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SCIENTIFIC COMMITTEE ON PLANTS

SCP/ANNEX VI B/002-Final

**OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS ON
THE WORKING DOCUMENT FROM THE COMMISSION
ESTABLISHING ANNEX VI B TO COUNCIL DIRECTIVE
91/414/EEC (Document SANCO/108/2002)**

(Opinion adopted by the Scientific Committee on Plants on 30/01/2003)

A. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS ON THE WORKING DOCUMENT FROM THE COMMISSION ESTABLISHING ANNEX VI B TO COUNCIL DIRECTIVE 91/414/EEC (Document SANCO/108/2002)
(Opinion adopted by the Scientific Committee on Plants on 30/01/2003)

B. TERMS OF REFERENCE

The Commission requested the Scientific Committee on Plants to review the draft working document establishing Annex VI B (Uniform principle) to Council Directive 91/414/EEC on the placing of plant protection products on the market, concerning products containing micro-organisms (Document SANCO/108/2002).

C. OPINION OF THE COMMITTEE

The Committee considered the draft working document Council Directive establishing Annex VI B (SANCO/108/2002) and evaluated it to determine if it fulfilled its stated objectives of providing Uniform Principles for evaluation and authorisation of Plant Protection Products (PPP) containing micro-organisms as part of a harmonised framework system.

Micro-organisms used as plant protection products have to be evaluated in terms of hazard and risk assessment for man and the environment, as are chemical plant protection products. However, due to the living nature of micro-organisms, there is a clear difference between chemicals and micro-organisms as PPP. Hazards are not necessarily of the same nature as those presented by chemicals, especially in relation to the capacity of micro-organisms to survive and multiply in different environments. In many cases, the available methodology has been developed and validated to assess the risks posed by chemical PPP. In contrast, appropriate methodology has not been fully developed and validated to assess the risks posed by micro-organisms.

The Committee strongly endorsed the need to harmonise Uniform Principles for authorising micro-organisms as PPP in the European Union. The Committee recognises that the task of developing Uniform Principles for micro-organisms is a novel and complex task in the context of regulating PPP. However the Committee is of the opinion that the draft working document establishing Annex VI B does not meet the stated objectives of providing useful Uniform Principles that could be followed in a harmonised way by Member States. In particular, it is felt that the draft document establishing Annex VI B does not provide sufficient detail and guidance advice compared to what is already contained in Directive 2001/36/EEC.

A number of key scientific areas in the Annex of the draft working document (SANCO/108/2002) could be improved by providing more clarity on the detail of the data required. For example, aspects including (i) identity of the micro-organism, (ii) analytical testing procedures, (iii) defining environmental damage, (iv) nomination of non-target organisms in test systems, (v) toxicological issues related to adverse effects on human and animal health from metabolites, toxins and adjuvants should

be re-evaluated and improved details included in the draft Annex. The Committee is of the opinion that this important draft Annex could be significantly improved for intended end users by addressing the key issues identified in this opinion.

A. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS ON THE WORKING DOCUMENT FROM THE COMMISSION ESTABLISHING ANNEX VI B TO COUNCIL DIRECTIVE 91/414/EEC (Document SANCO/108/2002)

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C. BACKGROUND

Council Directive 91/414/EEC concerning the placing of plant protection products (PPP) on the market requires all PPP to be evaluated prior to acceptance for the European Market. The evaluation must be performed in a uniform way for efficacy and risks to human health and the environment.

The Council Directive 97/57/EC of 22/09/1997 established Annexe VI to Council Directive 91/414/EEC concerning the placing of PPP on the market (Uniform principles for evaluation and authorisation of PPP). These address chemicals and contain no provisions for micro-organisms used as PPP. The principles developed in the Annex VI aim to ensure a high level of protection of human and animal health and the environment when Member States are evaluating applications and granting authorisations.

In the context of its work on updating the Annexes to Council Directive 91/414/EEC on the placing of PPP on the market, the Commission prepared the Directive 2001/36/ECC of 16/05/2001 establishing the data required for micro-organisms in the Annexes II and III Part B.

Currently, Uniform Principles can be used for PPP composed of chemical substances but no such procedures yet exist for dealing with micro-organisms as PPP. Thus the Commission consulted Member States during the preparation of the draft working document proposal for a Council Directive establishing Annex VI Part B (Uniform principle) to Council Directive 91/414/EEC concerning the placing of PPP on the market containing micro-organisms (SANCO/108/2002). The draft was finalised and submitted to the SCP by the Commission on 22 January 2002.

Source documents made available to the Committee:

- Draft working document on Council Directive: establishing Annex VI B to Council Directive 91/414/EEC concerning the placing of Plant Protection Products on the market SANCO/108/2002 (14/1/2002).

- SCP Opinion on the Necessity of repeated dose test to study risks on human health by microbial pesticides. (SCP/MICR-PPP/001, 31/07/2000).

- Working Group on Micro-organism (22 July 1998) amendments suggested during the first meeting (26 May 1998) and regarding the introduction and parts 1, 2 and 3 of Annex II (SCP/MICR-PPP/005).

- Draft working guidance document on criteria for evaluation and authorisation of Plant Protection Products containing micro-organisms SANCO/1023/2001 rev. 3 (24/8/2001).

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

- Summary of comments arising from the special multidisciplinary working group of the SCP, 16-17 April 2002.

D. SCIENTIFIC BACKGROUND ON WHICH THE OPINION IS BASED

I. General comments

Micro-organisms used as plant protection products have to be evaluated in terms of hazard and risk assessment for man and the environment, as are chemical plant protection products. However, due to the living nature of micro-organisms, there is a clear difference between chemicals and micro-organisms as PPP. Hazards are not necessarily of the same nature as those presented by chemicals, especially in relation to the capacity of micro-organisms to survive and multiply in different environments. In many cases, the available methodology has been developed and validated to assess the risks posed by chemical PPP. Methodology has not been fully developed and validated for micro-organisms.

Against this background, the SCP evaluated the draft working document Council Directive establishing Annex VI B (SANCO/108/2002) to determine if it fulfilled its stated objectives of providing Uniform Principles for evaluation and authorisation of PPP containing micro-organisms as part of a harmonised framework system. The main conclusions of the committee are summarised below.

II. Specific Comments

1. The Committee strongly endorsed the need for harmonising Uniform Principles for authorising micro-organisms as PPP in the European Union. Guidance information should be developed for implementation of the Directive by Member States. This is of particular importance to facilitate new product developments to progress in a structured, transparent and efficient manner.

2. The Committee considers that the content of the draft working document establishing Annex VI B (SANCO/108/2002) fails to recognise the complexity of the biological issues. In this particular context, the Committee decided that prior to formulating its scientific opinion of Annex VI B, it would draw on and incorporate its experiences of dealing with the first microbial PPP (*Pseudomonas chlororaphis*) that is proposed for inclusion in Annex I for the Standing Committee on Food Chain and Animal Health on 26 February 2003, as a case study to consider the existing draft proposals for Uniform Principles in Annex VI B in a realistic and practical way.

3. Based on this strategy and analyses, the Committee is of the opinion that elements of the “draft Annex VI B” do not meet the stated objectives of providing useful Uniform Principles that could be followed in a harmonised way by Member States. In particular, it is felt that the “draft Annex VI B” does not provide sufficient detail and guidance advice compared to what is already contained in Directive 2001/36/EEC. “Draft Annex VI B” does not provide the guidance necessary for establishing a useful set of Uniform Principles.

4. There are several key scientific areas which are not addressed, or where there is confusion and lack of knowledge or appropriate comparators for baseline evaluations. These include:

- a. The mode of action of the PPP in controlling its target pest or pathogen should be clearly defined. Guidance should be given on the level of identification required of the micro-organism comprising the PPP. Below species level, this should be in relation to the risks. Where the mode of action is due wholly or in part to an active chemical metabolite produced by the micro-organism, guidance should also be given on its identification. Minimum standards for all these parameters must be clearly defined.
- b. There is a requirement to define environmental damage.
- c. The complexities of biological PPP warrant more detail on testing procedures and interpretation of results of tests. In particular, there is a need for more information on the purpose of the testing, for example, fate of the metabolite and/or micro-organism in the environment or food chain, and an appraisal of the methods that are available, with comprehensive reference to published and previously accepted methods. The results of such testing must be discussed in relation to published and previously accepted results.
- d. There is a need to define, characterise and identify the contaminants and to determine to what level contaminants are acceptable. Microbial PPP are usually produced by culture in a nutrient broth. Since it is essential that they retain viability, the commercial product will also contain chemical compounds and other metabolic by-products in the nutrient broth, and perhaps some contaminant micro-organisms. The cells themselves will also contain other diffusible and nondiffusible metabolites or have the capability to produce them in a different

environment from that during culture. All such contaminants should be considered.

- e. Reappraisal of the basis for selection of key non-target organisms is required for assessment of the effects of exposure to other organisms in the environment. Those key non-target organisms usually used for assessment of chemical pesticides may simply not be appropriate.
 - f. Reappraisal of various toxicological issues is required e.g. the nature of other metabolites. Concerning the testing of micro-organisms a reference to accepted or proposed tests would be of great help. Complete rewriting of the section 2.5, dealing with adverse effects on human and animal health, is also required to clarify implementation and assessment. Micro-organisms produce a range of different metabolites (e.g. bacterial toxins or mycotoxins) many of which may have toxicological significance, but perhaps only one of which is involved in the mode of action of the PPP.
 - g. More clear distinction must be made regarding terms such as pathogenicity and infectivity and toxicity of different metabolites, toxins and adjuvants.
 - h. Specific guidance should be provided on which procedure should be used to assess operator exposure and risk.
5. Detail and terminology should be re-appraised and harmonised between the Directive and the Annex VI B particularly in the following aspects.
- a. The wording of the Uniform Principles should be more coherent with the wording of the Directive 2001/36/EEC.
 - b. Terminology should be more consistent with accepted international terminology.
 - c. There should be a reappraisal and definition of many terms used in the Directive and the Annex VI B.

CONCLUSION

The working documents SANCO/108/2002 establishing Annex VI B to Council Directive 91/414/EEC concerning the placing of plant protection products on the market does not give the guidance required for the placing of PPP on the market and will benefit from modification to take account of the recommendations outlined.

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