On the basis of the fifth paragraph of Article 32 of the Biocidal Products Act (Uradni list RS (Official Gazette of the Republic of Slovenia), No 61/06) the Minister for Health, in agreement with the Minister for the Environment and Spatial Planning, hereby issues

RULES
on permits for biocidal products based on the principle of mutual recognition within the European Union

Article 1

These Rules, in accordance with the Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (UL L No 123 of 24 April 1998, p. 1), as last amended by the Commission Directive 2007/20/EC of 3 April 2007 amending Directive 98/8/EC of the European Parliament and of the Council to include dichlofluanid as an active substance in Annex I thereto (UL L No 94 of 4 April 2007, p. 23) (hereinafter referred to as: Directive 98/8/EC), regulate the conditions and contents of documents necessary for mutual recognition of permits for biocidal products within the European Union.

Article 2

(1) The terms used in these Rules shall have the same meaning as the terms used in the Biocidal Products Act (Uradni list RS (Official Gazette of the Republic of Slovenia), No 61/06), hereinafter referred to as: Act).
(2) The competent authority shall be the Chemicals Office of the Republic of Slovenia (hereinafter referred to as: Office)

Article 3

(1) Documents for mutual recognition of the permit issued after a complete procedure, compose the summary documents listed in the Rules regulating regular permits for biocidal products and documents mentioned in the Section X Annex IIB of Directive 98/8/EC.
(2) Documents for mutual recognition of the permit issued after a summary procedure, shall include the required data listed in the Rules regulating regular permits for biocidal products, excluding data on efficiency, for which a summary shall suffice.

Article 4

When, in accordance with Article 16 and the first paragraph of Article 17 of the Act, the Office establishes that:

(a) the target species is not present in dangerous quantities,

(b) an unacceptable resistance of the target organism to biocidal product was proven, or

(c) important circumstances of use, such as climate and development cycle of the species significantly differ from the circumstances present in the EU Member State where the permit for biocidal product was originally issued and might therefore an unchanged permit pose an unacceptable risk to humans, animals and environment,

the Office may require that certain conditions under points 5, 6, 8 and 10 of the first paragraph and point 2 of the second paragraph of Article 5 of the Rules on the classification, packaging and labelling of biocidal products and on the Safety data sheet for biocidal products (Uradni list RS (Official Gazette of the Republic of Slovenia), No 53/07) shall be adjusted to the circumstances of use in the Republic of Slovenia through which the conditions for the issue of the permit under Article 16 of the Act shall be met.

Article 5

Notifying party wishing to further place the biocidal product on the market on the basis of a mutually recognized permit, shall, after the enforcement of the EU rules on inclusion of the active substance in Annex I or IA, submit the Office a notification of intention to submit an application for mutual recognition of the permit after the issue of a regular permit for biocidal product in another EU Member State (hereinafter referred to as: EU).

Article 6

The notification of intention to submit an application for mutual recognition of the permit shall include:

(a) the name and the address or business name and the registered office of the notifying party;

(b) the trade name of the biocidal product traded in the Republic of Slovenia, which will further stay on the market on the basis of the mutual recognition of the permit;

(c) the permit number, if accessible;

(d) complete composition of the biocidal product;

(e) type of biocidal product in accordance with Annex V to the Directive 98/8/ES;

(f) a statement that the notifying party intends to submit an application for mutual recognition in accordance with Article 32 of the Act;

(g) the name of the EU Member State where the application for the issue of the permit has been or will be lodged;

(h) names of other EU Member States where the application for the issue of the mutual recognition of the permit has been or will be lodged;

(i) names of other EU Member States where the biocidal product has already been marketed, including the list of the trade names under which the biocidal product has been marketed in those EU Member States;
(j) a declaration that the declaration on data accessibility also applies to the Office, when documents submitted to the EU Member State to issue the permit also include the declaration(-s) on data accessibility;
(k) a declaration stating that the notifying party agrees with the withdrawal of the product from the market when the notifying party fails to submit the application for the issue of the mutual recognition of the permit within two months of the first issuance of the permit to market the product.
(l) other data requested by the Office.

Article 7

This Rules shall come into force on the thirtieth day following its publication in the Official Gazette of the Republic of Slovenia (Uradni list Republike Slovenije).

No: 0223-13/2007-UK

Ljubljana, 22 June 2007

EVA 2007-2711-0060

Andrej Bručan
Minister

Agreed
Janez Podobnik
Minister