ORDER No. 10/368/11 of 8 January 2010
approving the advising procedure of biocidal products placed on the market in Romania

ISSUER: MINISTRY OF HEALTH
No. 10 of 8 January 2010
MINISTRY OF ENVIRONMENT AND FORESTS
No. 368 of 17 March 2010
NATIONAL AUTHORITY FOR SANITARY VETERINARY CARE AND FOOD SAFETY
No. 11 of 4 March 2010
PUBLISHED IN: OFFICIAL GAZETTE NO. 196 of 29 March 2010

Further to the Approval Report of the General Directorate of Public Health, Healthcare and programmes of the Ministry of Health no. 188/2010,
considering the provisions of art. 92 paragraph (3) of Government Decision no. 956/2005 on placing biocidal products on the market, as amended and supplemented,
by virtue of art. 7 paragraph (4) of Government Decision no. 1.718/2008 * on the organisation and operation of the Ministry of Health, as amended and supplemented, art. 15 paragraph (4) of Government Decision no. 1.635/2009 on the organisation and operation of the Ministry of Environment and Forests, art. 6 paragraph (2) of Government Ordinance no. 42/2004 on the organisation of the sanitary-veterinary and food safety activity, approved with amendments and supplemented by Law no. 215/2004, as amended and supplemented, as well as art. 4 paragraph (3) of Government Decision no. 1.415/2009 on the organisation and operation of the National Authority for Sanitary Veterinary Care and Food Safety and its subordinate units,

the minister of health, the minister of environment and forests and the president of the National Authority for Sanitary Veterinary Care and Food Safety issue this order.

ART. 1
The advising procedure for biocidal products that are placed on the market in Romania is approved.

ART. 2
For the purpose of this order, the following terms and phrases are defined as follows:

a) permit - administrative act issued by the National Committee for Biocidal Products (NCBP), whereby the biocidal product is approved for placing on the market in
Romania, based on an assessment report in which the data and properties of the product placed on the market are recorded; the field of use specified in this act is indicative and is not an approval to use the product in specifically regulated fields, such as medical, food, veterinary, drinking water, bathing water;

b) notice of extension - the administrative act issued by NCBP during the validity of the permit defined at letter a) based on the completion of the technical dossier of the biocidal product for: packaging, field and scope of use, efficacy, indications for use, labelling, category of users;

c) notice of renewal - administrative act issued by NCBP during the validity of the permit defined at letter a) based on the application submitted by the applicant for renewal of the validity of the biocidal product that has not changed in terms of composition or use;

d) assessment report - internal supporting document prepared by the experts appointed by the authorities referred to in art. 6 paragraph (1), which specifies the data on the identity of the applicant, manufacturer, classification of the biocidal products, active substances, presentation and packaging, field and indications for use, physicochemical properties, toxicological data, eco-toxicological data and behaviour in the environmental from the safety data sheet and the documentation underlying the preparation of the sheet, efficacy data of the biocidal product in test reports or equivalent, labelling and classification of the biocidal product and categories of users, according to the documents in the technical dossier of the biocidal product, conclusions concerning the risk posed by the product for health and environment, as well as the possibilities to control or reduce the risk;

e) technical dossier - documentation referred to in art. 4 paragraph (1);

f) applicant - legal person that intends to place a biocidal product on the Romanian market.

ART. 3

(1) In order to obtain the permit, the applicant submits with the National Public Health Institute (NPHI) - Technical Secretariat of the NCBP a technical dossier accompanied by a standard application form, according to the sample in annex no. 1.

(2) For each biocidal product, the technical dossier is submitted in 4 copies: 1 copy on paper and 3 copies on CDROM/DVD.

(3) For biocidal products classified as product types 3, 4, 5 and 20, the applicant registers the application with NPHI - Technical Secretariat of NCBP, where the 4 copies of the technical dossier are submitted. The technical dossier on paper is forwarded by the Technical Secretariat of NCBP to the Institute for Control of Biological Products and Veterinary Medicines.

ART. 4
(1) The technical dossier of the biocidal product subject to approval according to the provisions of this order contains the following documents:

a) presentation document issued by the applicant with the following information:
   a.1. trade name;
   a.2. type of biocidal product, according to annex no. 2 to Government Decision no. 956/2005 on placing biocidal products on the market, as amended and supplemented;
   a.3. field of use for the type of biocidal product, indications for use, concentration and contact time for each use (the contact time for use must be supported by the conclusion of the test report);
   a.4. presentation (e.g.: liquid concentrate, grainules, aerosols, powder), packaging and quantities expressed in metric units;
   a.5. chemical composition: identity of each active substance (name, CAS no., EC no.) and concentration in metric units;
   a.6. guidance on preservation, storage and final disposal conditions;
   a.7. category of uses;
   a.8. instructions concerning hazardousness and first aid measures;

b) applicant’s declaration concerning the identity of the active substance/substances, namely: for chemicals, CAS and CE identification numbers, as well as the concentration in metric units; for microorganisms, the common name of the organism, the taxonomic name and the strain, reference number of the collection and culture where this culture is stored;


d) draft label with Romanian text, containing the following information:
   d.1. identity of each active substance and concentration in metric units;
   d.2. type of mixture, such as: liquid concentrate, grainules, powder, solid substances and other;
   d.3. uses for which the biocid product is authorised, such as: wood preservation, disinfection, surface biocide, anti-depositing etc.;
   d.4. use and dosage instructions for each use, according to the conditions provided in the authorisation, expressed in metric units;
   d.5. details concerning possible direct or indirect adverse effects on health and the environment and first aid instructions, where appropriate;
d.6. the phrase “Read enclosed instructions before use”, if the product is accompanied by a package insert;

d.7. instructions for safe disposal of the biocidal product and the package, including an interdiction to reuse the packaging of biocidal products for the general public;

d.8. number or name of the batch and expiry date in normal storage conditions;

d.9. time interval required for the biocidal effect, interval to be observed between uses of the biocidal product or before the first application and, where applicable, information about: next application on the treated material or first access of people or animals in area in which the biocidal product was used, including details on decontamination methods and measures and ventilation period required for treated areas; details concerning proper cleaning of equipment; precaution measures during use, storage and transport, e.g. staff protection clothing and equipment, fire safety measures, covering of furniture, removal of food and instructions to prevent contamination of animals and according to the type of product;

d.10. categories of users for which the biocidal product is restricted;

d.11. information about any specific environmental risk, particularly to protect non-target organisms and to avoid water contamination;

d.12. for microbiological biocidal products, labelling requirements on protection of workers from risks related to exposure to biological agents at work;

d.13. it is accepted that the information provided at points d.4, d.5, d.7 and d.9 may appear on another side of the package or be included in the insert accompanying the product;

e) copy of the label for the biocidal product in the country of origin, where applicable;

f) insert in Romanian, according to art. 69 paragraph (2) of Government Decision no. 956/2005, as amended and supplemented;

g) the test reports to demonstrate biocidal efficacy according to the type of product, the activity stated on the product label and in recommendations for use shall be prepared in Romania or in a EU Member State, according to methods developed by the International Organisation for Standardisation (ISO), the European Committee for Standardisation (ECS). Test reports carried out by European standards (EN) are allowed on condition to be carried out in Romania or an EU Member State. In order to support the effect of the biocidal product on organisms other than those for which the European standards are provided, test reports carried out by similar methods, national methods or individual methods standardised after NCBP debates, at the proposal of the evaluator, are accepted;

h) proof of registration/notification/authorisation as biocidal product in the country of origin or another EU Member State, where appropriate;
i) a document issued and signed by the manufacturing company, authorising the applicant company as representative for placing the product on the Romanian market.

(2) The documents referred to in paragraph (1) are submitted as copy of the original and translated into Romanian by a certified translator according to art. 41 paragraph (2) of Government Decision no. 956/2005, as amended and supplemented.

(3) The documents must be submitted strictly in the order provided in paragraph (1).

ART. 5

(1) Within 15 business days from submission of the technical dossier of the biocidal product, the experts and the Technical Secretariat of NCBP review the technical dossier.

(2) If additions are necessary in the technical dossier, the Technical Secretariat of NCBP notifies the applicant in writing within the period provided in paragraph (1). In case the dossier was submitted for evaluation with the Institute for Control of Biological Products and Veterinary Medicines, the additions are requested by the latter and not by the Technical Secretariat of NCBP. In case the dossier with eco-toxicological and environmental behaviour data was submitted for evaluation with the National Environmental Protection Agency, the supplementations are requested by the National Environmental Protection Agency.

(3) If the applicant does not file the necessary supplements within 120 days from communication, the application and the technical dossier of the biocidal product are cancelled and returned to the applicant, which is advised to pick up its dossier at the contact address stated on the application. If within 30 days the applicant does not pick up the cancelled application and dossier, they are destroyed so that they cannot be recovered.

(4) The period for dossier evaluation begins only after the dossier is complete. The assessment report and the decision on issuing the permit are drafted within maximum 90 calendar days from the date of acceptance of the complete dossier for new biocidal products and maximum 45 days, respectively, for approved biocidal products and for which a notice of extension is requested.

(5) NCBP sets criteria for acceptance of the biocidal product and issue of the marketing permit, based on the internal procedure established in the first meeting of NCBP on the effective date of this order.

ART. 6

(1) The tasks of the experts provided in art. 4 paragraph (3) of Government Decision no. 956/2005, as amended and supplemented, are as follows:

a) NPHI experts draft assessment reports with the data provided in art. 4 paragraph (1) letter c), except the eco-toxicological and environmental behaviour data product types 1, 2 and 6 - 19, 21 - 23, as provided in annex no. 2 of Government Decision no. 956/2005, as amended and supplemented;
b) the experts appointed by the Ministry of Environment and Forests and the National Environmental Protection Agency draft assessment reports with the data under art. 4 letter c), except the eco-toxicological and environmental behaviour data for product types 3, 4, 5 and 20, as provided in annex no. 2 to Government Decision no. 956/2005, as amended and supplemented;

c) the experts appointed by the Ministry of Environment and Forests draft assessment reports with the eco-toxicological and environmental behaviour data provided in art. 2 letter d), for all product types provided in annex no. 2 of Government Decision no. 956/2005, as amended and supplemented.

(2) The appointment of experts, the preparation methodology for assessment reports and the circuit of documents are established by order of the management of the institutions referred to in paragraph (1).

(3) The list of experts shall be notified to the Ministry of Health, the Ministry of Environment and Forests and the National Authority for Sanitary Veterinary Care and Food Safety, as well as NCBP.

(4) The assessment reports prepared and signed by experts, endorsed by the Head of Service, shall be submitted with NPHI - Technical Secretariat of NCBP, which informs NCBP according to the deadlines.

(5) The experts are responsible for accuracy of the data specified in the assessment reports as against the documents in the technical dossier of the biocidal product in compliance with the related legal provisions.

ART. 7

(1) The permit sample for the biocidal product is provided in annex no. 2.

(2) The terms of validity of the permit issued pursuant to the provisions of this order is 14 May 2014, according to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 on the marketing of biocidal products, reviewed.

ART. 8

(1) At least 45 days before expiry of the permit validity, the applicant may request NCBP to issue a notice of extension.

(2) The extension is granted after submission by the applicant of an application with NPHI - Technical Secretariat of NCBP and supplementation of the technical dossier of the biocidal product with supporting documentation and preparation of the assessment report by the experts.

(3) Based on the assessment report, NCBP decides on the issue of a notice of extension for that biocidal product, valid during the validity of the permit.

(4) The sample notice of extension is provided in annex no. 3.

ART. 9

Any modification of the active substance and other ingredients of the biocidal product results in cancellation of the permit.

ART. 10
(1) The administrative acts issued for biocidal products before publication of this order and which are found in the National Register of Biocidal Products are extended until 14 May 2014. After 14 May 2010, the biocidal products existing on the market and whose administrative acts are issued by authorities other than the NCBP are subject to the advising procedure provided by this order.

(2) At least 30 days before expiry of the validity specified in the administrative act issued by NCBP, if the biocidal product is not subject to changes in composition or use, the applicant may submit with NPHI - Technical Secretariat of NCBP the standard application filled in according to annex no. 4 for renewal of the validity of the administrative act issued before the entry into force of this order, based on which the product is registered in the National Register of Biocidal Products.

ART. 11
Annexes no. 1 - 4 are part of this order.

ART. 12
This order is published in the Official Gazette of Romania, Part I.

for the Minister of Health,
Adrian Streinu-Cercel,
secretary of state

for the Minister of Environment and Forests,
Mircea Ioan Cotoşman,
secretary of state

for the President of the National Authority for Sanitary Veterinary Care and Food Safety,
Corneliu Ceică

ANNEX 1

Mr. President,

The Company ................................................................., as producer |_|, representative of the producer |_|, authorised importer |_|, requests the issue of the permit to place the biocidal product ................................................................. on the Romanian market.

(trade name)

Purpose of the biocidal product use

<table>
<thead>
<tr>
<th>Main group*</th>
<th>Product type*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field of use</td>
<td></td>
</tr>
</tbody>
</table>

| ................................................................. | ................................................................. |
Categories of users: industrial \_\_, professional \_\_, population \_\_

* According to **annex no. 2** to Government Decision no. 956/2005 on the placing of biocidal products on the market, as amended and supplemented.

Producer

Name and full address (including telephone, fax and e-mail)

Representative or authorised importer

Please find enclosed the technical dossier with the documentation of the biocidal product according to **art. 5** of the Order of the Minister of Health, Minister of Environment and Forests and president of the National Authority for Sanitary Veterinary Care and Food Safety no. 10/368/11/2010 approving the advising procedure of biocidal products placed on the Romanian market.

Name and full address (including country, telephone, fax and e-mail)

Registration no. with the Trade Registry

Name and full address (including telephone, fax and e-mail) of the contact person within the company

Date Signature and stamp

To the president of the National Committee for Biocidal Products

ANNEX 2

Header

Date of issue ..........

PERMIT

No. ...... BIO/TP ...

Pursuant to the **Order** of the Minister of Health, Minister of Environment and Forests and president of the National Authority for Sanitary Veterinary Care and Food Safety no. 10/368/11/2010 and the **Order** of the Minister for Health, Minister of Environment and Water Management and president of the National Authority for Sanitary Veterinary Care and Food Safety no. 1.182/1.277/114/2005, as amended, based on the documents filed in the technical dossier, NCBP, in the meeting of .............
decided that the biocidal product can be placed on the Romanian market, according to the legal provisions in force.

I. TRADE NAME IN ROMANIA

Other trade names, as applicable

II. PRODUCER’S IDENTIFICATION DATA (name, address, country)

III. APPLICANT’S IDENTIFICATION DATA (name, address, country)

IV. CLASSIFICATION OF THE BIOCIDAL PRODUCT (according to annex no. 2 to Government Decision no. 956/2005 on the placing of biocidal products on the market, as amended and supplemented)

A. Main group

B. Product type/ types

V. INFORMATION ABOUT THE ACTIVE SUBSTANCE/ SUBSTANCES

A. Chemical substances

B. Microorganisms

VI. PRESENTATION

VII. PACKAGING (type, capacity)
VIII. FIELD AND SCOPE OF USE

A. Field of use

B. Applicability

PERMIT No. ....... BIO/TP ...

IX. EFFICACY

<table>
<thead>
<tr>
<th>Activity</th>
<th>Testing method/ Testing protocol</th>
<th>Species</th>
<th>Concentrations</th>
<th>Reaction times</th>
</tr>
</thead>
</table>

X. INSTRUCTIONS FOR USE

<table>
<thead>
<tr>
<th>Application</th>
<th>Concentration of the solution/ dose</th>
<th>Reaction time</th>
</tr>
</thead>
</table>

XI. LABELLING OF THE BIOCIDA PRODUCT

A. Biocidal product with active substances - chemical substances

<table>
<thead>
<tr>
<th>Symbols and hazard indication</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk phrases (R)</td>
<td></td>
</tr>
<tr>
<td>Safety phrases (S)</td>
<td></td>
</tr>
</tbody>
</table>

B. Biocidal product with active substances - microorganisms

<table>
<thead>
<tr>
<th>Symbols and hazard indication</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk group</td>
<td></td>
</tr>
</tbody>
</table>

XII. CATEGORY OF USERS

| |

XIII. RECOMMENDATIONS/ RESTRICTIONS CONCERNING HEALTH AND ENVIRONMENTAL FACTORS PROTECTION

The permit is valid until: ............
The permit has - x - pages.

President,
ANNEX 3

Header

Date of issue ..........

NOTICE OF EXTENSION

According to art. ...... of the Order of the Minister of Health, the Minister of Environment and Forests and the president of the National Authority for Sanitary Veterinary Care and Food Safety no. 10/368/11/2010, based on the documents submitted to supplement the technical dossier, NCBP, in the meeting of ............... , decided that Permit no. .......... BIO/TP ...... for the biocidal product .......................................................... is (trade name in Romania) amended/ supplemented as follows:

The extension is valid during the validity of the permit.
The document has - x - pages.

President,

.........................

ANNEX 4

Mr. President,

The Company .........................................................., as producer |_|, representative of the producer |_|, authorised importer |_|, requests the extension of the validity of Permit no. .......... to place the biocidal product .......................................................... on the (trade name) Romanian market.

We represent, on our own responsibility, that the composition and use of the biocidal product ............... have not been changed.

Purpose of the biocidal product use

<table>
<thead>
<tr>
<th>Main group*</th>
<th>Product type*</th>
</tr>
</thead>
<tbody>
<tr>
<td>..................</td>
<td>..................</td>
</tr>
</tbody>
</table>

Field of use

..........................................................................

..........................................................................

..........................................................................

..........................................................................

Categories of users: industrial |_|, professional |_|, population |_|

* According to annex no. 2 to Government Decision no. 956/2005 on the placing of biocidal products on the market, as amended and supplemented.

Producer
<table>
<thead>
<tr>
<th>Name and full address (including telephone, fax and e-mail)</th>
<th>.................................................................</th>
</tr>
</thead>
<tbody>
<tr>
<td>Representative or authorised importer</td>
<td>Please find enclosed Permit no. ...............</td>
</tr>
<tr>
<td>Name and full address (including country, telephone, fax and e-mail)</td>
<td>.................................................................</td>
</tr>
<tr>
<td>Registration no. with the Trade Registry......................</td>
<td>....................................................................</td>
</tr>
<tr>
<td>Name and full address (including telephone, fax and e-mail) of the contact person within the company</td>
<td>....................................................................</td>
</tr>
<tr>
<td>Date</td>
<td>Signature and stamp</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>To the president of the National Committee for Biocidal Products</td>
<td>-------------------------------</td>
</tr>
</tbody>
</table>