides

PHILIPPE, King of the Belgians;

To all who are here now or will be hereafter, Greetings.

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 8(1), as amended by the Law of 28 March 2003;

Having regard to the Code of Economic Law, Article VI.35(1)(1), inserted by the law of 21 December 2013;

Having regard to the Royal Decree of 4 April 2019 on the making available on the market and use of biocides;

Having regard to the involvement of the regional governments in the implementation of this Decree within the framework of the Interministerial Conference on the Environment, of xx June 2023;

Having regard to the opinion of the Supreme Council for the Self-Employed and SMEs, issued on … 2023;

Having regard to the opinion of the Special Advisory Committee on Consumption, given on… 2023;

Having regard to 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, Article 6(7)(a);

Having regard to notification No 2023/xxx/B addressed to the European Commission on… 2023;

Having regard to the impact assessment on the legislation, conducted in accordance with Articles 6 and 7 of the Law of 15 December 2013 on various provisions concerning administrative simplification;

Having regard to the opinion of the Finance Inspector, given on… 2023;

Having regard to the acceptance by the State Secretary for Budget, given on… 2023;

Having regard to the opinion xx.xxx/x of the Council of State, given on... 2023, pursuant to Article 84(1)(2) of the Laws on the Council of State, coordinated on 12 January 1973;

At the proposal of the Minister for the Economy, the Minister for Health and the Environment, and on the advice of the Ministers meeting within the Council,

We have decided and hereby decree:

Article 1. The following amendments are made to Article 2 of the Royal Decree of 4 April 2019 on the making available on the market and use of biocides, as amended by the Royal Decrees of 6 September 2021 and 9 December 2021:

1° the provision under 11° is replaced as follows:

'11° product type: product type as provided for in Article 3 of the Biocides Regulation;';

2° the provision under 20° is replaced as follows:

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

3 ° the article shall be supplemented by the provisions of 38°, 39°, 40°, 41° and 42°, as follows:

'38° European authorisation: an administrative decision, issued in accordance with the Biocide Regulation, whereby the Minister or the European Commission, following an application submitted by an applicant, allows a biocide to be made available and used on the market;

39° biocide family: biocide family as provided for in Article 3 of the Biocide Regulation;

40° Summary of Product Characteristics: document containing the product characteristics of a biocide or, in the case of a biocide family, of the biocide within that biocide family, within the meaning of Article 22(2) of the Biocide Regulation and which forms an integral part of the European authorisation;

41° specific target organism: target organism specified at the level of the genus and species name in the biological taxonomy or equivalent;

42° substance of concern: substance of concern as provided for in Article 3 of the Biocide Regulation.';

Article 2. Article 3 of the same Decree shall be replaced with the following:

'Article 3. Making available on the market and use

Biocides shall only be made available on the market and used if:

1 ° a European authorisation has been granted for these biocide or;

2 ° for these biocide, the Minister has granted a registration in accordance with this Decree or has granted an authorisation or has accepted a notification in accordance with the Royal Decree of 8 May 2014.

Without prejudice to subparagraph 1, biocides may only be made available on the market and used:

1 ° insofar as the validity date of the European admission, authorisation, registration or acceptance of the notification referred to in subparagraph 1 has not been exceeded. For the biocides referred to in subparagraph 1(2), this date of validity is also determined by Article 89(2) of the Biocide Regulation;

2 ° in accordance with the applications and conditions granted of the European authorisation, authorisation, registration or acceptance of notification referred to in subparagraph 1;

3 ° insofar as the expiry date of the product, as referred to in Article 28(5)(14), is not exceeded.'.

Article 3. The following amendments are made to Article 4 of the Decree:

1 ° the words 'In application of Article 3(2)' shall be replaced with the words 'In application of Article 3(1)(2),';

2 ° the words 'one or more existing active substances that are being evaluated' are replaced with the words 'one or more existing active substances that have been or are being evaluated'.

Article 4. The following amendments are made to Article 5 of the decree:

1 ° the words 'A registration in accordance with Article 3(2)' shall be replaced with the words 'A registration in accordance with Article 3(1)(2)';

2 ° the words 'one or more existing active substances that are being evaluated' are replaced with the words 'one or more existing active substances that have been or are being evaluated';

3 ° the words 'in accordance with Article 10' shall be replaced with the words 'in accordance with Article 7 and, where applicable, Article 10'.

Article 5. In Article 7(2) of the same Decree, the following amendments are made:

1 ° the words '(specified at the level of generic and generic name or equivalent)' are deleted;

2 ° the words 'Article 10(4)' are replaced with the words 'Article 10(5)'.

Article 6. Article 8(2)(1) of the same Decree is replaced with the following:

'After the competent authority has received the application, payment of the required fee will be requested. Upon receipt of the fee, a file manager is appointed. The competent department shall review the administrative admissibility of the application and send a message to the applicant within 20 working days of the designation of the file manager.'.

Article 7. The following amendments are made to Article 9 of the decree:

1 ° in paragraph 1, the words '(specified at genus and species name level or equivalent)' are deleted;

2° paragraph 2(1) is replaced with the following:

'The Minister shall grant registration within 20 working days from the date on which the application was declared administratively admissible if the conditions set out in Article 5 are met.'.

Article 8. The following changes shall made to Article 10 of the same Decree, amended by the Royal Decree of 6 September 2021:

1° paragraph 2(1) is replaced with the following:

'The applicant may set out his defences against the decision taken by the Minister in a statement of objection and may submit a request to be heard by the Biocide Advisory Committee. This objection shall not be permitted to include elements that are part of or rely on data in accordance with Annex 1, B. The objection is only admissible if it is forwarded to the competent service by registered letter within 30 working days. This period shall start on the day on which the applicant is notified of the decision of the Minister. Any objection that is not admissible shall not be dealt with. The petitioner shall be informed of this by registered letter by the competent department". ;

2° paragraph 2(2) is replaced with the following:

'If admissible, the objection shall be examined by the Committee for Opinion on Biocides at day and hour by its chair. If requested, the applicant shall be heard or at least duly called upon by the Biocides Advisory Committee'. ;

3 ° in paragraph 2(3), the words 'The conservation or amendment' are replaced with the words 'The conservation or amendment';

4° paragraph 4 is replaced as follows:

'(4). If the minister retains the decision that a full assessment is required, or if no admissible objection is filed, the additional data in accordance with Annex 1, B, must be submitted to the competent department in accordance with the modalities of Article 7. This shall be done within 30 working days of notification of the Minister's decision or after the period of 30 working days provided for lodging an appeal.'.

Article 9. The following amendments are made to Article 11 of the decree:

1° paragraph 2 is replaced as follows:

'(2). Subject to the application of Articles 12 to 15, registration granted in accordance with the provisions of this Decree shall remain valid until the date specified in the registration. By way of derogation from this provision, the period of validity may run until the date of approval of the active substance for the product type to which the biocide belongs and up to the end of the work programme for systematic examination of all existing active substances referred to in Article 89(1) of the Biocide Regulation. In the case of biocides containing more than one active substance and/or classified in more than one product type, the validity period may run until the date on which all active substances are approved for the product types relevant to the action of the active substance in the biocide'. ;

2° paragraph 4(1) is replaced with the following:

'The registration may be re-examined at any time. Possible reasons may be:

1° if there are indications that the conditions laid down in Article 5 are no longer met; or

2 ° on the basis of new information received in accordance with Article 24.'.

Article 10. The following amendments are made to Article 12 of the Decree:

1 ° in subparagraph 1, the provision under 1° is replaced with the following:

'1° the Minister deems this necessary on the basis of developments in scientific and technical knowledge, or on the basis of research carried out in accordance with Article 11(4) and for the protection of health or the environment; or';

2° subparagraph 2 is replaced with the following:

'The application for variation of registration shall be submitted before the date of approval of the active substance or, in the case where a product contains several active substances, before the date of approval of the last active substance for that product-type at the latest six or three months before the date of approval of a scientific or administrative amendment. An amendment to the conditions of a registration pursuant to Paragraph 1 shall require an amended registration, causing the original registration to be cancelled.'.

Article 11. Article 13 of the same Decree shall be supplemented by a subparagraph, reading:

'By way of derogation from subparagraph 1(1) and (2), the suspended registration by the Minister shall be lifted in accordance with Article 14 if the suspension could not be terminated after six months in accordance with the provisions of subparagraph 1(1) and (2). However, the Minister may, after examining a reasoned request from the holder of the registration, submitted before the suspended registration was lifted by the Minister, extend that period.'.

Article 12. Article 14(1) of the same decree, as amended by the Royal Decree of 9 December 2021, is supplemented by the provisions 4° and 5°, which read as follows:

'4 ° Article 13(3) so provides; or

5 ° Chapter IV of the Royal Decree of 13 November 2011 so provides.'.

Article 13. The following amendments are made to Article 15 of the decree:

1° paragraph 1 is replaced as follows:

'(1). If the Minister takes the initiative to amend, suspend or cancel a registration, the competent department shall inform the holder of the registration by registered letter. This concerns the cases referred to in Article 12(1)(1°), Article 13 and Article 14(1),(2) and (4)". ;

2 ° in paragraph 2(2), the word 'opinion' is replaced with the words 'modified registration'.

Article 14. The following amendments are made to Article 16 of the decree:

1° subparagraph 1 is replaced with the following:

If a biocide has already been registered pursuant to Articles 5 to 10, then without prejudice to the obligations pursuant to Article 22, the Minister may grant a registration to a second or subsequent applicant if this party refers to details provided by the initial applicant, to the extent that the second or subsequent applicant successfully demonstrates that the biocide is identical in all respects to the biocide previously registered'. ;

2° subparagraph 4 shall be replaced as follows:

'The identical biocide shall be registered under either the same conditions or conditions that are different but do not affect the properties or efficacy of the biocide. The validity date stated on the registration of the same biocide shall be the same as the one on the registration of the biocide originally registered. There is a permanent link between the two biocides. However, it is not required to include all the applications of the biocide originally registered.'.

Article 15. Article 17 of the same decree, as amended by the Royal Decree of 6 September 2021, is replaced with the following:

'Article 17. Objections

The applicant may set out their defences against the decision taken by the Minister in accordance with Articles 9, 10, 12, 13, 14 and 16, with the exception of the decision referred to in Article 10(1) for which the procedure laid down in Article 10(2) is followed. It is not permitted to include new studies in the notice of objection. This objection shall be admissible only if it is transmitted within 30 working days by registered letter to the competent department. This period shall start on the third working day following the day on which the decision was sent to the applicant by the competent department.

Any objection that is not admissible shall not be dealt with. The petitioner shall be informed of this by registered letter by the competent department.

After an admissible objection letter is received by the relevant department, the required fee is requested.

The admissible objection, after payment of the required fee, shall be promptly communicated by the competent department to the Supreme Health Council for its opinion, which shall examine it within 60 working days from the date of receipt of the objection, at such day and time as may be determined by its chairperson. Within the next ninety working days, the Supreme Health Council shall submit its recommendation to the Minister.

Before the opinion is given, the applicant and the competent service shall be heard or at least duly called by the Supreme Health Council.

The decision on the objection shall be taken by the Minister before the expiry of a period of 160 working days, starting from the date on which the competent department has received payment of the fee required for the objection. The retention or modification of the Minister’s original decision shall be served by registered letter to the applicant and by email to the Supreme Health Council.'.

Article 16. In Article 18 of the same Decree, the words 'the provisions' are replaced with the words 'Chapter IV'.

Article 17. The following changes shall made to Article 19 of the same Decree, amended by the Royal Decree of 6 September 2021:

1° paragraph 1(2) is replaced with the following:

'The applicant intending to make the biocide available on the market shall submit the application for parallel trade authorisation by email to the competent service. The application for parallel trade authorisation shall be submitted no later than three months before the date of approval of the active substance or, where a product contains several active substances, before the date of approval of the last active substance for that product-type.';

2° paragraph 1(4) is replaced with the following:

Any person applying for a parallel trade permit shall pay the fee pursuant to Chapter IV of the Royal Decree of 13 November 2011. After the competent authority has received the application for a parallel trade permit, the required fee will be requested'. ;

3 ° in paragraph 7, the word 'immediately' is inserted between the words 'The holder of the authorisation shall report this' and the words 'to the competent service'.

Article 18. In the heading of Chapter 4 of the same Decree, the words 'in accordance with Article 3(2)' shall be replaced with the words 'in accordance with Article 3(1)(2)'.

Article 19. The following amendments are made to Article 20 of the decree:

1 ° the words 'in accordance with Article 3(2)' shall be replaced with the words 'in accordance with Article 3(1)(2);

2 ° the words 'one or more existing active substances that are being evaluated' are replaced with the words 'one or more existing active substances that have been or are being evaluated'.

Article 20. In Article 21 of the same Decree, the words 'up to 365 calendar days' are replaced with the words 'up to 550 calendar days'.

Article 21. In Article 26 of the same Decree, the words 'by way of derogation from Article 3(2) shall be replaced with the words 'by way of derogation from Article 3(1)(2)'.

Article 22. Article 28 of the same decree, as amended by the Royal Decree of 6 September 2021, is replaced with the following:

'Article 28. Classification, packaging and labelling

(1). Registration holders or European authorisations shall ensure that biocides are classified, packaged and labelled in accordance with the registration, the authorisation certificate or the approved summary of product characteristics, and, where applicable, the CLP Regulation.

(2). Biocides which may be mistaken for food, including beverages, or feed shall be packaged to minimise the likelihood of this confusion. If they are available to the general public, components are added that discourage their consumption.

Biocides, in particular, should not be attractive to children.

(3). Biocides may only be delivered to the user in the intact original packaging. They shall not be divided under any circumstances.

It is prohibited to alter the original packaging or the label. It shall be prohibited to re-use the packaging of biocides, except in the case of containers specifically intended for reuse, loading or filling by the holder of the registration or the European authorisation.

(4). Packaging of biocides placed on the market as aerosols shall meet the provisions of the Royal Decree of 31 July 2009 on aerosols.

(5). Holders of registrations or European authorisations shall ensure that a label is not misleading with regard to the risks posed by the biocide to human or animal health or to the environment, or to its effectiveness, and in no case bears the words 'low-risk biocide', 'non-toxic', 'non-hazardous', 'natural", 'bio', 'environmentally friendly', 'animal-friendly' or the like. In addition, the following information shall be clearly stated legibly and indelibly on the label:

1 ° the commercial designation of the biocide as indicated on the registration, the European authorisation or the summary of product characteristics. All other information on the label should remain subordinate to the commercial designation of the biocide;

2° the identity of every active substance and its concentration in metric units;

3° the identity of each substance of concern and its concentration in metric units;

4° any nanomaterials contained in the biocide and any specific associated risks and, following each reference to nanomaterials, the word ‘nano’ in brackets;

5° the registration or authorisation number assigned to the biocide by the competent authority or the authorisation number assigned by the European Commission;

6 ° the name and address of the holder of the registration or of the European authorisation. The name, address and logo of the distributor may be added, but must always be subordinate to the details of the holder of the registration or authorisation granted under the Biocides Regulation;

7° formulation type;

8 ° the use for which the biocide is registered or authorised in accordance with the Biocide Regulation;

9 ° for each use specified in the registration or the European authorisation, the instructions for use, the frequency of administration and the dosage, in metric units and in a clear and understandable manner for the user;

10° the phone number of the Belgian Poison Control Centre [Nationaal Centrum ter voorkoming en behandeling van intoxicaties];

11 ° details of possible direct or indirect adverse reactions and instructions for the provision of first aid;

12° the sentence 'Read attached instructions for use before use', if an enclosed leaflet is included and, where applicable, warnings for vulnerable groups;

13° directions for safe disposal of the biocide and its packaging and, where applicable, a prohibition on reuse of the packaging;

14 ° the lot number or batch designation of the formulation and expiry date under normal storage conditions;

15 °, where applicable, the time elapsed before the biocide occurs, the period to be observed between two successive treatments with the biocide or between a treatment and the next use of the treated biocide or the next human or animal entry into the space where the biocide was used, including details of decontamination agents and measures, and how long the spaces concerned are to be ventilated; details on proper cleaning of equipment; details on precautions during use and transport;

16° where applicable, the categories of users to which the biocide is restricted;

17° where appropriate, information on specific hazards to the environment, in particular in relation to the protection of non-target organisms and the avoidance of water pollution;

18° for biocides containing micro-organisms, the labelling requirements in accordance with Book VII – Organic agents of the Codex of 28 April 2017 on well-being at work;

19 ° the nominal quantity of the mixture in the package presented, unless that quantity is stated elsewhere on the packaging.

The information given in 1°, 2°, 5°, 6° and 10° shall be given in a clearly visible position on the front of the label.

By way of derogation from the first subparagraph, the information set out under 7°, 9°,11°, 13°, 14°, 15° and 17°, where this is necessary because of the size or the function of the biocide, may be included on the packaging or in a leaflet included in the packaging.

(6). The font size of the mandatory information on the label referred to in paragraph 5 shall be at least 1.2 mm, the height of the vowels being used as a size in lowercase letter. The same font size shall be used for information of equal importance.

(7). By way of derogation from Article 2 of the Royal Decree of 7 September 2012 laying down the language on the label and on the safety data sheet of substances and mixtures, and designating the National Centre for the Prevention and Treatment of Intoxications as an organ referred to in Article 45 of Regulation (EC) No 1272/2008, the information referred to in Article 17(1)(d) to (g) of Regulation CLP, to be displayed on the label of biocides classified as hazardous, shall be provided in Dutch, French and German.

By way of derogation from Article 2 of that Decree, the information referred to in Article 17(1) (a), (b), (c) and (h) of Regulation CLP, which must be displayed on the label of biocides classified as hazardous and which is also required in accordance with paragraph 5, shall be set out in Dutch and French. For German, reference may be made to a public, directly consultable label.

For biocides not classified as hazardous, all information required in accordance with paragraph 5 shall be provided in Dutch and French. For German, reference may be made to a public, directly consultable label.

(8). The Minister or official responsible for supervision may require submission of samples, models or designs of the packaging, labels and separate leaflet attached to the packaging".

Article 23. Article 29 of the same Decree shall be replaced with the following:

'Article 29. Advertising

(1). Advertising, in whatever form, for biocides shall be authorised only for biocides which, under the provisions of this Decree, may be made available or used on the market, provided that all uses referred to in the advertising are authorised, registered or are part of an acceptance of notification.

Publications or technical documents intended for the sellers and users of the biocides referred to in this Decree shall be deemed equivalent to advertising.

(2). By way of derogation from paragraph 1, advertising, in whatever form, shall be prohibited for applications authorised only by the general public if the number of points awarded to the biocide, in accordance with the provisions of Article 7(2) of the Royal Decree of 13 November 2011 determining the fees and contributions payable to the Budget Fund for raw materials and products, is different from 0.

By way of derogation from subparagraph 1, the Minister may grant an exception to this prohibition in respect of one or more provisional authorisations granted in accordance with the Biocide Regulation, or temporary registrations if that measure proves useful in combating an unforeseen danger to public health, animal health or the environment in any other way.

(3). Discounts, free quantities, free products or any similar form of direct or indirect promotion when purchasing the biocides referred to in paragraph 2(1) shall be prohibited.

(4). By way of derogation from paragraph 2(1), catalogues and price lists may indicate the biocides referred to in paragraph 2(1), provided that no information other than that mentioned in paragraph

5 is included in addition to the cost price. These catalogues and price lists may only be made available at the points of sale and through websites for online sales.

(5). Without prejudice to the legal provisions applicable to advertising and those contained in the Biocide Regulation, any advertising of biocides, in whatever form, should include the commercial designation, the authorisation, registration or notification number and the name of the active substances, as laid down in the European authorisation, the summary of product characteristics, the authorisation, registration or acceptance of notification. Only the uses included in the European authorisation, the authorisation, the registration or the acceptance of notification may be mentioned.

(6). In the case of advertising disseminated through a communication technique providing limited time for displaying information, the following mandatory particulars shall appear legibly for a period of at least:

– six seconds for the sentences 'Use biocides safely. Before use, read the label and product information, where the word 'biocides' may be replaced with a clear indication of the advertised product type;

– three seconds for the commercial designation;

– three seconds for the authorisation, registration or notification number;

– three seconds per active substance for the active substances.

Where more than one of these mandatory entries appear simultaneously, the number of seconds during which they appear shall be at least equal to the sum of the minimum periods of time for each of the entries separately.'.

Article 24. In Article 30(2) of the same Decree, the words 'authorisation granted in accordance with the Biocide Regulation' are replaced with the words 'European authorisation'.

Article 25. Article 31 of the same decree, as amended by the Royal Decree of 6 September 2021, is replaced with the following:

'Article 31. Annual declaration and reporting

(1). Each holder of a registration, parallel trade authorisation or European authorisation shall, in accordance with Chapter IV of the Royal Decree of 13 November 2011, declare each year to the competent authority the quantity of biocides which they have placed on the market in Belgium the previous year.

The competent department requests this declaration annually via Gestautor. The holder makes their declaration via Gestautor.

(2). Biocides which have been temporarily registered or provisionally authorised in accordance with Article 21 or in accordance with Article 55(1) or (3) of the Biocide Regulation shall not form part of the declaration referred to in paragraph 1. By way of derogation, biocides that were validly registered prior to the temporary registration or provisional authorisation, were authorised, or had an acceptance of notification and this for uses other than those that were the subject of the temporary registration or provisional authorisation, will be part of the declaration referred to in paragraph 1.

(3). Based on the aforementioned declaration in paragraph 1, an annual overview of the overall quantities of active substances placed on the market, and overall details regarding biocides that have been placed on the market for each product type, shall be made available to the general public.'.

Article 26. The heading of Article 32 of the same Decree is replaced with the following:

'Information obligations of the holder of the registration, authorisation, European authorisation or acceptance of notification'.

Article 27. In the same Decree, Article 32(1) is inserted and reads as follows:

'Article 32/1. Obligations of the holder of the registration, authorisation, European authorisation or acceptance of notification during the grace period

(1). During the grace period referred to in Article 15(4), or Article 43(2) and (3) of this Decree, or in Articles 52 or 89(3) and (4) of the Biocide Regulation, the holder of the registration, authorisation or acceptance of notification shall remain responsible for the biocides still on the market. The holder of the registration, authorisation or acceptance of notification shall inform distributors and all persons to whom they sell directly, indicating the commercial description of the biocide, the authorisation, notification or registration number, of the end date for making available on the market and the end date for use.

(2). The holder of the registration, authorisation or acceptance of notification shall be obliged to take back the remaining unopened packaging of the biocide remaining on the market after the expiry of the grace period free of charge. The same shall apply to any remaining unopened packaging of the biocide located at users' premises, if they so request.'.

Article 28. Article 33 of the same decree, as amended by the Royal Decree of 6 September 2021, is replaced with the following:

'Article 33. Minister's information requirement

The competent service shall keep an overview of all biocides registered, authorised, or for which parallel trade or acceptance of notification has been granted.

This overview is accessible to the general public. It shall be published on the website of the competent service, and updated at least weekly. The registration, the authorisation certificate, the notification acceptance or the parallel trade authorisation can be consulted via this overview. Of the biocides authorised under Article 3(1)(1), the summary of product characteristics can also be consulted through this overview.'.

Article 29. In Article 34 of the same Decree, the first subparagraph shall be replaced as follows:

'Without prejudice to Article 3, biocides shall be used in accordance with the conditions set out in the registration, temporary registration, experimentation or trial authorisation, or parallel trade authorisation granted in accordance with this Decree or in the European authorisation or provisional authorisation granted in accordance with the Biocides Regulation. It shall be prohibited to use a biocide registered or authorised for purposes other than those imposed by the Minister or the European Commission.'.

Article 30. Article 36 of the same Decree is supplemented by a paragraph 3 which reads as follows:

'(3). The Minister may, on the basis of the risk assessment and without prejudice to the classification in the closed circuit, grant partial exceptions to the obligations arising from the first and second paragraphs for a biocide.'.

Article 31. In Article 39 of the same Decree, the words 'online registration system' are each replaced with the words 'online registration system "Closed circuit"'.

Article 32. The following changes shall made to Article 40(1) of the same Decree, amended by the Royal Decree of 6 September 2021:

1° subparagraphs 1 and 2 are replaced with the following:

'Any seller making available on the market biocides classified in the closed circuit shall, subject to the exception granted in accordance with Article 36(3), register as a registered seller of biocides. The registered seller shall, subject to the exception granted in accordance with Article 36(3), register in the online registration system 'Closed circuit' any biocide classified in the closed circuit which they make available on the market. The registered seller shall meet the sales conditions stipulated in the registration, the authorisation document or the summary of product characteristics for each biocide in the possession of the seller and the conditions stipulated in Article 38.

Subject to the exception granted in accordance with Article 36(3), the registered seller may sell biocides classified in the closed circuit only to a registered seller or a registered user'. ;

2 ° in the provision under 5°, the words 'online registration system' are replaced with the words 'online registration system "Closed circuit"';

3 ° in the provision under 6°, the words 'this register' are replaced with the words 'this register'";

4° subparagraph 4 is removed.

Article 33. In Article 41(1) of the same decree, as amended by the Royal Decree of 17 February 2023, subparagraph 1 is replaced with the following:

'Subject to the exception granted in accordance with Article 36(3), any natural or legal person using biocides classified in the closed circuit shall register as a registered user of biocides.'.

Article 34. Article 44 of the same Decree shall be replaced with the following:

'Article 44. Transition to European admission

(1). For biocides registered or authorised or for which a notification was accepted pursuant to Article 3(1)(2), whose active substance was approved under the Biocides Regulation for the product type to which the biocide belongs, an application for authorisation or for parallel mutual recognition of the authorisation under the Biocides Regulation shall be submitted no later than the date on which the active substance(s) are approved.

(2). In the case of biocides containing more than one active substance and/or classified in more than one product type, an application for European authorisation or for parallel mutual recognition of the European authorisation in accordance with the Biocide Regulation shall be submitted at the latest by the date on which all active substances are approved for the product types relevant to the action of the active substance in the product.

(3). To the holder of a registration, authorisation or notifier who has submitted an application for European authorisation or for parallel mutual recognition of European authorisation in accordance

with the Biocide Regulation in application of the first subparagraph and within the period specified therein, the competent service may grant an extension of the existing registration, authorisation or acceptance of the notification, for a minimum period necessary for the processing of the application for European authorisation or for parallel mutual recognition of European authorisation in accordance with the Biocide Regulation, up to a maximum of three years from the date referred to in the first paragraph.'.

Article 35. In the same Decree, Annex 1 shall be replaced with Annex 1 to this Decree.

Article 36. In the same Decree, Annex 2 shall be replaced with Annex 2 to this Decree.

Article 37. In the same Decree, Annex 3 shall be replaced with Annex 3 to this Decree.

Article 38. This Decree shall enter into force on ....

By way of derogation from subparagraph 1, Articles... shall enter into force....

By way of derogation from subparagraph 1, Articles... shall enter into force....

Article 39. The Minister responsible for Economy, the Minister responsible for Public Health and the Minister responsible for the Environment are tasked with the implementation of this Decree, each within their own field.

Drawn up in Brussels,

On behalf of His Majesty:

The Minister of the Economy,

The Minister for Public Health,

The Minister of the Environment,

Annex 1 to the Royal Decree of... amending the Royal Decree of 4 April 2019 on the making available on the market and use of biocides (Article 35)

'Annex 1

# REGISTRATION: FILE REQUIREMENTS

A. For each application for registration, an electronic file is submitted via the 'Gestautor' application. The application is available via the website of the authorised service(www.biocide.be). This file contains the following information:

— trade description of the biocide;
— applicant and entity to be invoiced;
— producer of the biocide;
— producer or importer of the active substance;
— distributor;
— formulation type;
— product type and intended application;
— exact qualitative and quantitative composition;

— proposal for classification and labelling;
— label of the biocide;
— safety data sheet of the biocide;
— safety data sheet of all ingredients in the biocide;
— estimated quantity of biocide made available on the market in Belgium;
— packaging type and size;
— efficacy test with the biocide for which registration is submitted (only in case of claim against specific target organism or according to specific standard).

B. In addition, the following information shall be kept available and submitted where a full evaluation is required in accordance with Article 10:

— analysis of the active substance(s) content;
— stability test;
— entry letter for active substance(s);
— a draft risk assessment assessing the effects and properties referred to in Article 5;
— summary of the toxicological and ecotoxicological data, containing at least the data and appropriate references necessary for the preparation of the draft risk assessment (only if the European assessment report for the active substance(s) is not yet available or if a letter of access to the active substance(s) cannot be submitted);
— efficacy test(s) for all intended purposes;
— residue test (only if residues are possible in the diet).

The data mentioned under B. are submitted electronically via the application 'Gestautor'.”

Annex 2 to the Royal Decree of... amending the Royal Decree of 4 April 2019 on the making available on the market and use of biocides (Article 36)

'Annex 2

# PARALLEL TRADE FORM

| | |
|---|---|
| Applicant | Name: .....<br>Street: ..... No:.....<br>Postal code:..... Municipality:.....<br>Country:.....<br>Company number*: .....<br><br>**at Crossroads Bank Enterprises (CBE) (if applicable)* |
| Contact | Name: .....<br>Telephone: .....<br>Email address..... |
| Commercial designation for the biocide to be | .....<br>..... |

| | | |
|---|---|---|
| distributed | | |
| Member State of origin | .....<br>..... | |
| Name and address of the competent authority in the Member State of origin | Name: .....<br>Street: ..... No:.....<br>Postal code:..... Municipality:.....<br>Country:..... | |
| Name and address of the authorisation holder in the Member State of origin | Name: .....<br>Street: ..... No:.....<br>Postal code:..... Municipality:.....<br>Country:..... | |
| Name and authorisation number of the biocide in the Member State of origin | Name: .....<br>Authorisation number:..... | |
| Name and registration or authorisation number of the reference product | Name: .....<br>Registration or Admission Number:..... | |
| Manufacturer of the biocide | Name: .....<br>Street: ..... No:.....<br>Postal code:..... Municipality:.....<br>Country: | |
| Active substance(s) present in the biocide and their guaranteed content | <u>Active substance 1</u><br>Name: .....<br>CAS number: .....<br>Guaranteed level in the biocide: .....<br><br><u>Active substance 2</u><br>Name: .....<br>CAS number: .....<br>Guaranteed level in the biocide: .....<br><br><u>Active substance 3</u><br>Name: .....<br>CAS number: .....<br>Guaranteed level in the biocide: .....<br>*(if more than three active substances, further supplement)* | |
| Manufacturer of the active substance(s):<br>(if not established in the EU, the importer will be mentioned) | <u>Active substance 1</u><br>Name: .....<br>Street: ..... No:.....<br>Postal code:..... Municipality:.....<br>Country:.....<br><br><u>Active substance 2</u><br>Name: .....<br>Street: ..... No:.....<br>Postal code:..... Municipality:.....<br>Country:.....<br><br><u>Active substance 3</u><br>Name: .....<br>Street: ..... No:.....<br>Postal code:..... Municipality:.....<br>Country:.....<br>*(if more than three active substances, further supplement)* | |
| Name and CAS number of all non-active substances present in the biocide | Name | CAS number |
| | ..... | ..... |

| | | |
|---|---|---|
| | ..... | ..... |
| | ..... | ..... |
| | ..... | ..... |
| | ..... | ..... |
| Intended application and product type | Description of the intended use:<br>.....<br>.....<br>.....<br>Product type(s):..... | |
| Nature of the packaging in which the biocide will be placed on the market | Shape of the packaging:<br>.....<br>.....<br>Material of the packaging:<br>.....<br>.....<br>Contents of the package (weight or volume):<br>.....<br>..... | |
| Formulation type | .....<br>..... | |
| Quantity to be imported | .....<br>..... | |
| Planned period of imports | .....<br>..... | |

The following documents shall be submitted as annexes together with this form:

Annex 1: The original label and the original user instructions that accompany the biocide when distributed in the Member State of origin. If these documents have not been compiled in French or Dutch, a translation in French or Dutch is also required.

Annex 2: The draft label for the biocide to be placed on the market, in Dutch and French.

Annex 3: A declaration on honour that the biocide for which a parallel trade permit is requested was manufactured according to the same production process as the reference product.

Annex 4: A solemn declaration that the permit holder shall inform the competent authority if the authorisation for the imported biocide were to be withdrawn by the Member State of origin.

This application for authorisation will be sent by email to the following email address together with the corresponding data: info.gestautor@health.fgov.be

The fee must be paid upon receipt of the automatic notification in the 'Gestautor' application confirming receipt of the file and taking into account the payment modalities indicated on the invoice. In this invoice, available in the 'Gestautor' application, you will

find the amount to be paid, the account number and the structured communication that you must indicate when making the payment.

..... .....
*(location)* *(date)*

VERY CLEARLY indicate the name and capacity of the signatory:

Thus fully and truthfully filled

..... .....
*(signature)*

Annex 3 to the Royal Decree of... amending the Royal Decree of 4 April 2019 on the making available on the market and use of biocides (Article 37)

'Annex 3

# FORM FOR NOTIFICATION OF TRIAL OR EXPERIMENT IN WHICH THE BIOCIDES MAY END UP IN THE ENVIRONMENT OR RESULT IN ITS RELEASE

<table>
<tr><td>Notifier</td><td>Name: .....<br>Street: ..... No:.....<br>Postal code:..... Municipality:.....<br>Country:.....<br>Company number*: .....<br><br>*at Crossroads Bank Enterprises (CBE) (if applicable)</td></tr>
<tr><td>In the event of a test or experiment with a biocide:</td><td>Commercial designation of the biocide: .....<br>.....<br>.....<br><br>Full composition of the biocide: .....<br><br><table><tr><td></td><td>Chemical name</td><td>CAS No</td><td>Level (%)</td></tr><tr><td>Active substance(s)</td><td></td><td></td><td></td></tr><tr><td>Non-active substances</td><td></td><td></td><td></td></tr></table><br>Classification and labelling of the biocide:<br>.....</td></tr>
</table>

| | |
|---|---|
| | .....<br>.....<br>.....<br><br>Area of use of the biocide:<br>.....<br>.....<br>.....<br>..... |
| In the event of a test or experiment with an active substance | Name of the active substance:.....<br>CAS number:.....<br>Level of purity.....<br>Name and address of the manufacturer of the active substance (if not established in the EU: the importer):....<br>.....<br>.....<br>.....<br>.....<br><br>Classification and labelling: .....<br>.....<br>Scope:.....<br>.....<br>..... |
| Total quantity of biocide or active substance used in the test or experiment (in weight or volume) | .....<br>.....<br>..... |

The following documents shall be submitted as annexes together with this form:

Annex 1: A detailed description of the test or experiment to be executed with a valid reason for the execution of the test or experiment

Annex 2: If available, a label (draft or otherwise) for the biocide or the active substance with which the test or experiment is to be carried out

Annex 3: All available data on possible effects on human or animal health or on the environment.

Annex 4: A list of all persons, institutions involved in the trial or experiment and all locations where the biocide or active substance will take place

This notification will be sent by email to the following email address together with the corresponding data: info.gestautor@health.fgov.be

The fee must be paid upon receipt of the email confirming receipt of the file and in accordance with the payment modalities set out in the corresponding invoice. In this invoice you will find the amount to be paid, the account number and the structured communication that you must indicate when you make the payment.

..... .....
*(location)* *(date)*

VERY CLEARLY indicate the name and capacity of the signatory:

Thus fully and truthfully filled

..... .....
*(Signature)*

”