**340**

# ORDINANCE OF THE GOVERNMENT

## of the Slovak Republic

of 23 October 2013

## laying down the object, required particulars and tariffs applicable to payments and annual fees for the making available on the market and use of biocidal products

The Government of the Slovak Republic pursuant to Article 14 paragraph 10 of the Act No 319/2013 Coll. on competencies of national administrative authorities for the making available on the market and use of biocidal products and amending certain Acts (the Biocides Act) orders:

Article 1

(1) The tariffs applicable to payments for professional services pursuant to paragraph 2 and to annual fees for a biocidal product or a group of biocidal products made available on the market of the Slovak Republic are set out in the Annex.

(2) Professional services provided by the Centre for Chemical Substances and Preparations (hereinafter only "Centre") shall be

a) evaluation for completeness of an application for the approval of an active substance in accordance with a specific regulation[1]) for
   1. the first combination of an active substance and a product type,
   2. any other combination of an active substance and a product type,
b) evaluation of an application for the approval of an active substance in accordance with a specific regulation[2]) which does not meet exclusion criteria in accordance with a specific regulation[3]) and which does not meet criteria for active substances which are to be substituted in accordance with a specific regulation[4]) for
   1. the first combination of an active substance and a product type,
   2. any other combination of an active substance and a product type,
c) evaluation of an application for the approval of an active substance which
   1. does not meet the exclusion criteria in accordance with a specific regulation[3]) and which meets criteria for active substances to be substituted in accordance with a specific regulation;[4]) payments pursuant to letter b) shall be increased by a supplementary charge equal to two tenths of the sum stated therein,
   2. meets the exclusion criteria in accordance with a specific regulation[3]) and which meets criteria for active substances to be substituted in accordance with a specific regulation;[5]) payments pursuant to letter b) shall be increased by a supplementary charge equal to three tenths of the sum stated therein,
   3. meets the exclusion criteria in accordance with a specific regulation[3]) and which meets criteria for active substances to be substituted in accordance with a specific regulation[5]) and at least one of other criteria listed in a specific regulation;[6]) payments pursuant to letter b) shall be increased by a supplementary charge equal to four tenths of the sum stated therein,

d) evaluation of an application for the renewal of the approval in respect of an active substance in accordance with a specific regulation[7]) for
   1. the first combination of an active substance and a product type,
   2. any other combination of an active substance and a product type,

e) evaluation of an application for the renewal of the approval in respect of an active substance which
   1. does not meet exclusion criteria in accordance with a specific regulation[3]) and which meets criteria for active substances to be substituted in accordance with a specific regulation;[4]) payments pursuant to letter d) shall be increased by a supplementary charge equal to two tenths of the sum stated therein,
   2. meets the exclusion criteria in accordance with a specific regulation[3]) and which meets criteria for active substances to be substituted in accordance with a specific regulation;[5]) payments pursuant to letter d) shall be increased by a supplementary charge equal to three tenths of the sum stated therein,
   3. meets the exclusion criteria in accordance with a specific regulation[3]) and which meets criteria for active substances to be substituted in accordance with a specific regulation[5]) and at least one of other criteria listed in a specific regulation;[6]) payments pursuant to letter d) shall be increased by a supplementary charge equal to four tenths of the sum stated therein,

f) evaluation for completeness of an application for national authorisation in respect of a biocidal product in accordance with a specific regulation[8]) or evaluation of an application for European Union authorisation (hereinafter only “Union authorisation”) in respect of a biocidal product in accordance with a specific regulation[9]) as the evaluating competent authority in accordance with a specific regulation[10]) for
   1. the first type of a biocidal product,
   2. any other type of a biocidal product,

g) evaluation of an application for the national authorisation in respect of a biocidal product in accordance with a specific regulation[11]) or evaluation of an application for Union authorisation in respect of a biocidal product in accordance with a specific regulation[12]) as the evaluating competent authority in accordance with a specific regulation[8]) for
   1. the first type of a biocidal product,
   2. any other type of a biocidal product,

h) evaluation of an application for authorisation in respect of a biocidal product using simplified authorisation procedure in accordance with a specific regulation[13]) for
   1. the first type of a biocidal product,
   2. any other type of a biocidal product,

i) evaluation of an application for the renewal of national authorisation in respect of a biocidal product in accordance with a specific regulation[14]) or evaluation of an application for the renewal of Union authorisation in respect of a biocidal product in accordance with a specific regulation[15]) as the evaluating competent authority in accordance with a specific regulation[16]) for
   1. the first type of a biocidal product,
   2. any other type of a biocidal product,

j) evaluation of an application for parallel trade in accordance with a specific regulation,[17])

k) evaluation of a notification on a biocidal product intended for research and development in accordance with a specific regulation,[18])

l) evaluation of an application for national authorisation in respect of a biocidal product in accordance with a specific regulation,[19])

m) evaluation of an application for national authorisation in respect of a biocidal product or of an application for the renewal of national authorisation in respect of a biocidal product which is
   1. identical to a representative biocidal product having been part of an application in accordance with a specific regulation[20]) and for which there has to be carried out a comparative assessment in accordance with a specific regulation;[21]) payments under letters g) and i) shall be diminished by the sum equal to three tenths of the sum stated therein, save cases,
   2. subject to comparative assessment in accordance with a specific regulation;[21]) payments under letters f), g) and i) shall be increased by a supplementary charge equal to one half of the sum stated therein,

n) evaluation of an application for national authorisation in respect of a biocidal product which is to be approved for the period not exceeding
   1. 180 days in accordance with a specific regulation;[22]) payments under letters f) and g) shall be increased by a supplementary charge equal to one tenth of the sum stated therein,
   2. three years in accordance with a specific regulation;[23]) payments under letters f) and g) shall be increased by a supplementary charge equal to one half of the sum stated therein,

o) evaluation for completeness of an application for national authorisation in respect of a group of biocidal products in accordance with a specific regulation[8]) or evaluation for completeness of an application for Union authorisation in respect of a group of biocidal products in accordance with a specific regulation[9]) as the evaluating competent authority in accordance with a specific regulation,[10])

p) evaluation of an application for national authorisation in respect of a group of biocidal products in accordance with a specific regulation[11]) or evaluation of an application for Union authorisation in respect of a group of biocidal products in accordance with a specific regulation[9]) as the evaluating competent authority in accordance with a specific regulation,[8])

q) notification of an additional product within a group of biocidal products in accordance with a specific regulation,[24])

r) evaluation of an application for the renewal of national authorisation in respect of a group of biocidal products in accordance with a specific regulation[14]) or evaluation of an application for the renewal of Union authorisation in respect of a group of biocidal products in accordance with a specific regulation[15]) as the evaluating competent authority in accordance with a specific regulation,[16])

s) evaluation of an application for national authorisation in respect of a group of biocidal products or of an application for the renewal of national authorisation in respect of a group of biocidal products for which there has to be carried out a comparative assessment in accordance with a specific regulation;[21]) payments under letters p) and r) shall be increased by a supplementary charge equal to one half of the sum stated therein,

t) evaluation of an application for national authorisation in respect of a group of biocidal products which are to be approved for the period not exceeding
   1. 180 days in accordance with a specific regulation;[22]) payments under letter p) shall be increased by a supplementary charge equal to one tenth of the sum stated therein,
   2. three years in accordance with a specific regulation;[23]) payments under letter p) shall be increased by a supplementary charge equal to one half of the sum stated therein,

u) evaluation of an application for mutual recognition in sequence in respect of a biocidal product in accordance with a specific regulation,[25])

v) evaluation of an application for parallel mutual recognition in respect of a biocidal product in accordance with a specific regulation,[26])
w) evaluation of an application for authorisation in respect of a group of biocidal products via mutual recognition in sequence in accordance with a specific regulation,[25])
x) evaluation of an application for authorisation in respect of a group of biocidal products via parallel mutual recognition in accordance with a specific regulation,[25])
y) evaluation of an application for mutual recognition in sequence in respect of a biocidal product or of an application for parallel mutual recognition in respect of a biocidal product or of an application for authorisation in respect of a group of biocidal products via mutual recognition in sequence or of an application for authorisation in respect of a group of biocidal products via parallel mutual recognition for which there has to be carried out comparative assessment in accordance with a specific regulation;[21]) payments under letters u) to x) shall be increased by a supplementary charge equal to one half of the sum stated therein,
z) evaluation of applications under letters u) to x) provided the Centre reveals that a biocidal product or a group of biocidal products do not satisfy conditions laid down by a specific regulation[27]) and initiates proceedings in accordance with a specific regulation[28]) or proposes that the granting of authorisation be rejected or proposes modification to conditions of authorisation and initiates proceedings in accordance with a specific regulation,[29]) payments referred to under letters u) to x) shall be increased by a supplementary charge equal to one half of the sum stated therein,
aa) evaluation of an application for cancellation of authorisation at the request of the authorisation holder in accordance with a specific regulation,[30])
ab) evaluation of an application for amendment to authorisation at the request of the authorisation holder for
    1. an administrative change in accordance with a specific regulation,[31])
    2. a minor change,[32])
    3. a major change,[33])
ac) evaluation of an application for amendment to authorisation at the request of the authorisation holder in respect of a group of biocidal products; payments referred to under letter ab) points 1 to 3 shall be increased by a supplementary charge equal to one tenth of the sum stated therein for each biocidal product included in the group of biocidal products to which the amendment to authorisation applies,
ad) evaluation of an application for use of data in accordance with a specific regulation.[34])

(3) Annual fees for a biocidal product or a group of biocidal products shall be

a) the annual fee for a biocidal product made available on the market based on an application for national authorisation in respect of a biocidal product in accordance with a specific regulation[11]) or the annual fee for a biocidal product made available on the market based on an application for Union authorisation in accordance with a specific regulation,[12]) for which the Centre was the evaluating competent authority in accordance with a specific regulation,[10])
b) the annual fee for a group of biocidal products made available on the market based on an application for national authorisation in respect of a biocidal product in accordance with a specific regulation,[11]) or the annual fee for a group of biocidal products made available on the market based on an application for Union authorisation in accordance with a specific regulation,[12]) for which the Centre was the evaluating competent authority in accordance with a specific regulation,[10])

c) the annual fee for a biocidal product made available on the market based on an application for mutual recognition in sequence in accordance with a specific regulation[25]) or for a biocidal product made available on the market based on an application for parallel mutual recognition in respect of a biocidal product in accordance with a specific regulation,[26])
d) the annual fee for a group of biocidal products made available on the market based on an application for mutual recognition in sequence in accordance with a specific regulation[25]) or for a group of biocidal products made available on the market based on an application for parallel mutual recognition in respect of a biocidal product in accordance with a specific regulation,[26])
e) the annual fee for a biocidal product made available on the market based on an application for parallel trade in accordance with a specific regulation,[11])
f) the annual fee for a biocidal product made available on the market in accordance with a specific regulation.[35])

Article 2

(1) In making any payment for professional services pursuant to Article 1 paragraph 2 it shall be required to state the variable symbol number as referred to in the invitation to pay.

(2) In the settlement of annual fees pursuant to Article 1 paragraph 3 decision it shall be required to state the variable symbol number as referred to in the respective decision on the making available on the market of a biocidal product.

(3) Payments for professional services provided by the Centre pursuant to Article 1 paragraph 3 shall be transferred on the Centre´s third party account.

(4) The payments of annual fees pursuant to Article 1 paragraph 3 shall be transferred on the Centre´s revenue account.

Article 3

This Government Ordinance shall enter into force on the 1 November 2013.

**Robert Fico** by his own hand

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Footnotes:

[1]) Article 7 of the Regulation No 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27. 6. 2012), as amended.
[2]) Article 8 of the Regulation (EU) No 528/2012, as amended.
[3]) Article 5 paragraph 1 of the Regulation (EU) No 528/2012, as amended.
[4]) Article 10 paragraph 1 of the Regulation (EU) No 528/2012, as amended.
[5]) Article 10 paragraph 1(a) of the Regulation (EU) No 528/2012, as amended.
[6]) Article 10 paragraph 1(b) to (f) of the Regulation (EU) No 528/2012, as amended.
[7]) Artcle 13 of the Regulation (EU) No 528/2012, as amended.
[8]) Article 17 of the Regulation (EU) No 528/2012, as amended.
[9]) Article 43 of the Regulation (EU) No 528/2012, as amended.

[10]) Article 43 paragraph 1 of the Regulation (EU) No 528/2012, as amended.
[11]) Article 30 of the Regulation (EU) No 528/2012, as amended.
[12]) Article 44 of the Regulation (EU) No 528/2012, as amended.
[13]) Article 26 of the Regulation (EU) No 528/2012, as amended.
[14]) Article 31 of the Regulation (EU) No 528/2012, as amended.
[15]) Article 45 of the Regulation (EU) No 528/2012, as amended.
[16]) Article 45 paragraph 3 of the Regulation (EU) No 528/2012, as amended.
[17]) Article 53 of the Regulation (EU) No 528/2012, as amended.
[18]) Article 56 paragraph 2 of the Regulation (EU) No 528/2012, as amended.
[19]) Article 39 of the Regulation (EU) No 528/2012, as amended.
[20]) Article 6 paragraph 1(b) of the Regulation (EU) No 528/2012, as amended.
[21]) Article 23 of the Regulation (EU) No 528/2012, as amended.
[22]) Article 55 paragraph 1 of the Regulation (EU) No 528/2012, as amended.
[23]) Article 55 paragraph 2 of the Regulation (EU) No 528/2012, as amended.
[24]) Article 17 paragraph 6 and Article 30 of the Regulation (EU) No 528/2012, as amended.
[25]) Article 33 of the Regulation (EU) No 528/2012, as amended.
[26]) Article 34 of the Regulation (EU) No 528/2012, as amended.
[27]) Article 19 of the Regulation (EU) No 528/2012, as amended.
[28]) Article 35 of the Regulation (EU) No 528/2012, as amended.
[29]) Article 37 of the Regulation (EU) No 528/2012, as amended.
[30]) Article 49 of the Regulation (EU) No 528/2012, as amended.
[31]) Article 50 paragraph 3(a) of the Regulation (EU) No 528/2012, as amended.
[32]) Article 50 paragraph 3(b) of the Regulation (EU) No 528/2012, as amended.
[33]) Article 50 paragraph 3(c) of the Regulation (EU) No 528/2012, as amended.
[34]) Article 64 paragraph 1 of the Regulation (EU) No 528/2012, as amended.
[35]) Article 20 of the Act No 319/2013 Coll. on competencies of national administrative authorities for the making available on the market and use of biocidal products and amending certain Acts (the Biocides Act)

**Annex**
**to the Ordinance of the Government No 340/2013 Coll.**

## TARIFFS APPLICABLE TO PAYMENTS AND ANNUAL FEES PURSUANT TO ARTCLE 1 OF THE ORDINANCE OF THE GOVERNMENT

| To paragraph 2 letter | Point | Amounts to be paid in Euros |
|---|---|---|
| a) | 1. | 35,000.00 |
| | 2. | 9,000.00 |
| b) | 1. | 170,000.00 |
| | 2. | 50,000.00 |
| d) | 1. | 60,000.00 |
| | 2. | 15,000.00 |
| f) | 1. | 3,000.00 |
| | 2. | 600.00 |
| g) | 1. | 70,000.00 |
| | 2. | 10,000.00 |
| h) | 1. | 20,000.00 |
| | 2. | 3,000.00 |
| i) | 1. | 25,000.00 |
| | 2. | 5,000.00 |
| j) | | 15,000.00 |
| k) | | 10,000.00 |
| l) | | 15,000.00 |
| o) | | 10,000.00 |
| p) | | 150,000.00 |
| q) | | 3,000.00 |
| r) | | 30,000.00 |
| u) | | 6,000.00 |
| v) | | 7,000.00 |
| w) | | 8,000.00 |
| x) | | 9,000.00 |
| aa) | | 100.00 |
| ab) | 1. | 5,000.00 |
| | 2. | 20,000.00 |
| | 3. | 50,000.00 |
| ad) | | 2,000.00 |
| To paragraph 3 letter | | Annual fee in Euros |
| a) | | 350.00 |
| b) | | 750.00 |
| c) | | 300.00 |
| d) | | 400.00 |
| e) | | 200.00 |
| f) | | 150.00 |