II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DIRECTIVE 93/71/EEC

of 27 July 1993

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (1), and in particular Article 18 (2) thereof,

Whereas Annexes II and III to Directive 91/414/EEC lay down the requirements for the dossier to be submitted by applicants respectively for the inclusion of an active substance in Annex I and for the authorization of a plant protection product;

Whereas it is necessary to indicate to applicants in Annexes II and III, as precisely as possible, the details of the required information, such as the circumstances, conditions and technical protocols under which certain data have to be generated; whereas these provisions should be introduced as soon as available in order to permit applicants to use them in the preparation of their dossiers;

Whereas greater precision can be given at the present time to the general introductionary provisions to Annexes II and III and to the data requirements concerning efficacy testing provided for in Section 6 of Parts A and B of Annex III;

Whereas the introductions to the Annexes II and III currently refer to the application of the principles of good laboratory practice (GLP) for any data requirements; whereas, however, the application of such principles is not considered to be appropriate for efficacy testing and for the testing of certain physico-chemical properties or other information which are not related to data on the properties and/or safety with respect to human or animal health or the environment;

Whereas moreover it is necessary to provide for a temporary exemption of the application of these principles for certain data requirements to permit the laboratories concerned to adapt themselves to the requirements of GLP;

Whereas the specific European and Mediterranean Plant Protection Organization (EPPO) guidelines constitute for the time being the best available basis for setting the minimum requirements to be applied in all Member States with regard to the guidelines used for efficacy testing, whereas it appears necessary however to proceed urgently to a detailed examination of these guidelines and to provide for higher standards in Directive 91/414/EEC in cases where certain guidelines would appear inadequate for efficacy testing;

Whereas 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

Directive 91/414/EEC is amended as follows:

1. the section headed 'Introduction' in Annex II is replaced by Annex I hereto;

(1) OJ No L 230, 19. 8. 1991, p. 1.

2. the section headed 'Introduction' in Annex III is replaced by Annex II hereto,
3. Section 6 headed 'Efficacy data' in both Parts A and B of Annex III is replaced by Annex III hereto.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within twelve months following notification thereof. They shall immediately inform the Commission thereof.

When Member States adopt these measures, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 27 July 1993.

For the Commission
René STEICHEN
Member of the Commission

ANNEX I

'INTRODUCTION

The information required shall :

1.1. include a technical dossier supplying the information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for humans, animals and the environment and containing at least the information and results of the studies referred to below ;

1.2. where relevant, be generated using test guidelines referred to or described in this Annex, in the case of studies initiated before the adoption of the modification of this Annex, the information shall be generated using suitable internationally or nationally validated test guidelines or, in the absence thereof, test guidelines accepted by the competent authority ;

1.3. in the event of a test guideline being inappropriate or not described, or where another one than those referred to in this Annex has been used, inlcude a justification, which is acceptable to the competent authority for the guidelines used ;

1.4. include, when required by the competent authority, a full description of test guidelines used, except if they are referred to or described in this Annex, and a full description of any deviations from them including a justification, which is acceptable to the competent authority, for these deviations ;

1.5. include a full and unbiased report of the studies conducted as well as full description of them or a justification, which is acceptable to the competent authority where :

— particular data and information which would not be necessary owing to the nature of the product or its proposed uses, are not provided,

or

— it is not scientifically necessary, or technically possible to supply information and data ;

1.6. where relevant, have been generated in accordance with the requirements of Directive 86/609/EEC.

2.1. Tests and analyses must be conducted in accordance with the principles laid down in Directive 87/18/EEC (1) where testing is done to obtain data on the properties and/or safety with respect to human or animal health or the environment.

2.2. By way of derogation from point 2.1, tests and analyses done to obtain data on the properties and/or safety with respect to honeybees and beneficial arthropods other than bees may have been conducted by official or officially recognized testing facilities or organizations which satisfy at least the requirements as set out under points 2.2 and 2.3 of the introduction to Annex III.

This derogation expires on 31 December 1999.

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(1) OJ No L 15, 17. 1. 1987, p. 29.'

ANNEX II

'INTRODUCTION

The information required shall:

1.1. include a technical dossier supplying the information necessary for evaluating efficacy and the foreseeable risks, whether immediate or delayed, which the plant protection product may entail for humans, animals and the environment and containing at least the information and results of the studies referred to below;

1.2. where relevant, be generated using test guidelines referred to or described in this Annex; in the case of studies initiated before the adoption of the modification of this Annex, the information shall be generated using suitable internationally or nationally validated test guidelines or, in the absence thereof, test guidelines accepted by the competent authority;

1.3. in the event of a test guideline being inappropriate or not described, or where another one than those referred to in this Annex has been used, include a justification, which is acceptable to the competent authority for the guidelines used;

1.4. include when required by the competent authority, a full description of test guidelines used, except if they are referred to or described in this Annex, and a full description of any deviations from them including a justification, which is acceptable to the competent authority, for these deviations;

1.5. include a full and unbiased report of the studies conducted as well as a full description of them or a justification, which is acceptable to the competent authority where:

— particular data and information which would not be necessary owing to the nature of the product or its proposed uses, are not provided,

or

— it is not scientifically necessary, or technically possible to supply information and data.

1.6. where relevant, have been generated in accordance with the requirements of Directive 86/609/EEC.

2.1. Tests and analyses must be conducted in accordance with the principles laid down in Directive 87/18/EEC where testing is done to obtain data on the properties and/or safety with respect to human or animal health or the environment.

2.2. Tests and analyses, required under the provisions of Section 6 points 6.2 to 6.7 of this Annex, shall be conducted by official or officially recognized testing facilites or organizations which satisfy at least the following requirements:

— have at their disposal sufficient scientific and technical staff, having the necessary education, training, technical knowledge and experience for their assigned functions,

— have at their disposal suitable items of equipment required for correct performance of the tests and measurements which it claims to be competent to carry out. This equipment shall be properly maintained and calibrated where appropriate before being put into service and thereafter according to an established programme,

— have at their disposal appropriate experimental fields and, where necessary glasshouses, growth cabinets or storage rooms. The environment in which the tests are undertaken shall not invalide its results or adversely effect the required accuracy of measurement,

— make available to all relevant personnel operating procedures and protocols used for the trials,

— make available, where requested by the competent authority, prior to the commencement of a test, detailed information on it, containing at least its location and the plant protection products included in it,

— ensure that the quality of the work performed is appropriate to its type, range, volume and intended purpose,

— calibration records and the final test report as long as the product concerned authorized in the Community.

2.3. Member States shall require that officially recognized testing facilities and organizations, and, where requested, official facilities and organizations :

— report to the relevant national authority all detailed information necessary to demonstrate that they can satisfy the requirements provided for in point 2.2,

— accept at any time the inspections, which each Member State shall regularly organize on its territory in order to verify the compliance with the requirement as laid down in point 2.2.

2.4. By way of derogation from point 2.1 the provisions of points 2.2 and 2.3 also apply until 31 December 1999 for the tests and analyses done to obtain data on the properties and/or safety with respect to honeybees and beneficial arthropods other than bees.

3. The information required shall include the proposed classification and labelling of the plant protection product in accordance with relevant Community Directives.

4. In individial cases it may be necessary to require certain information as provided for in Annex II, Part A, for formulants. Before such information will be required and before possible new studies have to be performed, all information on the formulant, made available to the competent authority, will be considered, in particular when :

— the use of the formulant is permitted in food, animal feeding stuffs, medicines or cosmetics in accordance with Community legislation,

or

— a safety data sheet has been submitted for the formulant in accordance with Council Directive 67/548/EEC.'

ANNEX III

'6. *Efficacy data*

General

The data supplied must be sufficient to permit an evaluation of the plant protection product to be made. In particular it must be possible to evaluate the nature and extent of benefits that accrue following use of the preparation, where they exist in comparison to suitable reference products and damage thresholds, and to define its conditions of use.

The number of trials to be conducted and reported depends mainly on factors such as the extent to which the properties of the actieve substance(s) it contains are known and on the range of conditions that arise, including variability in plant health conditions, climatic differences, the range of agricultural practices, the uniformity of the crops, the mode of application the type of harmful organism and the type of plant protection product.

Sufficient data must be generated and submitted to confirm that patterns determined hold for the regions and the range of conditions, likely to be encountered in the regions concerned, for which its use is to be recommended. Where an applicant claims that tests in one or more of the proposed regions of use are unnecessary because conditions are comparable with those in other regions where tests have been carried out, the applicant must substantiate the claim for comparability with documentary evidence.

In order to assess seasonal differences, if any, sufficient data must be generated and submitted to confirm the performance of the plant protection product in each agronomically and climatically different region for each particular crop (or commodity)/harmful organism combination. Normally trials on effectiveness or phytotoxicity, where relevant, in at least two growing seasons must be reported.

If to the opinion of the applicant the trials from the first season adequately confirm the validity of claims made on the basis of extrapolation of results from other crops, commodities or situations or from tests with closely similar preparations, a justification, which is acceptable to the competent authority for not carrying out a second seaons's work must be provided. Conversely, where, because of climatic or plant health conditions or other reasons the data obtained in any particular season are of limited value for the assessment of performance, trials in one or more further seasons must be conducted and reported.

6.1. Preliminary tests

Reports in summary form of preliminary tests, including glasshouse and field studies, used to assess the biological activity and dose range finding of the plant protection product and of the active substance(s) it contains, must be submitted when requested by the competent authority. These reports will provide additional information for the competent authority when it evaluates the plant production product. Where this information is not submitted a justification which is acceptable to the competent authority must be provided.

6.2. Testing effectiveness

Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the level, duration and consistency of control or protection or other intended effects of the plant protection product in comparison to suitable reference products, where they exist.

Test conditions

Normally a trial consists of three components: test product, reference product and untreated control.

The performance of the plant protection product must be investigated in relation to suitable reference products, where they exist. A suitable reference product is defined as an authorized plant protection product which has proved a sufficient performance in practice under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use. In general, formulation type, effects on the harmful organisms, working spectrum and method of application should be close to those of the tested plant protection product.

Plant protection products must be tested in circumstances where the target harmful organism has been shown to have been present at a level causing or known to cause adverse effects (yield, quality, operational benefit) on an unprotected crop or area or on plants or plant products which have not been treated or where the harmful organism is present at such a level that an evaluation of the plant protection product can be made.

Trials to provide data on plant protection products for control of harmful organisms must show the level of control of the species of harmful organisms concerned or of species representative of groups for which claims are made. Trials must include the different stages of growth of life cycle of the harmful species, where this is relevant and the different strains or races, where these are likely to show different degrees of susceptibility.

Similarly, trials to provide data on plant protection products which are plant growth regulators, must how the level of effects on the species to be treated, and include investigation of differences in the response of a representative sample of the range of cultivars on which its use is proposed.

In order to clarify the dose response, dose rates lower than the recommended one must be included in some trials in order to enable to assess whether the recommended rate is the minimum necessary to achieve the desired effect.

The duration of the effects of treatment must be investigated in relation to the control of the target organism or effect on the treated plants or plant products, as appropriate. When more than one application is recommended, trials must be reported which establish the duration of the effects of an application, the number of applications necessary and the desired intervals between them.

Evidence must be submitted to show that the dose, timing and medthod of application recommended give adequate control, protection or have the intended effect in the range of circumstances likely to be encountered in practical use.

Unless there are clear indications that the performance of the plant protection production is unlikely to be affected to a significant degree by environemental factors, such as temperature or rain, an investigation of the effects of such factors on performace must be carried out and reported, particularly where it is known that the performance of chemically related products os so affected.

Where proposed label claims include recommendations for the use of the plant protection product with other plant protection product(s) or adjuvant(s) information on the performance of the mixture must be provided.

Test guideline

Trials must be designed to investigate specified issues, to minimize the effects of random variation between different parts of each site and to enable statistical analysis to be applied to results amenable to such analysis. The design, analysis and reporting of trials must be in accordance with European and Mediterranean Plant Protection Organization (EPPO) guidelines 152 and 181. The report shall include a detailed and critical assessment of the data.

The trials must be carried out in accordance to specific EPPO guidelines, where available, or when a requires so and when the test is carried out on the territory of this, with guidelines satisfying at least the requirements of the corresponding EPPO guideline.

A statistical analysis of results amenable to such analysis must be carried out ; where necessary the test guideline used must be adapted to enable such analysis.

6.3. Information on the occurrence or possible occurrence of the development of resistance

Laboratory data and where it exists, field information relating to the occurrence and development of resistance or cross-resistance in populations of harmful organisms to the active substance(s), or to related actived substances, must be provided. Where such information is not directly relevant to the uses for which authorization is ought or to be renewed (different species of harmful organism or different crops), it must, if available, nevertheless be provided, as it may provide and indication of the likelihood of resistance developing in the target population.

Where there is evidence or information to suggest that, in commercial use, the development of resistance is likely, evidence must be generated and submitted as to the sensitivity of the population of the harmful organism concerned to the plant protection product. In such cases a management strategy designed to minimize the likelihood of resistance or cross-resistance developing in target species must be provided.

6.4. Effects on the yield of treated plants or plant products in terms of quantity and/or quality

6.4.1. Effects on the quality of plants or plant product

Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the possible occurrence of taint or odour or other quality aspects of plants or plant products after treatment with the plant protection product.

Circumstances in which required

The possibility of the occurrence of taint or odour in food crops must be investigated and be reported where :

— the nature of the products or its use is such that a risk of occurrence of taint or odour might be expected,

or

— other products based on the same or a closely similar active ingredient have been shown to present a risk of occurrence of taint or odour.

The effects of plant protection products on other quality aspects of treated plants or plant products must be investigated and reported where :

— the nature of the plant protection product or it use could have an adverse influence on other quality aspects (for example in the case of use of plant growth regulators close or harvest), or

— other products based on the same or a closely similar active ingredient have been shown to have an adverse influence on the quality.

Testing should be conducted initially on the main crops on which the plant protection product is to be used, at twice the normal rates of application and using, where relevant, the main methods of processing. Where effects are observed it is necessary to perform testing at the normal rate of application.

The extent of investigation necessary on other crops will depend on their degree of similarity of the main crops already tested, the quantity and quality of data available on those main crops and how far the manner of use of the plant protection product and methods of processing the crops, are similar. It is generally sufficient to perform the test with the main formulation type to be authorized.

6.4.2. Effects on transformation processes

Aim of the tests

The tests shall provide sufficient data to permit an evaluation of the possible occurrence of adverse effects after treatment with the plant protection product on transformation processes or on the quality of their products.

Circumstances in which required

When the treated plants or plant products are normally intended for use in transformation process such as wine making, brewing or bread making and when at harvest significant residues are present, the possibility of the occurrence of adverse effects must be investigated and reported where :

— there are indications that the use of the plant protection product could have an influence on the processes involved (for example in the case of use of plant growth regulators or fungicides close to harvest),

or

— other products based on the same or a closely similar active ingredient have been shown to have an adverse influence on these processes or its products.

It is generally sufficient to perform the test with the main formulation type to be authorized.

6.4.3. Effects on the yield of treated plants or plant products

Aim of the tests

The test shall provide sufficient data to permit an evaluation of the performance of the plant protection product and of possible occurrence of yield reduction or loss in storage of treated plants or plant products.

Circumstances in which required

The effects of plant protection products on the yield or yield components of treated plant products must be determined where relevant. When treated plants or plant products are likely to be stored the effect on the yield after storage, including data on starage life must be determined where relevant.

This information will normally be available from the tests required under the provisions of point 6.2.

6.5. Phytotoxicity to target plants (including different cultivars), or to target plant products

Aim of the tests

The test shall provide sufficient data to permit an evaluation of the performance of the plant protection product and of the possible occurrence of phytotoxicity after treatment with the plant protection product.

Circumstances in which required

For herbicides and for other plant protection products for which adverse effects, however transitory, are seen during the trials, performed in accordance to point 6.2, the margins of selectivity on target crops must be established, using twice the recommended rate of application. Where serious phytotoxic effects are seen, an intermediate application rate must also be investigated.

Where adverse effects occur, but are claimed to be unimportant in comparison with the benefits of use or transient, evidence to support this claim is required. If necessary yield measurement must be submitted.

The safety of a plant protection product to the main cultivars of the main crops for which it is recommended must be demonstrated, including effects of crop growh stage, vigour, and other factors which may influence suspectibility to damage or injury.

The extent of investigation necessary on other crops will depend on their degree of similarity to the main crops already tested, the quantity and quality of data available on those main crops and how far the manner of use of the plant protection product, if relevant, is similar. It is generally sufficient to perform the test with the main formulation type to be authorized.

Where proposed label claims include recommendations for the use of the plant protection product with other plant protection product(s), the provisions of the previous paragraphs apply for the mixture.

Test guideline

Observations concerning phytotoxicity must be performed in the tests provided for under point 6.2.

Where phytotoxic effects are seen, they must be accurately assessed and recorded in accordance with EPPO guideline 135 or when a Member State requires so and when the test is carried out on the territory of this Member State, with guidelines satisfying at least the requirements of this EPPO guideline.

A statistical analysis of results amenable to such analysis must be carried out, where necessary the test guideline used must be adapted to enable such analysis.

6.6. Observations on undesirable or unintended side-effects, e. g. on beneficial and other non-target organisms, on succeeding crops, other plants or parts of treated plants used for propagating purposes (e. g. seeds, cuttings, runners)

6.6.1. Impact on succeeding crops

Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops.

Circumstances in which required

Where data, generated in accordance with Section 9, point 9.1, shows that signification residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials, such as straw or organic material up to sowing or planting time of possible succeeding crops, observations must be submitted on effects on the normal range of succeedings crops.

6.6.2. Impact on other plants, including adjacent crops

Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on other plants, including adjacent crops.

Circumstances in which required

Observations must be submitted on adverse effects on other plants, including the normal range of adjacent crops, when there are indications that the plant protection product could affect these plants via vapour drift.

6.6.3. Impact on treated plants or plant products to be used for propagation

Aim of the information required

Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on plants or plant products ot be used for propagation.

Circumstances in which required

Observations must be submitted on the impact of plant protection products on plant parts used for propagation except where the proposed uses preclude use on crops intended for production of seeds, cuttings, runners or tubers for planting, as appropriate.

(i) for seeds — viability, germination and vigour;

(ii) cuttings — rooting and growth rates;

(iii) runners — establishment and growth rates;

(iv) tubers — sprouting and normal growth.

Test guideline

Seeds testing shall be done according to ISTA Methods (1).

(1) International rules for seed testing, 1985. Proceedings of the International Seed Testing Association, *Seed Science and Technology*, Volume 13, No 2, 1985.

6.6.4. Effects on beneficial and other non-target organisms

Any effects, positive or negative, on the incidence of other harmful organisms, observed in the tests performed in accordance with the requirements of this section, shall be reported. Any observed environmental effects must also be reported, especially effects on wildlife and/or beneficial organisms.

6.7. Summary and evaluation of data presented under 6.1 to 6.6

A summary of all data and informations provided under points 6.1 to 6.6 must be provided, together with a detailed and a critical assessment of the data, with particular reference to the benefits that the plant protection product offers, adverse effects that do or may arise and measures necessary to avoid or minimize adverse effects.'