

## **AUTHORISATION OF BIOCIDAL PRODUCTS IN THE EUROPEAN UNION**

**P. CHORAINE**

European Commission, DG Environment.D.3  
Chemicals & Nanomaterials

**Abstract** Current regulatory framework. The placing on the market on biocidal products in the European Union is governed by Directive 98/8/EC (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0008:EN:NOT>). The current Directive establishes a two-step process of approval: 1. evaluation of the active substance at the Community level, and 2. product authorisation at Member State level. The main feature of the Directive is the so-called review programme; a 10-year programme of work established to assess the risk for the environment and public health of active substances contained in biocidal products placed on the market when the Directive came into force. Around 300 substances supported by industry are being evaluated under this review programme. Member States are carrying out the assessment and, when there are no unacceptable risks for the environment or public health, substances are included in Annex I of the Directive. During the transitional period, which runs since May 2000 and until the active substances have been evaluated, products can be placed on the market in accordance with national rules. Then, further to the inclusion of an active substance in Annex I, Member States have the obligation to authorise products in accordance with the provisions of the Directive. A proposal for a Regulation concerning the placing on the market and use of biocidal products that will repeal and replace Directive 98/8/EC was adopted in June 2009. The new Regulation is currently under discussion by the European Parliament and the Council and is expected to enter into force in 2013. Key elements of the proposed Regulation: Centralise the authorisation of certain biocidal products at the Union level; Improve the functioning of national authorisations and mutual recognition by introducing binding deadlines and strengthening the system of mutual recognition dispute settlement; Reduce the number of animal tests by obligatory data sharing with respect to vertebrate animal studies; Strengthen the rules on data waiving (i.e. not request data which is not necessary); Extend the scope to cover articles and materials treated with biocidal products (e.g. furniture treated with wood preservatives), which are imported from 3<sup>rd</sup> countries. Harmonised fee structure which will harmonise the conditions and criteria for setting the fees in all Member States. Under the new Regulation, the European Chemicals Agency (ECHA) will be involved in the scientific work on biocides. Persons placing biocidal products on the market will have to hold the data on active substances (before they are obliged to do so under the product authorisation application).

**Key Words** European insecticides, European Chemicals Agency

