

Opinion on the Data Requirements for Active Substances consisting of Micro-organisms, including viruses as Plant Protection Products (Opinion expressed by SCP on 2 October 1998)

Terms of Reference

The Commission requested the Scientific Committee on Plants to review the draft-revised annexes on the data requirements for micro-organisms pursuant to Council Directive 91/414/EEC (OJ No L230, 19.8.91 p.1) on the placing of plant protection products on the market.

Background

In the context of its work on updating the Annexes to Council Directive 91/414/EEC, the Commission consulted Member States during the preparation of the draft revised Annexes II Part B and III Part B on the 'Requirements for the Dossier to be submitted for the Authorisation of Plant Protection Products - Micro-organisms and viruses'. The Commission requested the Swedish authorities to organise a workshop in order to develop further consensus and agreement on the scientific basis concerning the information necessary for a risk assessment of microbiological plant protection products. As a result, the National Chemicals Inspectorate will organise a workshop 'Microbiological Plant Protection Products - Workshop on the Scientific Basis for Risk Assessment' in Stockholm, Sweden 26-28 October 1998.

In order to achieve wide international agreement the draft guidelines were also circulated for comment and suggestions to non-EU OECD Member Countries and these countries are also invited to participate in the workshop. Furthermore, the Organisation for Economic Co-operation and Development (OECD) has announced that it will initiate a group to address the question of test methods for biological pesticides.

Opinion of the Committee

The Scientific Committee on Plants decided that it would be appropriate to address the request for opinion as follows:

- 1) to formulate an overall scientific opinion on the key elements and principles associated with the use of micro-organisms as plant protection products and suitable for inclusion in a final document;
- (2) to produce and transmit directly to the Commission, to facilitate drafting, a modified version of Annex II Part B containing relevant amendments to the text. The Committee decided that due to the similarity of Annexes II and III and considering the time constraints, it would confine its opinion to Annex II. The Committee will address both Annexes when consulted on the final draft documents.

The following section outlines the main points discussed under (1)

Key Elements and Principles Associated with the Use of Micro-organisms as Plant Protection Products.

(i) Microbial inoculants have major potential for enhanced use in environmentally friendly food production systems and in the promotion of the principles of sustainable agriculture. Legislation dealing with the use of micro-organisms to assist or enhance plant productivity should have a balanced mix of appropriate measures and safeguards governing their use. In this context, it is important to ensure that fundamental issues, including (a) the development of a realistic framework to encourage the commercial development of effective bioproducts and (b) a regulatory system that should ensure that all microbial inoculants released into the environment be subject to the same examination procedures, are adequately catered for in a final directive.

Consequently, the Committee strongly recommends that procedures for the use of microorganism(s) in other areas of application (eg growth promoters, biofertilizers) should be consistent with the regulation of the use of microbial inoculants for use as plant protection products. This would avoid possible attempts to circumvent regulations and ensure that microbial inoculants would be regulated in an equitable fashion, irrespective of their use.

(ii) In the provision of information on the nature of the micro-organism to be used by the notifier, all relevant information available in the scientific literature regarding the genus and the species of the given strain should be reviewed and submitted by the notifier for the decision-making process under the Directive and its annexes.

(iii) In the context of plant protection, it is important to distinguish between microbial inoculants and traditional chemical protection technology. Since microbial inoculants behave differently from chemical products, it would seem more appropriate to describe their 'biological function', such as, biocontrol of insects, fungi etc, rather than to use chemically related terminology (such as fungicide, growth regulator, etc).

(iv) When submitted by a notifier, micro-organisms which are clearly classified as part of a safety category should be considered for inclusion in a consolidated list in an Annex to Directive 91/414/EEC in order to provide an exemption or waiver for the regulated use of such micro-organisms. The Committee would strongly recommend that such a consolidated list be prepared as a matter of urgency.

(v) Once base line information on both short-term and long-term use and impact of specific micro-organisms has been established, a procedure should be set up for dealing with future applications to take account of such information (i.e. 'established precedents'). In addition, to the extent that there is no exposure of non-targets in the context of the use of the micro-organism, a system to evoke a waiver should be available.

(vi) Due to the inherent properties of micro-organisms, it is important to consider, in addition to short-term consequences, the longer-term implications of micro-organisms as plant protection products on ecosystems and human health. This should include both direct and indirect effects. In practical terms, in the context of facilitating commercial development and the use of environmentally friendly microbial inoculants, a post registration monitoring system would enable relevant information on longer-term effects to be considered as part of a normal re-registration licence application.

(vii) It should also be noted that many test protocols that have been developed for chemical substances may not be appropriate or may not have been validated for micro-organisms authorisation purposes.

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- Prof. F. O'Gara (Chairman)
- Committee Members Prof. A. Hardy and Dr M.P.Delcour
- Invited experts Profs. G. Defago, Prof. M. Nuti and Drs C. Alabouvette and O. Meyer.