# COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 21 March 1991

Second amendment to the proposal for a

COUNCIL DIRECTIVE

**concerning the placing of EEC-accepted plant protection products on the market**

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(presented by the Commission pursuant to Article 149(3) of the EEC-Treaty)

# EXPLANATORY MEMORANDUM

At its session of 19 February 1991, the European Parliament delivered its opinion on the Commission proposal contained in document COM(89) 34, concerning the Amended proposal for a Council Directive concerning the placing of EEC-accepted plant protection products on the market.

The present amended proposal takes into account these amendments suggested by the European Parliament on which the Commission has taken a favourable position.

Second amendment to the proposal for a

COUNCIL DIRECTIVE

concerning the placing of EEC-accepted plant protection products on the market

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In response to the opinion delivered by the European Parliament(1) on the amended proposal for a Directive sent by the Commission to the Council on 24 February 1989 and concerning the placing of EEC-accepted plant protection products on the market, and in accordance with the third paragraph of Article 149 of the Treaty establishing the European Economic Community, the Commission has decided to amend the aforementioned proposal as follows.

1. Throughout the proposal the terminology "acceptance" or "accept" is replaced by "authorisation" and "authorise" respectively.

2. In the 4th recital the word "animals" is introduced between the words "man" and "and the environment".

3. The following recital is introduced after the 8th recital:
"Whereas the provisions governing authorization, must ensure a high standard of protection, which, in particular, must prevent the authorization of plant protection products whose risks to health, groundwater and the environment has not been adequately investigated; whereas the protection of the environment and human and animal health should take priority over the objective of increasing plant production;".

4. The 14th recital is amended as follows:
"Whereas, in the interest of safety, substances on the Community list should be reviewed periodically to take account of scientific and technological developments and of impact studies based on actual use of the authorized substances;".

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(1)

5. The following recital is introduced after the 14th recital:
"Whereas resources devoted to the conduct of tests should not be squandered by the unnecessary repetition of tests as a result of different regulations in the Member States; whereas considerations of public interest militate against the undue repetition of tests on animals;".

6. The 18th recital is completed with the following sentence:
"whereas to this end there is a need to harmonize the methods of experimentation and control applied by the Member States for the purpose of granting authorization;".

7. The following recital is introduced after the 18th recital:
"Whereas it is necessary to maintain consistency between this directive and Community rules on the residues of plant protection products in agricultural products and the free movement of the latter in the Community;".

8. The 19th recital is amended as follows:
"Whereas, in order to ensure that the requirements laid down are satisfied, Member States must make provision for appropriate control and inspection arrangements with regard to the marketing and use of plant protection products;".

9. The 20th recital is amended as follows:
"Whereas this Directive is not adequate for the full environmental risk assessment necessary for release into the environment of plant protection products containing or composed of genetically modified organisms, but must nonetheless be used to authorize the marketing of such products, provided that they have first received a clearance for release into the environment under Directive 90/220/EEC on deliberate release into the environment of genetically modified organisms;".

10. The following titles are introduced in the proposal;
    - before Article 1: "Scope"
    - before Article 2: "Definitions"
    - before Article 3: "General provisions"
    - before Article 4: "Granting, review and withdrawal of authorizations of plant protection products"
    - before Article 6: "Inclusion of active substances in Annex I"
    - before Article 7: "Information on potentially harmful effects"
    - before Article 8: "Transitional measures and derogations"
    - before Article 9: "Application for authorization"
    - before Article 10: "Mutual recognition of authorizations"
    - before Article 11: "Exchange of information between Member States and Commission"
    - before Article 12: "Data requirements, data protection and confidentiality"
    - before Article 14: "Packaging and labelling of plant protection products"
    - before Article 16: "Control measures"
    - before Article 17: "Administrative provisions""
    - before Article 20: "Release of plant protection products for research and development"
    - before Article 21: "Implementation of the Directive".

11. Article 1(1) is amended as follows:

    "1. This Directive concerns the authorization, placing on the market, use and control within the Community of plant protection products put up in commercial form, and the placing on the market and control within the Community of active substances intended for a use as specified in Article 2(1)."

12. The following paragraphs are introduced after paragraph 2 of Article 1:

"3. This directive shall apply to the authorization to place on the market products consisting of or containing genetically modified organisms, provided authorization to release them into the environment has already been granted following assessment of the environmental risk under Directive 90/220/EEC(1) on the deliberate release of genetically modified organisms into the environment. The Commission shall, within five years of the date of implementation of this Directive, draw up a report for the Council and the European Parliament, on the basis of the experience acquired, on the operation of the arrangement laid down in the preceeding subparagraph, accompanied, where appropriate, by a proposal for amendment of this Directive.

4. This directive shall apply without prejudice to Regulation (EEC) No 1734/88(2) of 16 June 1988 concerning export from and import into the Community of certain dangerous chemicals;".

13. In Article 2, point 8, the word "bacteria" is introduced between the words "viruses" and "mycoplasms".

14. In Article 2, point 12, the word "physical" is introduced between the words "chemical" and "cultural".

15. The following words are introduced in Article 4(1)(b) between "(b)" and the words "it is established ...":
"and, following application of the uniform principles provided for in Annex VI,".

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(1) OJ No L 117, 8.5.1990, p. 15.

(2) OJ No L 155, 22.6.1988, p. 2.

16. Article 4(1)(b), points (iii) and (iv) are amended as follows:

"(iii) it has no harmful effect on human or animal health, directly or indirectly (e.g. through drinking water, food or feed),

(iv) it has no unacceptable influence on the environment, having particular regard to its fate and distribution in the environment, particularly contamination of water including groundwater and drinking water,".

17. Article 4(1)(c) is amended as follows:

"(c) if the nature and quantity of its active substances and, where appropriate, any toxicologically or ecotoxicologically significant impurities and coformulants, can be determined by appropriate methods harmonised according to the procedure provided in Article 19, or, if not, agreed by the authorities responsible for the authorisation."

18. In Article 5(2), the words "at the request of the interested party," are introduced after the words "in each case".

19. Article 6(3) is amended as follows:

"3. As part of the procedure for assessing the dossier, the interested party may be invited by the Commission or may make a request to:

- [unchanged]
- [unchanged].

The interested party shall have the right to be heard by the Committee whenever an unfavourable opinion is envisaged."

20. In Article 8(2) the words "for a period not exceeding three years" are replaced by "for a period which shall under no circumstances exceed three years".

21. Article 8(3) is completed by the following subparagraph:
"No later than two years before completion of the work programme, the Commission shall forward to the Council and the European Parliament a report on the progress achieved with the programme."

22. The provisions of Article 11(4) are introduced as a paragraph 3 in Article 4. The following sentence is added to this paragraph:
"The interested party is immediately informed of any such decision."

23. In Article 12(2), 2nd indent, the words "or the maintaining" are introduced between the words "the inclusion" and "of the active substance".

24. Article 15(1)(b) is amended as follows:
"(b) the name and address of the holder of the authorization and the registration number of the plant protection product, and if different, the name and address of the person responsible for the final packaging and labelling or final labelling of the plant protection product;".

25. Article 15(1)(k) is amended as follows:
"(k) the uses for which the plant protection product has been authorized and any specific agricultural, plant health and environmental conditions under which the product may be used or should not be used;".

26. In Article 15(3) the statement "unsuitable for domestic use" is replaced by "reserved for agricultural use".

27. Article 16 is amended as follows:
"Member States shall make suitable arrangements for plant protection products which have been placed on the market to be officially checked and inspected to see whether they comply with the requirements of this Directive and the conditions of the authorization.

The inspections shall also concern the proper use of the plant protection product, and in particular include checks on compliance with good plant protection practice.

The Member States shall report annually, before the 1st of April, to other Member States and the Commission on the results of the inspection measures taken in the previous year."

28. Article 17(1), third hyphen is amended as follows:

"- Annex VI, including uniform principles for checking compliance with the requirements set out in Article 4(1)(b) and any necessary amendments thereto;".

29. In Annex II, part A, subpart "Further information on the active substance", the following point is introduced between points 3.10 and 3.11:

"3.10a - Where necessary, in the light of the test results, any specific agricultural, plant health or environmental conditions under which the active substance may or may not be used."

30. In Annex II, part B, subpart "Further information on the organism" the following point is introduced between points 3.15 and 3.16:

"3.15a - Where necessary, in the light of the test results, any specific agricultural, plant health and/or environmental conditions under which the organism may or may not be used."

31. In Annex III, part A, subpart "Further technical information on the preparation" the following point is introduced between points 4.6 and 4.7:

"4.6a - Where necessary in the light of the test results, any specific agricultural, plant health and/or environmental conditions under which the product may or may not be used."

32. In Annex III, part B, subpart "Further technical information on the preparation" the following point is introduced between points 2.5 and 2.6:

"2.5a - Where necessary in the light of the test results, any specific agricultural, plant health and/or environmental conditions under which the product may or may not be used".

33. A new Annex VI is included with the following title:
"Uniform principles for the assessment of plant protection products".