

Project description

## **Study on Impact of the implementation of Directive 98/8/EC concerning the placing on the market of biocidal products**

(Study contract 07010401/2006/443173/MAR/B3)

**Commissioned by:**  
European Commission

**Carried out by:**  
Hydrotox GmbH, Stefan Gartiser

**Co-operation partners:**  
Okopol GmbH, Antonia Reihlen  
Risk & Policy Analysts Ltd., Jan Vernon

**Duration:**  
September 2006 - September 2007

### **1. Background**

Directive 98/8/EC (the Directive) governs the authorisation and the placing on the market of biocidal products in the European Union. This Directive establishes a 2-tier system where the Community evaluates and approves active substances, whilst thereafter individual Member States authorise products containing these substances. A basic provision of the Directive is the establishment of a positive list of active substances that may be used in biocidal products without unacceptable effects on the environment, human or animal health (Annex I or IA of the Directive). In addition, Member States are obliged to mutually recognise authorisations and registrations granted by other Member States.

An evaluation of all so-called existing substances is to be carried out during a transition period, ending in May 2010. Details of the work programme are specified in three Review Regulations.

Within the scope of this review programme, it was also agreed that products containing existing undefended substances which had not been notified for evaluation shall be removed from the market by 1 September 2006. Other products containing defended substances can remain on the market while the substances are being evaluated. Once the evaluation of an active substance is finalised and a decision made as to whether or not to include it in Annex I or IA of the Directive, marketing authorisations must be, as appropriate, granted, modified or cancelled for products containing that substance.

### **2. Objectives of the study**

Hydrotox, RPA and Okopol have been selected to carry out a study on behalf of the European Commission (DG Environment) to identify positive and negative impacts of the implementation of Directive 98/8/EC on biocidal products (the Directive).

The purpose of the study is to provide the Commission with key findings and lessons learned from the implementation of the Directive, six years after its coming into force and, more critically, at the turn of 1 September 2006, which was the deadline for removing from the market all products containing undefended active substances.

The findings and lessons shall also be accompanied by a set of detailed recommendations to mitigate any unwanted effects of the implementation of the Directive.

The key objective of the study is to learn from the main stakeholders, including Member States competent authorities and industry, the positive and negative impacts of the implementation of the Directive (impacts on companies business, availability of products, influence on retail prices of products, effects on competition, etc.). This will include also a quantitative (number of products available) and qualitative (adequacy of the products offer to respond to market demands and specific needs) analysis of the consequences of the removal from the market by 1 September 2006 of products containing undefended substances.

A further objective of the study is to analyse whether, and if so, how the current regulatory framework should be amended to solve the problems identified, taking into consideration the likely environmental, economic and social impacts of any amendment.

The findings, lessons and recommendations of the study will provide a basis for the Commission to prepare its own report on the implementation of the Directive as required under Article 18(5) of the Directive and propose, where appropriate, amendments to the current regulatory framework.

### **3. Study approach**

An analysis of the biocide market will be performed, with special emphasis on the withdrawal of biocidal products after the implementation of the Directive in 1998. Several national biocidal product registers will be evaluated. Additionally stakeholders from competent authorities, industry, commercial associations, users of biocides and other experts will be consulted to obtain their general views on the positive and negative impacts of the Directive and the reasons why certain active substances have not been defended. The stakeholder consultation will be supported by tailored questionnaires, available from the Commission website. (<http://ec.europa.eu/environment/biocides/index.htm>)

Following the analytical overview, four case studies will be selected for further evaluation of the issues identified. These will cover different product types, companies (SME and large companies, producers and downstream users) and member states. Due to the ongoing process of evaluation of active substances the product types concerned will belong to the first and second priority lists. The assessment will focus on issues such as the suitability of simplified procedures, problems experienced by large or SME producers as well as formulators and any impacts on their competitiveness and economic viability, the influence of the Directive on competition between R&D-based producers and generic producers and the impact of non-availability of suitable Biocidal products on users. Consultation will be supported by interviews, company visits, and potentially workshops. Amendments to the Directive, proposed by Member States or stakeholders in order to address any negative impacts of the Directive, will be analysed in order to identify their potential impacts. Key advantages and disadvantages of the amendments, compared to the current situation, will be described. The overall results of all three work items will be summarized in a final report.

### **4. Time schedule**

The study began on September 19th 2006 and has a duration of 12 months.

#### **Contact:**

Expert Advisor in the European Commission:

Pierre Choraine

[pierre.choraine@ec.europa.eu](mailto:pierre.choraine@ec.europa.eu)

Project Direction:

Stefan Gartiser

[gartiser@hydrotox.de](mailto:gartiser@hydrotox.de)

Subcontracted partner:

Antonia Reihlen

Jan Vernon

[reihlen@okopol.de](mailto:reihlen@okopol.de)

[jan@rpalon.demon.co.uk](mailto:jan@rpalon.demon.co.uk)