	DRAFT
	KINGDOM OF BELGIUM
	FEDERAL PUBLIC SERVICE FOR HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT
	Royal Decree amending the Royal Decree of 13 November 2011 laying down the fees and contributions payable to the Budgetary Fund for raw materials and products, the Royal Decree of 4 April 2019 on the making available on the market and use of biocidal products and the Royal Decree of 9 December 2021 establishing an Advisory Committee on Biocidal Products
	PHILIPPE, King of the Belgians,
	To all present, and those to come, salutations.
	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 Act 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, Section 1(1) and (2), as amended by the Act of 27 December 2004, and (3), Article 8, as amended by the Act of 28 March 2003, Article 9(1), as last amended by the Act of 16 December 2015, and 20*a*, Section 1, inserted by Article 16 of the Act of 28 March 2003, replaced by the Programme Act of 9 July 2004, and amended by the Acts of 27 December 2004, 10 September 2009 and 26 April 2023;
	Having regard to the Royal Decree of 13 November 2011 laying down the fees and contributions payable to the Budgetary Fund for raw materials and products;
	Having regard to the Royal Decree of 4 April 2019 on the making available on the market and use of biocidal products;
	Having regard to the Royal Decree of 9 December 2021 setting up an Advisory Committee on Biocidal Products;

	Having regard to the involvement of the regional governments in the implementation of this Decree within the framework of the Inter-ministerial Conference on the Environment, of xxx;
	Having regard to the opinion of the Special Advisory Committee on Consumption, given on xxx;
	Having regard to the opinion of the Federal Council for Sustainable Development, issued on xxx;
	Having regard to the opinion of the Central Economic Council, issued on xxx;
	Having regard to the opinion of the Belgian Health Council, given on xxx;
	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 XXX addressed to the European Commission on XXX;
	Having regard to the impact assessment of the legislation, conducted in accordance with Articles 6 and 7 of the Act of 15 December 2013 laying down various provisions on administrative simplification;
	Having regard to the opinion of the Inspectorate of Finance, issued on XXX;
	Having regard to the approval of the Minister for the Budget, dated XXX;
	Having regard to the opinion XX.XXX/XX of the Council of State, given on XXX, pursuant to Article 84(1)(2) of the Laws on the Council of State, coordinated on 12 January 1973;
	Giving consideration to 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;
	At the proposal of the Minister of Public Health and the Minister of the Environment, and at the recommendation of the Ministers convened in Council,
	We have decided and hereby decree:

	CHAPTER I. – Amendments to the Royal Decree of 13 November 2011 laying down the fees and contributions payable to the Budgetary Fund for raw materials and products
	Article 1. In Article 5/1 of the Royal Decree of 13 November 2011 laying down the fees and contributions payable to the Budgetary Fund for raw materials and products, inserted by the Royal Decree of 25 December 2017 and amended by the Royal Decree of 27 February 2019, the following amendments are made:
	1 the provision under 7 is replaced as follows:
	‘7 Regulation 414/2013: Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 laying down the procedure for the authorisation of the same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council;’;
	2 the Article is supplemented by the provisions of 8 and 9, reading:
	''8 European authorisation: European authorisation as provided for in Article 2 of the Royal Decree of 4 April 2019;
	9 Annual declaration: annual declaration as described in Article 31 of the Royal Decree of 4 April 2019.'.
	Article 2. In Article 6 of the same Decree, last amended by the Royal Decree of 26 March 2024, the following amendments are made:
	1 paragraph 1(3) is replaced with the following:
	‘Any person applying to the FOD VVL pursuant to Regulation 528/2012, Regulation 88/2014 or Regulation 1062/2014, for the approval, modification or renewal of an active substance or for the inclusion or modification of an active substance under Annex I to Regulation 528/2012, shall pay a fee to the Budgetary Fund for raw materials and products.’;
	2 paragraph 2(1) is replaced with the following:
	‘The fees set out in Annex 1 shall apply to applications for approval, amendment or renewal of an active substance or for inclusion or amendment of an active substance in Annex I to Regulation (EC) No 528/2012, where Belgium acts as evaluating competent authority for the purposes of Article 7(1), Article 13(3), Article 28

	of Regulation (EC) No 528/2012, Article 3 of Regulation (EC) No 88/2014 or Article 17 of Regulation (EC) No 1062/2014.'.
	Article 3. Article 7 of the same Decree, last amended by the Royal Decree of 26 March 2024, is replaced with the following:
	'Article 7. Section 1. Any person who has obtained a registration, a parallel trade permit, a European authorisation, an authorisation, a notification or an acceptance of a notification of a biocidal product in accordance with the Royal Decree of 4 April 2019 or Regulation 528/2012 or the Royal Decree of 8 May 2014 on the making available on the market and use of biocidal products, shall pay an annual contribution to the Budgetary Fund for raw materials and products. The total amount of the annual contribution payable by that person shall be calculated by adding together the annual contribution payable for each individual biocidal product.
	Section 2. The annual contribution due for a biocidal product, as referred to in paragraph 1, shall be due from the year following that of the delivery of the registration, the parallel trade permit, the European authorisation, the authorisation, the notification or the acceptance of the notification. This annual contribution shall be payable for each year in which the biocidal product was registered or authorised, even if the registration, parallel trade permit, European authorisation, authorisation, notification or acceptance of notification expired, was suspended, revoked or withdrawn during that year.
	Section 3. The annual fee payable for a biocidal product, as referred to in paragraph 1, is expressed in EUR and calculated by multiplying the following factors:
	1 the quantity of the biocidal product placed on the Belgian market in the year preceding that in which the annual fee is paid, rounded up and expressed in kg or L, depending on whether the active substance content is stated on the certificate as a percentage or in g/L, respectively;
	2 the number of points awarded in accordance with the provisions of paragraph 6;
	3 a factor equal to EUR 0.005/kg or EUR/L, depending on the unit in which the quantity referred to in 1 is to be expressed.

	Section 4. By derogation from paragraph 3, if, for a given biocidal product, the product of the factors referred to in paragraph 3(2) and (3) exceeds 3.5% of the annual average of the selling price applicable in the year preceding the payment of the annual contribution, expressed in EUR/kg or EUR/L, depending on the unit in which the quantity referred to in paragraph 3(1) is to be expressed, then the annual contribution due for that biocidal product, expressed in EUR, may be limited to the amount obtained by multiplying the following factors:
	1 the quantity of the biocidal product placed on the Belgian market in the year preceding that in which the annual fee is paid, rounded up and expressed in kg or L, depending on whether the active substance content is stated on the certificate as a percentage or in g/L, respectively;
	2 3.5% of the annual average of the selling price applicable in the year preceding the payment of the annual contribution, expressed in EUR/kg or EUR/L, depending on the unit in which the quantity referred to in 1 is to be expressed.
	Section 5. The person referred to in paragraph 1 who wishes to rely on the alternative calculation described in paragraph 4 shall request this from the FOD VVL with proof of the annual average sales price referred to in paragraph 4. This application shall be valid only if it is submitted for the purpose of lodging the annual declaration or within 14 days of lodging the annual declaration.
	Section 6. Notwithstanding paragraphs 3 and 4, if the annual fee payable for a particular biocidal product, as calculated in accordance with the provisions of paragraph 3 or, where applicable, paragraph 4, is less than EUR 500, the annual fee payable for that biocidal product shall be increased to EUR 500.
	Section 7. The number of points referred to in paragraph 3(2), including the score attributed to the biocidal product, depends on the classification of the biocidal product into hazard categories as at 1 December of the year 20XX-2, if the annual contribution is paid in the year 20XX. Biocidal products with registration, a parallel trade permit, a European authorisation, an authorisation, a notification or an acceptance of notification issued between 2 December 20XX-2 and 30 November 20XX-1 shall be classified as established at the time of delivery of the registration, the parallel trade permit, the European authorisation, the authorisation,

	the notification or the acceptance of notification.
	The allocation of the points referred to in the first paragraph shall be carried out in accordance with the table below. The hazard statements set out therein refer to the hazard statements specified in the registration, the parallel trade authorisation, the European authorisation, the authorisation, the notification or the acknowledgement of notification. The hazard statements are used to identify the hazard categories. The points of a certain hazard category may only be given once. If a biocide has been classified under more than one of the different hazard categories, the points for these hazard categories shall be added up.

Nº	Hazard category	Hazard statement(s)	Number of points
1	Explosive	H200, H201, H202, H203	2
2	Oxidising	H270, H271, H272	1
3	Extremely flammable	H220, H222, H224	2
4	Highly flammable	H225, H228, H241, H242, H250, H260, H261	1,5
5	Flammable	H221, H223, H226	1
6	Corrosive	H314	2
7	Irritant	H315, H318, H319, H335, H336	1
8	Awareness-raising	H317, H334	1
9	Harmful on short-term exposure	H302, H312, H332, H371	1
10	Harmful on long-term exposure	H373	1
11	Harmful (C)	H351	1
12	Harmful (M)	H341	1
13	Harmful (R)	H361	1
14	Toxic on short-term exposure	H301, H304, H311, H331,	2

		H370	
15	Toxic on long-term exposure	H372	2
16	Toxic (C)	H350	2
17	Toxic (M)	H340	2
18	Toxic (R)	H360	2
19	Very toxic on short-term exposure	H300, H310, H330	3
20	Harmful to the environment	H400, H410, H411, H420	2
21	Endocrine disruption with implications for human health (cat. 1)	EUH380	2
22	Endocrine disruption with implications for human health (cat. 2)	EUH381	1
23	Endocrine disruption with environmental implications (cat. 1)	EUH430	2
24	Endocrine disruption with environmental implications (cat. 2)	EUH431	1
25	Persistent, bioaccumulative and toxic	EUH440	2
26	Very persistent, very bioaccumulative	EUH441	2
27	Persistent, mobile and toxic	EUH450	1,5
28	Very persistent, very mobile	EUH451	1,5

Notwithstanding the second paragraph, the points for the following groups of hazard categories shall not be added together; instead, for each of these groups, only the hazard category with the highest score shall be taken into account:

	1 Group 1: hazard categories 9, 14 and 19
	2 Group 2: hazard categories 25 and 26
	3 Group 3: hazard categories 27 and 28
	Section 8. The total amount of the annual contribution referred to in paragraph 1 shall be automatically increased by 20% if the required annual declaration has not been received by 15 February. In addition, any registrations, parallel trade authorisations, European authorisations, authorisations, notifications and acknowledgements of notification relating to the person referred to in paragraph 1 shall be suspended. Within one week of this suspension, the FOD VVL shall send a registered letter to the person concerned to inform him of this and to request that they submit the required annual declaration by 15 March at the latest.
	If, after 15 March, it is established that the request described in the first paragraph has not been complied with, or has not been complied with in a timely manner, the suspended registrations, parallel trade licences, European authorisations, authorisations, notifications and acceptances of notification of the person concerned shall be definitively revoked or withdrawn. Furthermore, an annual declaration submitted after 15 March shall be deemed null and void.
	Section 9. When the annual declaration is submitted, a payment request will be made available to the person referred to in paragraph 1 or to the debtor designated by that person. If the total amount of the annual contribution referred to in paragraph 1 is not paid in full by the final payment date stated in the payment request, the registrations, parallel trade licences, European authorisations, authorisations, notifications and acknowledgements of notification of the person referred to in paragraph 1 shall be suspended. Within one week of this suspension, the FOD VVL will send a registered letter to the person concerned to inform them of this and to request that they make full payment by 15 April at the latest.
	If, after 15 April, it is established that the request described in the first paragraph has not been complied with, or has not been complied with in a timely manner, the suspended registrations, parallel trade authorisations, European authorisations, authorisations, notifications and acceptances of notification of the person concerned shall be definitively revoked or withdrawn. Furthermore, any payment made after 15 April shall be deemed null and void.

	Section 10. If an audit of an annual declaration shows it to be incorrect or incomplete, the difference in the total annual contribution due at the time shall be calculated in accordance with the provisions of paragraph 1. If this calculation shows that the annual contribution paid was insufficient, the calculated difference, plus 20%, will be charged. However, it is not possible to apply for a refund of any overpaid annual contribution, nor can such a refund be made.
	An audit referred to in the first paragraph which takes place during the year 20XX may, at most, relate to the annual declarations which were due in the years 20XX, 20XX-1, 20XX-2 and 20XX-3.'.
	Article 4. In Article 7/1 of the same Decree, inserted by Royal Decree of 4 August 2014 and last amended by the Royal Decree of 26 March 2024, the following amendments are made:
	1(1) is replaced as follows:
	'§ 1. All payments referred to in Article 6 and Article 7 shall comply with the following modalities:
	1 The amounts are paid in EUR and the payment costs for foreign companies shall be borne by those companies;
	2 Each fee, or, where applicable, the tranches of this fee referred to in 7, and each contribution shall be paid with an indication of the structured communication indicated on the payment request. However, if it is not possible to determine the purpose of a payment, the FOD VVL shall set a deadline for the payer must communicate in writing the purpose of the payment. If the purpose of the payment is not communicated to the FOD VVL within that period, the payment shall be considered invalid and the amount concerned shall be refunded to the payer;
	3 Unless otherwise stated, fees, or where applicable the bands of such fees as set out in 7, and contributions shall be paid within thirty days of the payment request being issued;
	4 A payment period shall be considered to have been complied with only if the full amount of the fee, or, where appropriate, the instalments of this fee as referred to in 7 or the contribution was paid in due time. The payment date shall be deemed to be the date on which the payer gave the instruction to transfer the full amount of the payment, or the relevant instalment, to the bank account specified by the FPS VVL. A confirmation of the transfer order issued by a financial institution shall

	be considered sufficient proof in the event of a dispute concerning this date;
	5 If the full amount of the fee, or, where applicable, the instalments referred to in 7, are not paid on time, the application shall be rejected or its processing discontinued;
	6 The FOD VVL shall reimburse overpayments in accordance with the rules laid down by the Chairman of the Management Committee of the FOD VVL. However, if the overpayment is less than EUR 200 and the person concerned has not expressly requested a refund, the overpayment shall not be refunded. Non-refunded overpayments cannot, however, be used against future payments to the FPS VVL;
	7 The fees referred to in the first paragraph of § 6(2), where the basic fee exceeds EUR 50 000, shall be divided into two or three instalments, as set out in Annex 1, each instalment amounting to one half or one third of the total fee respectively.
	The first instalment shall is payable within 30 days of the competent authority notifying the applicant of the fee due in accordance with Article 7(3) or Article 14(2) of Regulation 528/2012 or Article 4(4) of Regulation 1062/2014.
	If the total fee has been divided into three instalments, the second instalment shall be payable no later than 12 months of the submission of the application for approval, amendment or renewal of the approval of the active substance or the application for inclusion or amendment of an active substance in Annex I to Regulation 528/2012 to the European Chemicals Agency in accordance with Article 7(1) or Article 13(1) of Regulation 528/2012 or Article 3(2) of Regulation 1062/2014.
	The last instalment shall be paid at the latest before the competent authority forwards the assessment report on the active substance to the applicant in accordance with Article 8(1) or Article 14(2) of Regulation 528/2012, Article 4(1) of Regulation 88/2014, or Article 6(4) of Regulation 1062/2014.'
	2 paragraph 8 is replaced as follows:
	‘Section 8. Where several persons submit a joint application for approval, amendment, renewal of an approval of an active substance, or authorisation of a biocidal product in accordance with Regulation 528/2012 or an application for inclusion or amendment

	of an active substance in Annex I to Regulation 528/2012 in accordance with Regulation 88/2014, only one fee shall be payable per application.’
	Article 5. In the same Decree, Annex 1, replaced by the Royal Decree of 26 March 2024, is replaced by Annex 1 to this Decree.
	Article 6. In Annex 3 to the same Decree, replaced by the Royal Decree of 26 March 2024, the words ‘Certified copy of an instrument of authorisation/acceptance of notification/registration into another national language’ are replaced by the words ‘certified copy of a deed of authorisation/acceptance of notification/registration’.
	CHAPTER II. – Amendments to the Royal Decree of 4 April 2019 on the making available on the market and use of biocidal products
	Article 7. In Article 1(1)(4) of the Royal Decree of 4 April 2019 on the making available on the market and use of biocidal products, the words ‘the implementation’ are replaced by the words ‘the implementing’.
	Article 8. In Article 2(27) of the same Decree, the words ‘registered user’ are replaced with the words ‘registered user’.
	Article 9. In 2(28) of the same Decree, the words ‘registered seller’ are replaced with the words ‘registered seller’.
	Article 10. Article 2(33) of the same Decree, replaced by the Royal Decree of 9 December 2021, is replaced as follows:
	‘33 Advisory Committee on Biocidal Products means the Committee established by the Royal Decree of 9 December 2021 establishing an Advisory Committee on Biocidal Products;’.
	Article 11. Article 10(2)(1) of the same Decree, replaced by the Royal Decree of 14 July 2024, is replaced as follows:
	‘The applicant may set out his defence 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. The objection will be admissible only if it is submitted to the competent authority by registered post within a period of thirty working days and does not contain any elements that form part of or are based on the information set out in

	Annex 1, B. This period of thirty working days shall commence on the day on which the Minister's decision is sent to the applicant. Inadmissible objections shall not be dealt with. The petitioner shall be informed of this by the competent department by registered mail.'.
	Article 12. Article 13(1)(1) of the same Decree is replaced by the following:
	'1 there is serious evidence, such as a report from the poison control centre or a scientific publication, that the biocidal product no longer meets the efficacy criteria or poses an unacceptable risk to human or animal health or to the environment, and it has been sufficiently demonstrated that these indications lack substance; or'.
	Article 13. Article 14 of the same Decree, last amended by the Royal Decree of 14 July 2024, is replaced as follows:
	'Article 14. Cancellation of registration
	The registration shall be cancelled by the Minister, if necessary after the opinion of the Advisory Committee on Biocidal Products has been obtained, if:
	1 the conditions of Article 5 or, for an identical biocidal product, Article 16(1) are no longer met; or
	2 it is found that any of the submitted information based on which the registration was granted has been incorrect or misleading; or
	3 the holder of the registration requests it; or
	4 Article 13(3) or Article 19(7) so provides; or
	5 Chapter IV of the Royal Decree of 13 November 2011 so provides.'.
	Article 14. In Article 17(1) of the same Decree, as amended by the Royal Decree of 14 July 2024, the third and fourth sentences are replaced as follows:
	'This notice of objection is admissible only if it is submitted to the competent authority by registered post within a period of thirty working days and if it does not introduce any new studies. This period shall be counted from the third working day following the day on which the decision was sent to the applicant by the relevant department.'.
	Article 15. In Article 29(6) of the same Decree, as amended by the Royal Decree of 14 July 2024, the

	sentences ‘Utilisation des produits biocides en toute sécurité. Lire l’étiquette et les informations sur le produit avant l’emploi’ are replaced by the sentences ‘Utilisez les produits biocides avec précaution. Avant toute utilisation, lisez l’étiquette et les informations concernant le produit.’.
	Article 16. In Article 32(1) of the same Decree, the first sentence is replaced by the following sentences:
	‘Without prejudice to Article 2 of the Royal Decree of 21 April 2016 on the notification of mixtures classified as hazardous on the basis of their health or physical effects to the National Centre for the Prevention and Treatment of Intoxication and amending the Royal Decree of 13 November 2011 laying down the fees and contributions payable to the Budgetary Fund for raw materials and products, a notification shall be submitted to the National Centre for the Prevention and Treatment of Intoxication for each biocide. This notification shall be submitted by the manufacturer or the person responsible for placing the product on the market, no later than forty-eight hours before the biocidal product is placed on the market.’
	Article 17. Article 35 of the same Decree is replaced by the following:
	‘Article 35. Categorisation as closed-loop or open-loop
	Section 1. Biocides are classified as either ‘closed-loop’ or ‘open-loop’ based on their hazard and/or risk. The categorisation as closed-loop or open-loop shall be announced in the manner stipulated by the Minister.
	Section 2. In assessing whether a biocidal product meets one or more of the conditions described in paragraphs 3 to 6, consideration shall be given to the factors set out in the second paragraph of Article 19 of the Biocidal Products Regulation.
	Section 3. The biocidal products referred to in Article 3(1)(1) of this Decree shall be classified as closed-loop if at least one of the following conditions is met:
	1 the biocide meets at least one of the criteria referred to in Article 19(4) of the Biocides Regulation;
	2 the biocidal product meets all the criteria set out in Article 19(1) of the Biocides Regulation, and the use of personal protective equipment is required in order to comply with the criterion set out in Article 19(1)(b)(iii) of the Biocides Regulation;

	3 the biocide, with the sole exception of the criterion referred to in Article 19(1)(b)(iii), meets all the criteria referred to in Article 19(1) of the Biocides Regulation, and the Minister decides to apply Article 19(5) of the Biocides Regulation, and additionally, taking into account the use associated with this biocide, the Minister considers that it is necessary and practically feasible to wear personal protective equipment in the pursuit minimum possible human exposure to the biocide;
	4 the biocide, with the sole exception of the criterion referred to in Article 19(1)(b)(iv), meets all the criteria referred to in Article 19(1) of the Biocides Regulation, and the Minister decides to apply Article 19(5) of the Biocides Regulation, and in addition, wearing personal protective equipment is necessary to meet the criterion referred to in Article 19(1)(b)(iii) of the Biocides Regulation;
	5 the biocide meets all the criteria set out in Article 19(1) of the Biocides Regulation, with the exception of the criteria set out in Article 19(1)(b)(iii) and (iv), and the Minister decides to apply Article 19(5) of the Biocides Regulation, and additionally, taking into account the intended use of this biocide, the Minister considers that it is necessary and practically feasible to wear personal protective equipment in order to achieve the lowest possible human exposure to the biocide.
	Section 4. The biocidal products referred to in Article 3(1)(1) of this Decree shall be classified as open-loop products if at least one of the following conditions is met:
	1 the biocide meets the criteria referred to in Article 25 of the Biocides Regulation;
	2 the biocide meets all the criteria set out in Article 19(1) of the Biocides Regulation and the wearing of personal protective equipment is not required to meet the criterion set out in Article 19(1)(b)(iii) of the Biocides Regulation;
	3 the biocide, with the sole exception of the criterion set out in Article 19(1)(b)(iii), meets all the criteria set out in Article 19(1) of the Biocides Regulation, and the Minister decides to apply Article 19(5) of the Biocides Regulation, and additionally, taking into account the use associated with this biocide, the Minister considers that it should be required but is practically impossible to wear personal protective equipment in order to achieve the lowest possible human exposure to the biocide;

	4 the biocide, with the sole exception of the criterion set out in Article 19(1)(b)(iv), meets all the criteria set out in Article 19(1) of the Biocides Regulation and the Minister decides to apply Article 19(5) of the Biocides Regulation, and additionally, the wearing of personal protective equipment is not required to meet the criterion set out in Article 19(1)(b)(iii) of the Biocides Regulation;
	5 the biocide meets all the criteria set out in Article 19(1) of the Biocides Regulation, with the exception of those set out in Article 19(1)(b)(iii) and (iv), and the Minister decides to apply Article 19(5) of the Biocides Regulation, and additionally, taking into account the use associated with this biocide, the Minister considers that it would be required but is not practically feasible to wear personal protective equipment in order to achieve the lowest possible human exposure to the biocide.
	Section 5. The biocidal products referred to in Article 3(1)(2) of this Decree shall be classified as closed-loop products if at least one of the following conditions is met:
	1 the biocide meets at least one of the criteria referred to in Article 19(4) of the Biocides Regulation;
	2 the Minister considers that the wearing of personal protective equipment is required in order to reduce the human exposure caused by the use of the biocidal product to an acceptable level.
	Section 6. The biocidal products referred to in Article 3(1)(2) of this Decree shall be classified as open-loop products if at least one of the conditions set out in paragraph 5 is not met.’
	Article 18. In Article 36 (3) and (4) of the same Decree, inserted by the Royal Decree of 14 July 2024, in the French text the words ‘circuit fermé’ are replaced by the words ‘circuit restreint’.
	Article 19. In Article 38(2) of the same Decree, the words ‘registered seller or registered user’ are replaced by the words ‘registered seller or registered user’.
	Article 20. In Article 40(1)(3)(6) of the same Decree, the words ‘31 January’ shall be replaced by the words ‘15 February’.
	Article 21. In Article 41(1)(1) of the same Decree, the words ‘registered seller’ shall be replaced by the words ‘registered seller’.

	Article 22. In the same Decree, Annex 1, replaced by Royal Decree of 14 July 2024, is replaced by Annex 2 to this Decree.
	CHAPTER III. – Amendments to Royal Decree of 9 December 2021 setting up an Advisory Committee on Biocidal Products
	Article 23. Chapter II of Royal Decree of 9 December 2021 establishing a Advisory Committee on Biocidal Products is hereby repealed.
	CHAPTER IV. - Final provisions
	Article 24. This Decree shall come into force on its date of publication in the Belgian Official Gazette.
	Notwithstanding the first paragraph, Articles 2, 3, 4, 5, 15 and 20 shall enter into force on 1 January 2027.
	Article 25. The Minister responsible for Public Health and the Minister responsible for the Environment are each responsible for their relevant duties in the implementation of this Decree.
	Drawn up in Brussels,
	On behalf of His Majesty:

	The Minister for Public Health,
	Frank VANDENBROUCKE

	The Minister of the Environment,
Jean-Luc CRUCKE	

Annex 1 to the Royal Decree of … amending the Royal Decree of 13 November 2011 laying down the fees and contributions payable to the Budget Fund for Raw Materials and Products, the Royal Decree of 4 April 2019 on the making available on the market and use of biocidal products and the Royal Decree of 9 December 2021 establishing an Advisory Committee on Biocidal Products (Art. 5)

‘**Annex 1 to the Royal Decree of 13 November 2011 laying down the fees and contributions payable to the Budgetary Fund for raw materials and products**

Where Belgium acts as the competent authority responsible for assessing:

1°. an application for the approval, amendment or renewal of the approval of an active substance pursuant to Article 7(1) or Article 13(3) of Regulation 528/2012, or
2°. an application for the approval of an active substance under Article 17 of Regulation 1062/2014, or
3°. an application for the inclusion or amendment of an active substance in Annex I to Regulation 528/2012 pursuant to Article 3(1) of Regulation 88/2014 or Article 28 of Regulation 528/2012,

the fees indicated in the table below shall apply.

1 Basic fees

General description of the task		Reference article of Regulation 528/2012 (unless otherwise stated)	Basic fee	Number of instalments (if applicable)	No
Assessment of an application for the approval of an active substance for one product type		Article 7(3) or Article 4(4) of Regulation 1062/2014	EUR 187,500	3	1
Assessment of an application for the addition of a product type to an already approved active substance		Article 7(3) or Article 4(4) of Regulation 1062/2014	EUR 93,750	2	2
Assessment of an application for renewal of an already approved active substance for one product-type	Full assessment	Article 14(2)	EUR 187,500	3	3
	No complete assessment	Article 14(2)	EUR 93,750	2	4
Assessment of an application for inclusion of an active substance in Annex I to Regulation No 528/2012	Cat. 1, 2, 3, 4, 5	Article 28 or Article 4(1) of Regulation 88/2014	EUR 93,750	2	5
	Cat. 6, 7	Article 28 or Article 4(1) of Regulation 88/2014	EUR 187,500	3	6
Assessment of an application for review of an active substance in Annex I to		Article 28 or Article 4(1) of Regulation	EUR 25,000	-	7

Regulation (EU) No 528/2012		88/2014			
Application for the evaluation of data generated following the approval of the active substance for which Belgium acts as the competent assessing authority		Article 80(2)	EUR 20,000	-	8
For each meeting held to prepare the application dossier. The amount will be deducted when the application is submitted.		Article 80(2)	EUR 4,000	-	9

2 Additional fees to be added to the basic fee

General description of the task	Number of the basic fee to which the additional fee is added	Additional fee
For each additional product type	1, 2, 3	EUR 93,750
	4	EUR 50,000

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	Having regard to the annex to the Royal Decree of ... amending the Royal Decree of 13 November 2011 laying down the fees and contributions payable to the Budgetary Fund for raw materials and products, the Royal Decree of 4 April 2019 concerning the making available on the market and the use of biocidal products, and the Royal Decree of 9 December 2021 establishing an Advisory Committee on Biocidal Products.
	On behalf of His Majesty:

	The Minister for Public Health,
Frank VANDENBROUCKE	

	The Minister of the Environment,
Jean-Luc CRUCKE	

Annex 2 to the Royal Decree of … amending the Royal Decree of 13 November 2011 laying down the fees and contributions payable to the Budget Fund for Raw Materials and Products, the Royal Decree of 4 April 2019 on the making available on the market and use of biocidal products and the Royal Decree of 9 December 2021 establishing an Advisory Committee on Biocidal Products (Art. 22)

'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). The file must contain the following information:

- proprietary name of the biocide;
- applicant and entity for invoicing;
- manufacturer of the biocide;
- manufacturer 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;
- unique Formula Identifier (UFI) (only if required by the CLP Regulation, or on a voluntary basis);
- 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 whose registration is being sought (only in case of a claim against a specific target organism or to a 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 information mentioned under B. should be submitted electronically via the 'Gestautor' application.'

	Having regard to the annex to the Royal Decree of ... amending the Royal Decree of 13 November 2011 laying down the fees and contributions payable to the Budgetary Fund for raw materials and products, the Royal Decree of 4 April 2019 concerning the making available on the market and the use of biocidal products, and the Royal Decree of 9 December 2021 establishing an Advisory Committee on Biocidal Products.
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	The Minister for Public Health,
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