Government of Romania

# Emergency Ordinance No 41/2019 establishing some measures to implement the assessment activities necessary for the approval of active substances of biocidal products and for the authorization of biocidal products

In force as of June 13, 2019
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Whereas the Ministry of Health is the central authority in the field of public health, namely the competent authority for coordinating the national measures necessary for the implementation of Regulation (EU) no. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products in the biocidal products sector,
Given that currently only national regulations provide for the setting of a fee for a number of activities concerning the placing on the market of biocidal products, namely a fee for the mutual recognition in parallel or in sequence and for renewal of the authorization of a biocidal product, a fee for a simplified authorization of a biocidal product and a fee for the provisional biocidal product, the same biocidal product, the parallel biocidal product trade, the experimental and the effective authorizations,
Considering that for the evaluation and authorization of biocidal products and substances it is also necessary to regulate the fee charged for the activities related to the evaluation procedures of an active substance for its approval or renewal of approval at the level of the European Union as a result of the designation of Romania by the European Commission as rapporteur Member State for national authorization of biocidal products in Romania,
Taking into account the fact that there are no legal provisions on the fee for carrying out activities for two types of procedures, namely the national authorization of biocidal products and the evaluation of biocidal active substances,
Considering the need to regulate the legal framework regarding the independent expert, in order to eliminate the restriction to participate only in the evaluation activity, namely the removal of the barrier imposed on him to individually fulfill, as a minimum qualification and selection criterion, the activity within at least a scientific committee or group established at European level,
Whereas without these amendments, the independent expert contracted by the Ministry of Health is unable to evaluate biocidal products and substances for the purpose of the approval of active substances or the authorization of biocidal products,
Considering that, in the absence of such fee, Romania did not fulfill its status as Rapporteur Member State responsible for the first evaluation and, respectively, as reference Member State for carrying out the activities covered by the aforementioned procedures,
Given that Romania is the only Member State that does not have legal provisions for pricing the active substance and biocidal product evaluation activities in view of obtaining a national authorization, it is imperative to establish the legal framework for the

authorization of the institutions responsible for carrying out the authorization-related evaluation activities and for charging fees for the two types of authorization procedures,
For the purpose of expeditiously taking the necessary measures in Case 2016/4149 - action brought by the European Commission against Romania as a result of non-fulfillment of obligations under Regulation (EU) No. 528/2012, according to Article 80(2) in conjunction with Articles 7, 14, 29, 31, 34, 43 and 46 and considering that the current stage of the case is the first pre-litigation phase, namely the putting on notice,
On the basis of Article 115(4) of the Romanian Constitution, republished,
The Government of Romania adopts this Emergency Ordinance, as follows:.

**Article 1.** (1) The fee for the evaluation activities necessary for the approval and renewal of the approval for the active substances of the biocidal products, as well as for the authorization and renewal of the authorization of the biocidal products, as stipulated in the Annex that is an integral part of this Emergency Ordinance shall be approved.
(2) The fee provided in paragraph (1) shall be charged by the Ministry of Health as Competent Authority for the coordination of national measures necessary for the implementation of Regulation (EU) No. (EC) 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, hereinafter referred to as the 'RBP', and as main Authorizing Officer when Romania is the Competent Authority responsible for the evaluation under the provisions of Articles 7(1), 13(1), 43(1), 44(1) and 46(2) of the RBP, with the exception of the tariff rate charged for the technical secretariat activity of the National Commission for Biocidal Products, as established by point 11 of the Annex, which shall be paid on behalf of the National Institute of Public Health.
(3) The fee provided in paragraph (1) shall be charged, according to the provisions of Article 80(2) of the RBP, for the following activities:
(a) Evaluation of an active substance according to the provisions of Article 7(1) of the RPB, as well as of the representative product in the first type of product;
b) Evaluation of an active substance according to the provisions of Article 7(1) of the RPB, as well as the representative product in the additional type of product;
c) Evaluation of an active substance according to the provisions of Article 13(1), as well as of the representative product in the first type of product according to the provisions of Article 14(2)(1) of the RBP;
d) Evaluation of an active substance according to the provisions of Article 13(1), as well as of the representative product in the first type of product, according to the provisions of Article 14(2)(2) of the RBP;
e) Evaluation of an active substance according to the provisions of Article 13(1), as well as of the representative product in an additional type of product, according to the provisions of Article 14(2)(1) of the RBP;
f) Evaluation of an active substance according to the provisions of Article 13(1), as well as of the representative product in an additional type of product, according to the provisions of Article 14(2)(2) of the RBP;
g) Evaluation of a biocidal product for the activities stipulated in Article 30(1) of the RBP in order to obtain a national authorization;
h) Evaluation of a family of products for the activities stipulated in Article 30(1) of the RBP in order to obtain a national authorization;

i) Evaluation of a biocidal product for the activities stipulated in Article 44(1) of the RBP in order to obtain the authorization of the European Union;
j) Evaluation of a family of biocidal products for the activities stipulated in Article 44(1) of the RBP in order to obtain the authorization of the European Union;
k) Evaluation, in the capacity of reference Member State, of a biocidal product for the activities stipulated in Article 34(4) of the RBP with a view to mutual recognition in parallel;
l) Full evaluation of a biocidal product for the activities stipulated in Article 31(5) of the RBP with a view to renewing the national authorization;
m) Renewal of the national authorization, as stipulated in Article 31(1) of the RBP, for activities that do not require a full evaluation of a biocidal product for the activities stipulated in Article 31(6) of the RBP;
n) Full evaluation of a family of biocidal products for the activities stipulated in Article 31(6) of the RBP with a view to renewing the national authorization;
o) Renewal of the national authorization according to the provisions of Article 31(1) of the RBP for activities that do not require a full evaluation of a family of biocidal products as established in Article 31(6) of the RBP;
p) Full evaluation of a biocidal product for the activities stipulated in Article 46(2) of the RBP with a view to renewing the authorization of the European Union;
q) Renewal of the European Union authorization according to the provisions of Article 45(1) of the RBP for activities that do not require a full evaluation of a biocidal product for the activities referred to in Article 46(2) of the RBP;
r) Full evaluation of a family of biocidal products for the activities stipulated in Article 46(2) of the RBP with a view to renewing the authorization of the European Union;
s) Renewal of the European Union authorization for families of biocidal products for the activities stipulated in Article 46(2) of the RBP;
s1) Evaluation of a minor change of a biocidal product for the activities stipulated in Article 7(4) of the Commission Implementing Regulation (EU) No. 354/2013 of 18 April 2013 on changes of biocidal products authorized in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council, hereinafter referred to as Regulation No 354/2013;
t) Evaluation of a minor change of the product families for the activities stipulated in Article 7(4) of Regulation No 354/2013 on the basis of the application submitted according to the provisions of Article 50(2) of the RBP and Article 7(3) of Regulation No. 354/2013;
t1) Evaluation of a major change of a biocidal product as set forth in Article 8(3) of Regulation No 354/2013 on the basis of the application submitted according to the provisions of Article 50(2) of the RBP and Article 8(3) of Regulation No 354/2013;
u) Evaluation of a major change of the product families as set forth in Article 8(4) of Regulation No 354/2013 on the basis of the application submitted according to the provisions of Article 50(2) of the RBP and Article 8(3) of Regulation No 354/2013;
v) Evaluation stipulated in Article 19(6) of the RBP with a view to introducing another biocidal product into a family of biocidal products authorized on the basis of the application submitted in accordance with Article 17(6) of the RBP;

w) Establishment of the limits of an active substance contained in a biocidal product according to the requirements of the respective provisions, based on the application filed according to the provisions of Article 19(7) of the RBP.
(4) The amount of the fee stipulated in para (1) collected and unused by the Ministry of Health until the end of the financial year shall be carried over the following year, with the same destination, until it is fully utilized.
(5) Where the potential authorization holder belongs to the SME category established in the European Union, the fee for the authorization applications set out in the Annex, unless the product contains an active substance that is susceptible to replacement or an minor or major administrative change is requested in the authorization, may be reduced according to the following table:

| Type of enterprise | Discount (% of the standard fee) |
|---|---|
| Micro-enterprise | 30 |
| Small sized enterprise | 20 |
| Medium sized enterprise | 10 |

**Article 2.** Based on the request of the Technical Secretariat of the National Commission for Biocidal Products accompanied by the technical specifications of the biocidal product / substance to be evaluated, the Ministry of Health shall contract services, in compliance with the provisions on public procurement, for carrying out the evaluation activities stipulated in Article 1(3).

**Article 3.** (1) The fee set out in the Annex shall be paid within 30 days from the issuance of the payment documents, in the account of the Ministry of Health and the National Institute of Public Health, in lei, to the National Bank of Romania exchange rate valid on the last working day preceding the day of actual payment.
(2) If the applicant falls into one of the categories stipulated in Article 1(5), the applicant may opt to pay the fee in two installments with a maximum timeframe of 90 days between them, the amount of the first installment accounting for 50% of the applicable fee.
(3) If the applicant fails to pay the fees on the deadlines stipulated in Article 3(1) and Article 3(2), the application shall be rejected.

**Article 4.** The Ministry of Health shall contract, by using the fee collected from the applicants, independent natural or legal person experts, specialized in the evaluation of biocidal substances and products, for the purpose of obtaining the approval for the active substances or the authorization for the biocidal products, as the case may be, subject to the legal provisions on public procurement.

**Article 5.** In case the applicant did not provide the additional information according to the provisions of Articles 7(4), 29(3) and 43(4) of the RBP, as well as the provisions of Articles 7(3), 7(5) and 8(3) of Regulation No 354/2013, and the application was rejected, a share, representing 80% of the collected fee, from the fee fully paid shall be reimbursed.

**Article 6.** For the implementation of the discounts stipulated in Article 1(5), the applicant shall support his / her classification in the categories specified by the relevant financial and accounting documents related to the last 3 years preceding the one in which he / she applied for.

**Article 7.** The Ministry of Health may conclude protocols of inter-ministerial collaboration with ministries in other Member States for the purpose of evaluating active substances and / or Union authorization.

**Article 8.** In Article 5 of the Government Decision no 617/2014 establishing the institutional framework and measures for the implementation of Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, published in the Official Gazette of Romania, Part I, no. 589 of 6 August 2014, as further amended and supplemented, the paragraph 5 shall be amended and shall have the following content:
"(5) Independent expert means a specialist who has relevant experience, abilities and skills in the disciplines required to undertake an evaluation".

**Article 9.** In Article 19 (2) of the Annex to the Joint Order no 629/900/82/2017 of the Minister of Health, Vice Prime Minister, Minister of the Environment and President of the National Sanitary Veterinary and Food Safety Authority, on the approval of the Methodological Norms for the application of the provisions of the Government Decision no 617/2014 establishing the institutional framework and measures for the implementation of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, published in the Official Gazette of Romania, Part I, no. 563 of July 17, 2017, the letter d) shall be repealed.

Prime Minister

VASILICA-VIORICA DĂNCILĂ

Countersigned by:

For Minister of Health,

Dan-Octavian Alexandrescu,

State Secretary

Vice-Prime Minister and Minister of Environment,

Grațiela Leocadia Gavrilescu

Minister of Foreign Affairs,

Teodor-Viorel Meleșcanu

Alternate Minister for Foreign Affairs,

George Ciamba

Minister of Public Finances,

Eugen Orlando Teodorovici

Bucharest, June 12, 2019
No 41

**ANNEX**

**FEE**

**structured on tariff levels for the implementation of the evaluation activities necessary for the approval and renewal of the approval of active substances of biocidal products, as well as for the authorization and renewal of the authorization of biocidal products (national or union, as the case may be)**

| Fee Position | Activity | Fee rate (EUR) |
|---|---|---|
| 1. | Evaluation activities as stipulated in Article 1(3)(a) and Article 1(3)(c) of this legislative instrument | 332,000 |
| 2. | Evaluation activities as stipulated in Article 1(3)(d) of this legislative instrument | 160,000 |
| 3. | Evaluation activities as stipulated in Articles 1(3)(h), 1(3)(j), 1(3)(n) and 1(3)(s) of this legislative instrument | 145,000 |
| 4. | Evaluation activities as stipulated in Articles 1(3)(g), 1(3)(i), 1(3)(k), 1(3)(l), 1(3)(o), 1(3)(p) and 1(3)(t) of this legislative instrument | 85,000 |

| | | |
|---|---|---|
| 5. | Evaluation activities as stipulated in Articles 1(3)(b) and 1(3)(e) of this legislative instrument | 75,000 |
| 6. | Evaluation activities as stipulated in Articles 1(3)(m) and 1(3)(q) of this legislative instrument | 55,000 |
| 7. | Evaluation activities as stipulated in Article 1(3)(f) of this legislative instrument | 35,000 |
| 8. | Evaluation activities as stipulated in Article 1(3)(u) of this legislative instrument | 8,000 |
| 9. | Evaluation activities as stipulated in Articles 1(3)(t), 1(3)($t^1$), 1(3)(v) and 1(3)(w) of this legislative instrument | 4,000 |
| 10. | Evaluation activities as stipulated in Article 1(3)($s^1$) of this legislative instrument | 2,000 |
| | | |
| Fee position | Activity | Fee rate (lei) |
| 11. | Activity of the Technical Secretariat of the National Commission for Biocidal Products | 936 |