NB: Unofficial translation
Ministry of the Environment, Finland

Ministry of the Environment Decree

on applying for authorisation or registration of biocidal products, withdrawing such products from the market and special provisions concerning such products (20/2008)

Section 1 – *Scope*

(1) This Decree concerns the deadlines for applying for authorisation or registration of biocidal products referred to in Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (Biocide Directive), the deadlines for withdrawing biocidal products from the market, special provisions concerning biocidal products and information affecting authorisation.

(2) Provisions on the active substances approved for biocidal products and the conditions for their use are laid down in Annexes I and IA of the Biocide Directive.

Section 2 – *Applying for authorisation of a biocidal product*

(1) Applications for authorisation of biocidal products must be submitted to the competent authorities referred to in section 25 of the Chemicals Act within two years of the date given for the active substance concerned in column E of Appendix 1 or Appendix 2 of this Decree. Applications for the mutual recognition of biocidal products laid down in section 12 of the Government Decree on biocidal products (466/2000) must also be submitted by the same deadline. Otherwise, what is provided in the Ministry of the Environment Decree on applications and notifications concerning biocidal products and their active substances (467/2000) will apply to the applications.

(2) If a biocidal product contains one or more active substances included in Appendix 1 or Appendix 2, the deadline must be calculated as from the latest of the dates.

(3) Applicants for mutual recognition must submit a copy of the first authorisation issued by the competent authorities for the biocidal product concerned within two months of the issue of the authorisation decision, provided that the decision was not issued before the application for mutual recognition.

Section 3 – *Processing of applications*

(1) Within three months of the submission of an application the competent authorities must examine the application to ascertain that it includes the information laid down in the Ministry of the Environment Decree referred to in section 2(1), that the active substance in the product is included in Appendix 1 or Appendix 2 of this Decree and that it meets the minimum purity requirements given in the Appendices. The competent authorities must make a decision on the matter within 12 months of the completion of the examination process. In matters concerning mutual recognition, however, the decision must be given by the deadline laid down in section 12 of the Government Decree on biocidal products.

(2) The competent authorities must, however, make a decision on an application not later than on the date given in column F of Appendix 1 or Appendix 2 of this Decree.

(3) If a biocidal product contains two or more active substances included in Appendix 1 or Appendix 2 of this Decree, the deadline for the decision is the latest of the dates.

Section 4 – *Withdrawal of a biocidal product from the market*

(1) If the Commission does not approve inclusion of an active substance in Annex I or Annex IA of the Biocide Directive, supply of biocidal products containing this active substance to the market must be discontinued as laid down in the Commission decision. The competent authorities must amend their decision on such a biocidal product or revoke it in accordance with the Commission decision.

(2) If the competent authorities do not authorise a biocidal product or if a copy of an authorisation decision concerning the biocidal product in question has not been submitted within the deadline laid down in section 2(3) for mutual recognition, supply of the product to the market for the purpose in question must be discontinued and the product must be withdrawn from the market within six months of the date on which the application decision issued by the competent authorities became legally valid.

(3) If no application has been submitted for authorisation of a biocidal product before the deadline laid down in section 2(1) or section 2(2), supply of the product to the market must be discontinued within six months of the expiry of the deadline. The product must also be withdrawn from the market within the same time limit.

Section 5 – *Registration*

The provisions of sections 2-4 on the deadlines for applications for authorisation of biocidal products, processing of such applications and withdrawal from the market also apply as appropriate to registration of low-risk biocidal products referred to in section 30b(1)(2) of the Chemicals Act, with the exception of the deadline for issuing a registration decision for which provisions are laid down in section 5(3) of the Government Decree on biocidal products.

Section 6 – *Information affecting authorisation*

In addition to what is laid down on the authorisation of biocidal products in or under the Chemicals Act, the active substance risk assessment required under the Biocide Directive and the related risk management must also be taken into account when considering authorisation.

Section 7 – *Authorisation or registration decision*

Authorisation or registration decisions on biocidal products must include the special provisions given in Appendix 1 or Appendix 2 of this Decree concerning the use of active substances.

Section 8 – *Entry into force*

This Decree enters into force on 1 February 2008.

Appendix 1

A	B	C	D	E	F	G	H
Number according to Biocide Directive	**Common name of active substance, IUPAC name and identification numbers**	**Minimum purity of the active substance in the biocidal product as placed on the market**	**Product type and date of inclusion of the active substance in Annex I of the Biocide Directive**	**Corresponding EC Directive and its date of entry into force**	**Deadline for decision on authorisation of the biocidal product containing the active substance**	**Expiry date of inclusion in Annex I of the Biocide Directive**	**Special provisions to be taken into account in the authorisation decision**

Appendix 2

A	B	C	D	E	F	G	H
Number according to Biocide Directive	**Common name of active substance, IUPAC name and identification numbers**	**Minimum purity of the active substance in the low-risk biocidal product as placed on the market**	**Product type and date of inclusion of the active substance in Annex IA of the Biocide Directive**	**Corresponding EC Directive and its date of entry into force**	**Deadline for decision on registration of the low-risk biocidal product containing an active substance**	**Expiry date of inclusion in Annex IA of the Biocide Directive**	**Special provisions to be taken into account in the registration decision**