

# COMMISSION OF THE EUROPEAN COMMUNITIES

COM(89) 34 final

Brussels, 16 February 1989

Amended 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

1. The Commission White Paper on completing the internal market calls for the adoption by the Council during 1986 of this proposal, which was made by the Commission in 1976(1). The proposal was examined actively by the Council over the period 1977-1983, since when it has remained blocked due to reservations by a number of delegations.
  
2. The original proposal, which did not provide for total harmonisation, envisaged the creation of an optional "EEC-acceptance" to operate in parallel with existing national arrangements for approving plant protection products. EEC-acceptance, if granted by one Member State, was to be recognised, subject to certain safeguards, automatically by all other Member States normally within a 1 - 2 year period. It was to permit the free circulation of the product throughout the Community except that Member States might, because of local conditions, be authorised by derogation under a Community procedure to prohibit its circulation in their territory or to restrict or vary its field of use. Member States were to be permitted, subject to the limitations of Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances, to continue to approve for marketing in their own territory products complying with national provisions.

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(1) OJ N° C 212, 9.9.1976, p. 3, COM(76) 437

3. Opposition to the original proposal by certain Member States was based on their view that:
- a) there was a disproportionate burden of proof placed on a Member State requesting a national derogation (cf. paragraph 2), and
  - b) the envisaged Community procedure for mutual recognition and granting of derogations was too cumbersome and slow.

Some Member States also called into question the very concept of "EEC-acceptance", arguing that only Member States can judge possible adverse effects of a product, particularly on the environment, under local conditions.

4. To meet these reservations, the Commission is of the opinion that the proposal should be modified to:
- a) simplify the proposed Community procedure by limiting it to the establishment of a Community positive list of active substances, whose use may be considered a priori safe to human and animal health and to the environment, and
  - b) give greater flexibility to Member States to judge, in the first instance, the acceptability under local conditions, safety, efficacy and environmental impact of individual preparations containing active substances authorized at Community level.

On the other hand, the Commission considers that the provisions of the directive should be made applicable to all plant protection products marketed in the Community, thus rendering the harmonisation total, and that the principle of mutual recognition of national acceptance should be maintained. The provisions of the Directive have also been strengthened to ensure the proper use of plant protection products including the application, where appropriate, of the principles of integrated pest control. Compared with the original proposal, this modified proposal in fact reinforces the envisaged Community regulatory regime, so that it corresponds more closely to the objectives of the White Paper and contributes to the policy on pesticides announced in the Commission's Green paper (2) and the Communication "Environment and Agriculture"(3). It also takes account of Parliament's opinion (4) on the original proposal, which:

- a) approved the proposal only as a transitional measure;
- b) called on the Commission to introduce more far-reaching proposals to bring about total standardization and stressed the need for flexibility in harmonizing national provisions, particularly with regard to environmental protection.

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- (2) Perspectives for the Common Agricultural Policy, July 1985, Part IV, item 9
  - (3) Communication "Environment and Agriculture" of 8.6.1988, document COM(88)338 final.
  - (4) OJ N° C 30, 7.2.1977, p. 38

5. The proposal does not only cover chemical substances but also microorganisms and viruses used as plant protection products.

In June 1988 the Commission introduced to the Council a proposal for a Council Directive concerning the deliberate release of genetically modified organisms (GMO) in the environment (COM(88)160 final).

The Commission noticed however that currently GMOs are not put on the market and that their use will be very limited before 1995. Moreover, there is only few experience in relation to the methodology of risk assessment in this area.

The Commission follows with attention the evolution in relation to the development of GMOs which may be marketed as plant protection products.

In this context, the Commission does not exclude that in future it will be induced to propose to the Council the introduction in this Directive of complementary and specific provisions concerning the risk evaluation and acceptance of plant protection products containing or composed of GMOs.

6. To facilitate comprehension, the amended proposal is presented below in the form of the full text of the preamble, enacting terms and annexes now proposed.

7. The proposal provides a Regulatory Committee procedure for the establishment of standards of composition and purity of active substances, for the inclusion of active substances in annex I and for the establishment of uniform principles for checking of compliance with the requirements to be satisfied for the acceptance of plant protection products. This procedure has also been provided for deciding if the decision of a Member State to refuse the placing on the market of a plant protection product which has been accepted by another Member State or to refuse tests carried out in another Member State in view of such acceptance, is effectively justified on the ground that the phytosanitary, agricultural and environmental conditions are not comparable in the other Member State in comparison with those conditions in his own territory.

The decision to propose this procedure does not prejudice future proposals of the Commission concerning decision procedures in this area. Moreover the Commission proposed the Advisory Committee procedure for the other management acts required for the implementation of the Directive.