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(Acts whose publication is obligatory)

COMMISSION DIRECTIVE 2001/36/EC

of 16 May 2001

amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ([1]), as last amended by Commission Directive 2001/28/EC ([2]), and in particular Article 18(2) thereof,

Whereas:

(1) Annexes IIB and IIIB to Directive 91/414/EEC set out the requirements for the dossier to be submitted by an applicant respectively for the inclusion of an active substance consisting of micro-organisms or viruses in Annex I to that Directive and for the authorisation of a plant protection product based on preparations of micro-organisms or viruses.

(2) It is necessary to indicate, in Annexes IIB and IIIB to applicants, as precisely as possible, any details on the required information, such as the circumstances, conditions and technical protocols, under which certain data have to be generated; these provisions should be introduced as soon as available in order to permit applicants to use them in preparation of their dossiers.

(3) It is appropriate to differentiate data requirements for chemical substances and micro-organisms in some respects, as several requirements, e.g. on some issues concerning fate and behaviour in the environment and residues, are specific to chemicals while others, such as those on infectiveness, are specific to micro-organisms.

(4) It is now possible to introduce more precision with regard to the data requirements as experience was gained during the evaluation of several new active substances consisting of micro-organisms. In particular the areas of occupational health, consumer exposure, environmental risk have been subject to major changes.

(5) The Scientific Committee on Plants provided an opinion which dealt with the principles associated with the use of micro-organisms as plant protection products and the Committee provided comments on an early draft of the data requirements. The recommendations made by the Committee in the opinion ([3]), including the proposed amendments to the text of the draft data requirements were taken into account by the Commission.

(6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 91/414/EEC shall be amended as set out in Annex I to this Directive.

Article 2

Annex III to Directive 91/414/EEC shall be amended as set out in Annex II to this Directive.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 May 2002 at the latest. They shall forthwith inform the Commission thereof.

([1]) OJ L 230, 19.8.1991, p. 1.
([2]) OJ L 113, 24.4.2001, p. 5.
([3]) Scientific Committee on Plants SCP/MICR/006 final.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 4

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 16 May 2001.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

Annex II to Directive 91/414/EEC is amended as follows:

(1) The following point 2.4 is added to the introduction:

'2.4. By way of derogation from point 2.1, for active substances consisting of micro-organisms or viruses, tests and analyses done to obtain data on the properties and/or safety with respect to other aspects than human health, may have been conducted by official or officially recognised testing facilities or organisations which satisfy at least the requirements under points 2.2 and 2.3 of the introduction of Annex III.'

(2) Part B is replaced by the following:

'**PART B**

Introduction

(i) Active substances are defined in Article 2(4) and include chemical substances and micro-organisms including viruses.

This Part provides data requirements for active substances consisting of micro-organisms, including viruses.

For the purposes of Annex II, Part B, the term "micro-organism" is used and is defined as follows:

"A microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material".

The definition applies to, but is not limited to, bacteria, fungi, protozoa, viruses and viroids.

(ii) For all micro-organisms that are subject to application all available relevant knowledge and information in literature should be provided.

The most important and informative information is obtained by the characterisation and identification of a micro-organism. Such information is found in sections 1 to 3 (identity, biological properties and further information) which form the basis for an assessment of human health and environmental effects.

Newly generated data from conventional toxicological and/or pathological experiments on laboratory animals are normally required unless the applicant can justify, on the basis of the previous information, that the use of the micro-organism, under the proposed conditions of use, does not have any harmful effects on human and animal health or on groundwater or any unacceptable influence on the environment.

(iii) Pending the acceptance of specific guidelines at international level, the information required shall be generated using available test guidelines accepted by the competent authority (e.g. USEPA guideline ([1])); where appropriate test guidelines as described in Annex II, Part A, should be adapted in such a way that they are appropriate for micro-organisms. Testing should include viable and, if appropriate, non-viable micro-organisms, and a blank control.

(iv) Where testing is done, a detailed description (specification) of the material used and its impurities, according to the provisions of section 1, point 1.4, must be provided. The material used should be of that specification that will be used in the manufacture of preparations to be authorised.

Where studies are conducted using micro-organisms produced in the laboratory or in a pilot plant production system, the studies must be repeated using micro-organisms as manufactured, unless it can be demonstrated that the test material used is essentially the same for the purposes of the testing and assessment.

([1]) USEPA Microbial Pesticide Test Guidelines, OPPTS Series 885, February 1996 (http://www.epa.gov/oppbppd1/biopesticides/guidelines/series885.htm).

(v) Where the micro-organism has been genetically modified, as defined in Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms ([2]), a copy of the evaluation of the data concerning the assessment of risk to the environment, as stated in Article 1(3) of Directive 91/414/EEC, has to be submitted.

(vi) Where relevant, data should be analysed using appropriate statistical methods. Full details of the statistical analysis should be reported (e.g. all point estimates should be given with confidence intervals, exact p-values should be given rather than stating significant/non significant).

(vii) In the case of studies in which dosing extends over a period, dosing should preferably be done using a single batch of the micro-organism, if stability permits.

If the studies are not performed using a single batch of the micro-organism, the similarity of the different batches has to be stated.

Whenever a study implies the use of different doses, the relationship between dose and adverse effect must be reported.

(viii) If the plant protection action is known to be due to the residual effect of a toxin/metabolite or if significant residues of toxins/metabolites are to be expected not related to the effect of the active substance, a dossier for the toxin/metabolite has to be submitted in accordance with the requirements of Annex II, Part A.

1. IDENTITY OF THE MICRO-ORGANISM

The identification together with the characterisation of the micro-organism provides the most important information and is a key point for decision-making.

1.1. **Applicant**

The name and address of the applicant (permanent community address) must be provided, as must the name, position, telephone and fax number of the appropriate person to contact.

Where, in addition, the applicant has an office, agent or representative in the Member State to which the application for inclusion in Annex I is submitted, and if different, in the rapporteur Member State appointed by the Commission, the name and address of the local office, agent or representative must be provided, as must the name, position, telephone and fax number of the appropriate person to contact.

1.2. **Producer**

The name and address of the producer or producers of the micro-organism must be provided as must the name and address of each plant in which the micro-organism is produced. A contact point (preferably a central contact point, to include name, telephone and fax number) must be provided, with a view to providing updating information and responding to queries arising, regarding production technology, processes and the quality of product (including where relevant, individual batches). Where, following inclusion of the micro-organism in Annex I, there are changes in the location or number of producers, the information required must again be notified to the Commission and the Member States.

1.3. **Name and species description, strain characterisation**

(i) The micro-organism should be deposited at an internationally recognised culture collection and given an accession number and these details must be submitted.

(ii) Each micro-organism that is subject to the application should be identified and named at the species level. The scientific name and taxonomic grouping, i.e. family, genus, species, strain, serotype, pathovar or any other denomination relevant to the micro-organism, must be stated.

It must be indicated whether the micro-organism:

— is indigenous or non-indigenous at the species level to the intended area of application,

— is a wild type,

([2]) OJ L 117, 8.5.1990, p. 15.

— is a spontaneous or induced mutant,

— has been modified, using techniques described in Annex IA, Part 2, and Annex IB to Directive 90/220/EEC.

In the latter two cases, all known differences between the modified micro-organism and the parent wild strain must be provided.

iii) Best available technology should be used to identify and characterise the micro-organism at the strain level. The appropriate test procedures and criteria used for identification (e.g. morphology, biochemistry, serology, molecular identification) must be provided.

iv) Common name or alternative and superseded names and code names used during the development, if any, must be provided.

(v) Relationships to known pathogens should be indicated.

1.4. **Specification of the material used for manufacturing of formulated products**

1.4.1. *Content of the micro-organism*

The minimum and maximum content of the micro-organism in the material used for manufacturing of formulated products, must be reported. The content should be expressed in appropriate terms, such as number of active units per volume or weight or any other manner that is relevant to the micro-organism.

Where the information provided relates to a pilot plant production system, the information required must again be provided to the Commission and the Member States once industrial scale production methods and procedures have stabilised, if production changes result in a changed specification of purity.

1.4.2. *Identity and content of impurities, additives, contaminating micro-organisms*

It is desirable to have a plant protection product without contaminants (including contaminating micro-organisms), if possible. The level and nature of acceptable contaminants should be judged from a risk assessment point of view, by the competent authority.

If possible and appropriate, the identity and maximum content of all contaminating micro-organisms, expressed in the appropriate unit, must be reported. The information on identity must be provided where possible as outlined in Annex II, Part B, section1, point 1.3.

Relevant metabolites (i.e. if expected to be of concern to human health and/or the environment) known to be formed by the micro-organism should be identified and characterised at different states or growth stages of the micro-organism (see Annex IIB, Introduction, (viii)).

Where relevant detailed information on all components such as condensates, culture medium, etc. must be provided.

In the case of chemical impurities that are relevant for human health and/or the environment, the identity and maximum content, expressed in appropriate terms, must be provided.

In the case of additives, the identity and content in g/kg must be provided.

The information on identity of chemical substances such as additives must be provided as outlined in Annex II, Part A, section 1, point 1.10.

1.4.3. *Analytical profile of batches*

Where relevant, the same data as outlined in Annex II, Part A, section 1, point 1.11, have to be reported, using the appropriate units.

2. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM

2.1. **History of the micro-organism and its uses. Natural occurrence and geographical distribution**

Familiarity, interpreted as the availability of relevant knowledge of the micro-organism, should be presented.