COMMISSION OF THE EUROPEAN COMMUNITIES

COM (82) 332 final

Brussels, 9 June 1982

COMMUNICATION FROM THE COMMISSION TO THE COUNCIL

concerning the marketing and use of
plant protection products containing 2,4,5-T

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I. Introduction

1. 2,4,5-trichlorophenoxyacetic acid ("2,4,5-T") is used in certain Member States as a herbicide, particularly in forestry, on cereals and grassland and in total weed control. Although 2,4,5-T was introduced as long ago as 1944, its safety has been questioned several times since the early 1970's following its controversial use as a defoliant during the Vietnam war. The main concern has been over contamination by the impurity 2,3,7,8-tetrachlorodibenzo-p-dioxin ("TCDD"), whose high toxicity has been highlighted by a number of industrial accidents during the manufacture of trichlorophenol - notably at Seveso, Italy (1976) in which a significant quantity of TCDD was released into the environment. Trichlorophenol is a raw material for the manufacture of 2,4,5-T and the TCDD which is formed during its production may therefore be present in trace amounts in 2,4,5-T formulations.

2. 2,4,5-T is presently authorised for use as a plant protection product in Belgium, France, Greece, Ireland, Luxembourg and the United Kingdom. Authorisation has been withdrawn in Italy (1970) and the Netherlands (1978) and 2,4,5-T has not been commercially available in Denmark since 1979. In Germany, authorisation was revoked in August 1981 but is not yet effective.

3. All Member States in which 2,4,5-T is authorised have set a maximum permitted level of 0.1 mg TCDD per kg of 2,4,5-T in the technical active substance in conformity with the internationally approved specification (1). In 1980 Belgium, Germany and the U.K. reduced this to 0.01 mg/kg and the European manufacturers of the active substance now guarantee a TCDD content below 0.01 mg/kg.

4. The production of the sole manufacturer of 2,4,5-T within the Community was about 1000 tonnes in 1980 and consumption is estimated to have been approximately 600 tonnes in 1979. Of this, less than 20% was used in forestry and consumption appears to be declining.

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II. Scientific Data

1. Reports have appeared over the years linking the use of 2,4,5-T with miscarriages, birth deformities, increased incidence of cancer and circulatory system diseases. As a result, 2,4,5-T has been the subject of numerous thorough reviews by the authorities of certain Member States (2). On the basis of these, the Commission has been satisfied that, when properly applied for the purpose intended, herbicides containing 2,4,5-T complying with the internationally approved specification, particularly regarding limits on TCDD-content, could be used without risk to human or animal health and with minimal risk to the environment.

2. On the other hand, the Commission is aware that there is continuing concern in some quarters, particularly following the emergency suspension of the registrations for certain uses of 2,4,5-T in the U.S.A. in 1979. In view of the apparent divergence of views, the Commission decided to review all the available evidence to establish a scientific basis for possible Community action. Directive 79/117/EEC (3) provides the Community with the means to prohibit, if necessary, the marketing and use of hazardous or environmentally harmful plant protection products. To this end, it referred the matter to the Scientific Committee for Pesticides in May 1980.

3. In July 1981, the Scientific Committee for Pesticides expressed its opinion, which was published (4) by the Commission in December 1981. The Committee's conclusions are set out in full in the Annex to this communication.

   In summary, the Committee was satisfied that the marketing and proper agricultural use of 2,4,5-T is not dangerous for human or animal health or prejudicial to the environment. It made, however, a number of detailed recommendations concerning particularly the maximum permitted level of TCDD in 2,4,5-T and the avoidance of 2,4,5-T residues in foodstuffs.

III. Conclusions concerning possible Community action

1. The Commission accepts the broad conclusions of the opinion of the Scientific Committee for Pesticides and concludes that on the basis

of existing scientific evidence a Community-wide prohibition of the marketing and use of 2,4,5-T herbicides, in the context of Directive 79/117/EEC, would not be justified.

2. The Commission recognises that 2,4,5-T, by its efficacy against particular types of weeds, offers advantages to agriculture in many parts of the Community.

3. The Commission considers that a number of precautionary measures concerning the marketing and use of 2,4,5-T should be taken, in particular:

a) the immediate reduction of the maximum permitted level of TCDD to 0.01 mg/kg and its further reduction to 0.005 mg/kg as soon as an internationally standardised method of analysis becomes available. The Commission will press for the early adoption of such an internationally standardised method through the Collaborative International Pesticide Analytical Council (CIPAC).

b) a detailed review of current uses of 2,4,5-T in Member States to ensure avoidance of its residues in food and feedingstuffs and to eliminate uses where its efficacy is insufficient compared with available, safe alternatives. In this context, the Commission considers it desirable:

(i) to discontinue the use of 2,4,5-T on cereals and to withdraw 2,4,5-T formulations from home garden use, and

(ii) to prohibit the spraying of woodland with 2,4,5-T during the ripening and harvesting periods of wild fruits and mushrooms.

c) the fixing of maximum permitted levels for 2,4,5-T residues in food and feedingstuffs at or near the relevant lower limits of determination. For its part, the Commission will take the necessary measures to have such levels established in Community legislation, where it exists.

4. There is at present no adopted Community legislation available for implementing at Community level the measures envisaged under 3 a) and b). In 1976, the Commission submitted to the Council a proposal for a directive concerning the type approval of plant protection products (5). This proposal envisages the creation of a type of "EEC-acceptance" and seeks to create conditions under which plant protection products may circulate within the Community whilst

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ensuring the safety of users, consumers, animals, crops and the environment. In the Commission's opinion, this proposal, when adopted, would provide the appropriate framework in which to adopt the measures referred to under 3.

5. The Commission will continue to keep under review new scientific data on 2,4,5-T and information on exposure as it becomes available.

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(1) FAO Specification for Pesticides, Herbicides 1977;

(2) - Bundesgesundheitsblatt (Berlin) 18. 1975, 16, 264-265;
- Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft, Berlin-Dahlem, Heft 181, 1978;
- "Review of the safety for use in the U.K. of the herbicide 2,4,5-T" March 1979; Ministry of Agriculture, Fisheries and Food, London;
- "Further review of the safety for use in the U.K. of the herbicide 2,4,5-T", December 1980; Ministry of Agriculture, Fisheries and Food, London;

(3) OJ No. L 33 of 8.2.1979, p. 36;

(4) Reports of the Scientific Committee for Pesticides, Office for Official Publications of the European Communities, EUR 7581 (1981);

(5) OJ No. C 212 of 9.9.1976, p. 3.

ANNEX

Recommendations and conclusions of the Scientific Committee for Pesticides

(extract from opinion delivered on 15 July 1981)

1. 2,4,5-T is a selective herbicide, which has been in continuous but limited use within the Community for more than 25 years and still remains the most effective product in nearly all its fields of use.

2. A "no observable effect" level has been demonstrated for 2,4,5-T containing 0.05 ppm TCDD in animal toxicological studies and the 1979 FAO/WHO Joint Meeting on Pesticide Residues has accordingly recommended a temporary ADI of 0.003 mg/kg body weight/day, which the Committee accepts.

3. However, in order to avoid the possibility, as far as is practicable in relation to the use of 2,4,5-T, of the occurrence of traces of TCDD in foodstuffs, the Committee is of the opinion that permitted uses of 2,4,5-T should be such as not to leave residues in food crops at harvest above the lower limit of determination of 2,4,5-T. Areas to which the public has access should not be sprayed during the ripening and harvesting periods of wild fruits and mushrooms.

4. The Committee noted that on the basis of existing manufacturing technology, an average TCDD content of about 0.002 mg/kg 2,4,5-T can be achieved and consequently considers that a guarantee level of 0.005 mg/kg should be possible. The Committee, however, is aware that no standardised method to control such a low level exists and recommends that candidate methods be collaboratively tested with a view to reducing the present guarantee of 0.01 mg/kg as soon as possible. In the meantime, this maximum level of 0.01 mg/kg, already enforced in some Member States, should be adopted by the Community.

5. There is no evidence that the proper use of 2,4,5-T preparations has in practice given rise directly to ecotoxicological effects or that 2,4,5-T and TCDD accumulate in nature when 2,4,5-T is used in accordance with good agricultural practice.

6. **Whilst** the Committee is satisfied that there is no particular risk to operators handling formulations containing 2,4,5-T complying with this specification, it stresses the importance, as for all pesticides, of strict observance of the appropriate precautions for use.

The Committee concludes that the marketing and proper agricultural use of 2,4,5-T, the average TCDD content of which is not more than 0.002 mg/kg (see 4 above),

is not dangerous for human or animal health or prejudicial to the environment, assuming that any residues left in food crops offered or accessible to the public are not above the lower limit of determination of 2,4,5-T (presently at or about 0.05 mg/kg).