

THE PROPOSED BIOCIDES DIRECTIVE

G. WILSON

DG XI.E.2, European Commission

Abstract—This paper outlines the main objectives of the proposed biocides directive, details the products it will cover and briefly explains how it will operate. It explains the recent modification to the proposal (inclusion of the Common Principles), gives the current position and suggests how it will progress (through the Council and the Parliament). Finally, it gives a possible implementation date.

INTRODUCTION

A proposal for a Council directive concerning the placing of biocidal products on the market was presented by the Commission on 27/07/93 (document COM(93) 351 final - SYN 465)

The proposed directive has as its objectives:

- harmonization of the internal market for biocidal products and their active substances
- a high level of protection for humans and the environment

The proposal covers a wide range of product types (listed in annex V of the proposal), namely pest control products, disinfectants, preservatives, and anti-fouling products and ultimately only those active substances which are listed in annex I of the finalized directive will be authorized for use in these biocidal products. It will harmonize the authorization schemes for biocidal products, by use of the Common Principles, with these authorizations being mutually recognized in all Member States.

Following adoption of the directive existing active substances will be reviewed to ascertain whether or not they can be included in the annex I list. This review will require the submission of data by industry, with a system of data protection, which will be evaluated by Member States with decisions as to the annex I entry being taken at Community level. The review period will last for 10 years and will be controlled by a Regulation (yet to be written).

During the transition period existing national rules in Member States with regard to the marketing of biocidal products containing existing active substances will continue to apply until such time as active substances are added to, or refused entry to, the annex I list.

MODIFIED PROPOSAL

Article 4 of the original proposal refers to Common Principles; these are technical provisions to ensure harmonization of authorizations and to enable mutual recognition to work properly. In its original proposal the Commission intended to adopt these at a later stage but, following requests from the Parliament and the Council, they have been written recently. The modified proposal, which contains the Common Principles (as a new annex VI), together with the necessary reference changes in the original proposal, was adopted by the Commission on 20 July 1995 (document COM(95) 387 final COD 465).

This modified proposal together with the original proposal now form the proposal for a directive on biocides and, as a consequence of the Maastricht Treaty, this will now be a European Parliament and Council directive.

OVERVIEW OF THE CONTENT OF THE PROPOSAL

The proposed directive will operate by requiring all biocidal products on the E.U. market to be authorized. Authorization of biocidal products will be carried out by Member States applying the Common Principles with a system of mutual recognition of authorizations.

The granting of authorizations will be dependent upon:

- the submission of data in accordance with the data requirements in annexes III & IV
- the evaluation of data in accordance with the Common Principle (annex VI)
- the active substance being listed in annex I

Annex I entry will also be based upon the evaluation of data (listed in annex II), this will initially be done by Member States, but the ultimate decision will rest with the Standing Committee on Biocidal Products. The proposal also contains provisions for mutual recognition, data protection, confidentiality, labelling and packaging and transitional measures.

CURRENT POSITION

The proposal has been accepted by the Economic and Social Committee but, because of the requirement to produce the Common Principles, the discussion on the proposal in the Parliament has been limited. There have been a number of discussions in Council working groups starting at the end of June 1994 and, under the German Presidency, there were several meetings of the Environmental working group devoted specifically to this subject. The German Presidency produced a paper entitled "Guidelines for further discussion"; this document was intended to assist the next Presidency in its work on this subject. Unfortunately the French Presidency were not able to devote any time to the proposal but Spain, who took over Presidency of the Council in July 1995, afforded it a high priority and held a number of working group meetings on this subject. The current Italian Presidency is also giving the proposal a high priority and, like the Spanish Presidency, is using the document prepared by the Germans as the basis for discussions.

This document, "Guidelines for further discussion", highlights the following:

- scope
- authorization procedures
- mutual recognition
- risk management
- transitional measures
- common principles

Following the introduction of the Common Principles the proposal has been discussed in the Parliamentary Environmental Committee group which has proposed a number of amendments. These amendments, although numerous, do not affect the basic principles of the proposal.

FUTURE PROGRESS

Discussions in Council Environment Working groups will continue under the Italian Presidency and, whilst it is impossible to give any firm predictions, it is possible that a common position could be reached at the end of their Presidency ie July 1996. As the Common Principles have now been incorporated, the Parliament is now discussing the proposal and again, whilst it is very difficult to speculate, it is possible that the agreement of the Parliament could be anticipated in mid 1996.

Given these two dates for agreement the earliest implementation date in Member States for the proposed biocides directive would be in January 1998.

IMPACT ON FUTURE URBAN PEST CONTROL

Implementation of this directive will result in harmonisation of authorization requirements for biocidal products throughout the European Union. Whilst this may result in a more limited choice of existing active substances in the short term; in the longer term, it will lead to the introduction of new active substances which pose less risk to humans and the environment.