Registration under Polish national procedure

I. Registration of biocidal products according to the national procedure is applicable for products containing at least one active substance, which is still under review program based on the provisions of Regulation No 1062/2014. Registration under the transitional regime is carried out in accordance with the Article 16 of the Polish Act on biocidal products.

II. Authorization may be granted if all the conditions listed below are met:

1. The product complies with the definition of a biocidal product according to the Article 3 paragraph 1 of Regulation No 528/2012;
2. Active substances in the product should be notified and listed in the Annex II of Regulation No 1062/2014, in product types appropriate for the intended use, taking into account all published decisions on the approval of active substances;
3. The biocidal product is efficient in destroying harmful organism;
4. Safety principles for the use of the biocidal product have been defined;
5. The intended use of the product should be included in the product types listed in Annex V of Regulation No 528/2012;
6. The active substance or biocidal product supplier should be included in the Article 95 List (to ensure compliance with requirements of Article 95 of Regulation No 528/2012).

III. Applications for authorisation for the placing of a biocidal product on the market shall be submitted to the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

A complete application should consist of the following parts:

1. A filled-in application form (see attachment)

The application form should be filled in electronically (by computer or typewriter) in Polish.

2. Evidence of payment for submitting the application.

Liable charges are according to Annex 3 of the Minister of Health Regulation of December 17, 2015 concerning fees for activities related to the placing of a biocidal product on the market.

1000 PLN – is charged for an application for authorisation for the placing of a biocidal product on the market,

The title of the payment charge shall be given (1000 PLN- *„payment concerning application for authorisation for the placing of a biocidal product (name of product) on the market*".

Payment shall be made by bank transfer to the following account:

Payments from abroad:

Narodowy Bank Polski

00-950 Warszawa, Plac Powstańców Warszawy 4

Nr konta: PL30 1010 1010 0094 1022 3100 0000

Kod BIC NBP – NBPLPLPW

Payments from Poland:

NBP O/O Warszawa: 30 1010 1010 0094 1022 3100 0000

Payments should be made separately for each application.

3. Documents certifying the applicant's legal status.

- An original or copy certified by a notary, not older than 6 months;

- A sworn translation into Polish (an original or a notarised copy);

- A notary statement nominating person authorised to represent the applicant (in case, when there is no person authorised to represent the company in the document). Statement should be original together with a sworn translation into Polish.

For Polish applicants, the appropriate documents are either an authenticated copy from the National Registration Certificate or an authenticated copy from the Company's Certificate for Trading.

If several applications are simultaneously filed by the same applicant or during 3 months, it is sufficient to submit just one original, (or a copy certified by a notary), in the documentation with the rest being copies containing the declaration that „*the original document is enclosed in the application of the biocidal product named…*"

4. Data report confirming the efficacy of the biocidal product.

Testing should be carried out according to international methods, national standard methods, methods recommended by the OECD or others methods accepted by the President of the Office in Poland. The efficacy data report should be submitted in Polish or English.

In cases when it is not possible to submit efficacy data report in Polish or English, the applicant is obliged to submit the original data report (or certified copy), accompanied by a sworn translation into Polish.

Applicants are allowed to translate data report by themselves which can then be certified by a sworn translator. Such translations are thus considered legally binding in accordance to Art. 13, point 2 of the Act of November 25, 2004 concerning the sworn translator's profession (Official Journal No. 273, item 2702). This states that: „*a sworn translator is authorised to prepare certified copies of written material in foreign languages as well as to check and verify copies of written material in foreign languages made by another person*".

5. Information given on the label.

In cases when the packaging is too small to allow all the required data to be placed, a leaflet should as well be included. Documents should fulfil the requirements of Art. 33 of the Act of October 9, 2015 on biocidal products.

Applicants are also obliged to place such information on the label as stipulated by other regulations in force. This information being not referred to the biocidal product regulation is not assessed by the Office. It may also include marketing information or graphic marks may be placed on the label as well. Any of placed information cannot be contrary to the elements of the label already accepted during the registration process (information given on the label attached to the decision of authorisation for placing on the market of biocidal product) and regulations being in force.

6. Safety Data Sheet

If applicable, this should be submitted both in paper and electronic version (PDF format). It should fulfil the requirements of Commission Regulation (EU) No 453/2010 of the 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

7. Information on the active substance or the biocidal product supplier, which should be included in the Article 95 List (in order to ensure compliance with the requirements of Article 95 of Regulation No 528/2012)

8. Power of Attorney (if applicable)

An applicant may act in person or by attorney.

Any power of attorney from abroad should be translated into Polish.

The power of attorney should be in the form of original documentation.

The document confirming that authority has been granted to the attorney is subject to the revenue duty. Revenue duty charges are given according to the payment scales published in the Appendix to the Act of November 16, 2006 on Revenue Duty (Official Journal No. 225, item 1635), this amounts to 17 PLN. If several applications are simultaneously filed by the same applicant, it is sufficient to submit just one original in the documentation, with the rest being copies containing the declaration that „*the original document is enclosed in the application of the biocidal product named…*"

The revenue duty of 17 PLN should be paid for submitting both an original and copy.

The title of the payment charge shall be given: 17 PLN - „*payment concerning the power of attorney (names of products shall be listed as well)*"

Payment(s) shall be made by bank transfer to :

Urząd Miasta Stołecznego Warszawy, Centrum Obsługi Podatnika

via the following accounts:

Payments from abroad:

PL 21 1030 1508 0000 0005 5000 0070

kod SWIFT – CITIPLPX

Payments from Poland:

21 1030 1508 0000 0005 5000 0070

All documents in foreign languages require a sworn translation into Polish, as Polish language is the official language in Poland according to the Act of October 7, 1999 on the Polish language (Official Journal No.90 item 999, with amendments).

The concordance of the copy with the original may be authorised by either:

a notary in accordance to Art. 79, point 7 of the Act of February 14, 1991 concerning the entitlements of Notaries (Official Journal from 2002, No. 42 item 369, with amendments)

or by “Apostille”

In justified cases, The Office for Registration may demand to see originals of documents submitted by the applicant during the registration process.

The authorisation is issued within 6 months from the date of submission of the complete application.