federal public service
HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT

Directorate-General for Environment
Division of Product Policy and Chemical Substances
Unit Risk management - Biocides

YOUR LETTER OF –
YOUR REF –

OUR REF MRB/2023/SFR/RPE
DATE 16/08/2023

Exp./Afz. : FPS PHFCSE - DGEM - Biocides, Galilee Avenue 5 box 2, 1210 Brussels, Belgium

ENCL(S) 1 (LETTER INCL. ANNEX)

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SUBJECT UPCOMING POSTPONEMENT OF THE REVIEW PROGRAMME DEADLINE AND ITS IMPACT ON BIOCIDES UNDER NATIONAL TRANSITIONAL PROCEDURES ON THE BELGIAN MARKET

Dear Madam, Dear Sir,

Article 89(1) of Regulation (EU) No 528/2012[1] determines that the Commission is to carry on with the work programme for the systematic examination of all existing active substances[2] with the aim of achieving it by December 31st 2024. Commission Delegated Regulation (EU) No 1062/2014[3] lays down the rules for carrying out the aforementioned work programme.

While it has become clear that an **extension of the previously set deadline of December 31st 2024 will be needed**[4], a formal decision regarding the new date is still pending. Nevertheless, all of the proposals currently put forward would result in the postponement of the aforementioned deadline by multiple years.

The Belgian Competent Authority (BE CA) therefore **wishes to inform** all current authorisation/notification/registration holders for biocides under national transitional procedures on the Belgian market **on the impact** of the aforementioned deadline postponement. In addition, BE CA wishes to **notify them on the actions that must be taken** in order to avoid disruptions within the market, whilst at the same time continuing to ensure a high level of protection of human and animal health and the environment.

A first element relates to upcoming **amendments to different legal texts**[5] governing, amongst others, biocides under national transitional procedures. These amendments will:

- instate the possibility to renew/prolong national registrations;
- amend the already existing provision related to renewals/prolongations of national notifications and authorisations[6];
- establish a fee for renewal/prolongation dossiers;
- empower the Advisory Committee on Biocidal products to give advise on renewal/prolongation dossiers, provided that a full evaluation[7] was performed.

[1] 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] Commenced in accordance with Article 16(2) of Directive 98/8/EC and commonly referred to as the Review Programme
[3] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council
[4] 99th and 100th meeting of the Competent Authorities for Biocidal Products
[5] Royal Decree of 4 April 2019 concerning the making available on the market and use of biocidal products, Royal Decree of 13 November 2011 establishing the fees and contributions payable to the Budget Fund for Raw Materials and Products, and the Royal Decree of 9 December 2021 establishing an Advisory Committee on Biocidal Products and amending the Royal Decree of 4 April 2019 concerning the making available on the market and use of biocidal products
[6] As granted under Royal Decree of 8 May 2014 concerning the making available on the market and use of biocidal products
[7] In accordance with articles 8 and 10 of the Royal Decree of 4 April 2019 concerning the making available on the market and use of biocidal products

When assessing the impact of the aforementioned postponement, current estimations indicate that around **2000 dossiers for renewal/prolongation are to expected**. An unknown number of them will be selected for full evaluation, which means that it will take longer for them to be evaluated. Considering the mere scale of the upcoming renewal/prolongation process, it must be recognised that the legally foreseen deadline for submission of renewal/prolongation dossiers[8] will not make it possible to manage all dossiers and perform all evaluations in due time.

Therefore, in order to avoid causing disruptions within the market, whilst at the same time continuing to ensure a high level of protection of human and animal health and the environment, **BE CA calls upon industry to**:

- thoroughly **prepare the dossiers** to be submitted for renewals/prolongations[9];
- **voluntarily submit** dossiers for renewals/prolongations **earlier** than the legal deadline;
- **actively communicate** with the dossier manager during the management and evaluation of the renewal/prolongation dossiers.

Annexed to this letter, you will find important information related to the early submission of the aforementioned renewal/prolongation dossiers.

To conclude, the upcoming postponement of the Review Programme will have a significant impact on authorities and industry. The common goal throughout the upcoming renewal/prolongation process is to avoid disruptions within the market, via the prolongation/renewal of granted authorisations/notifications/registrations in a timely manner, whilst continuing to ensure a high level of protection of human and animal health and the environment. We are of the opinion that when both parties are joining the effort, the upcoming renewal/prolongation process can be a success.

We wish to thank you in advance for your efforts regarding the above. As always, should you have any remaining questions related to the upcoming renewal/prolongation process, feel free to contact our helpdesk (https://www.helpdeskdppc.be/).

Sincerely,

Lucrèce Louis
Head of unit
Risk management – Biocides (BE CA)

[8] 6 months prior to the end date of the authorisation/notification/registration
[9] Based on the requirements set forth by Annex I of the Royal Decree of 4 April 2019 concerning the making available on the market and use of biocidal products

ANNEX I - Information related to the early submission of renewal/prolongation dossiers

1. Applicability

This information only applies to transitional biocidal products[10] on the Belgian market for which a valid authorisation/notification/registration exists to date and having an end date of authorisation/notification/registration ≤ 31/12/2024; yet excluding those that will be entitled to an extension, in accordance with Art.89(2) of Regulation (EU) No 528/2012, prior to 01/01/2025.

2. Submission

Renewal/Prolongation dossiers must be submitted **via our "Gestautor"-platform**[11]. Upon submission of the dossier, the resulting invoice is automatically generated and made available in the dossier.

Determining if your product requires the submission of a renewal or a prolongation dossier is based on when the product's authorisation/notification/registration was last renewed[12] or, if it was not yet renewed before, initially granted.

If the product has not yet been authorised/notified/registered for a 10-year period since its last renewal or, if it was not yet renewed before, initially granted, a prolongation dossier must be submitted. In any other case, a renewal dossier must be submitted.

- *Example 1: Product registered on 1/2/2021 and valid until 31/12/2024*
  - *Prolongation to be submitted, since not yet on the market for a 10-year period.*
- *Example 2: Product authorised on 1/2/2002, renewed in 2012, renewed in 2022, and valid until 31/12/2024*
  - *Prolongation to be submitted, since not yet on the market for a 10-year period since its last renewal (in 2022)*
- *Example 3: Product authorised on 1/4/2004, renewed in 2014, and valid until 31/12/2024*
  - *Renewal to be submitted, since on the market for a 10-year period since its last renewal (in 2014)*

3. Timeline for early submission:

- **By December 1st 2023**: All dossiers for renewal/prolongation of products meeting the "NOTIF…"- authorisation number format or having an authorisation number BE-REG-00800 or higher.
- **By March 1st 2024**: All dossiers for renewal/prolongation of products meeting the "…B"-authorisation number format or having an authorisation number BE-REG-00799 or lower.

[10] Easily identifiable by the format of the authorisation number: "BE-REG-…" (e.g. BE-REG-01248), "NOTIF…" (e.g. NOTIF200), or "…B" (e.g. 108B)
[11] https://appsm.health.belgium.be/gestautor-frontoffice/. Manual available via https://docs.health.belgium.be/NG/Manual%20Gestautor.pdf
[12] You can check when your product was renewed by consulting the signing history, located at the end of the certificate (above the (e-)signature), on your latest certificate. Look for the word "hernieuwing" (NL) or "renouvellement" (FR).