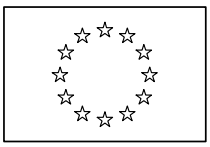

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13.6.2006
COM(2006) 297 final

Proposal for a

COUNCIL DIRECTIVE

amending Council Directive 91/414/EEC to include vinclozolin as active substance

(presented by the Commission)

EXPLANATORY MEMORANDUM

The attached draft proposal for a Council Directive concerns the inclusion under strict conditions of vinclozolin as active substance in the positive list (Annex I) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market.

Council Directive 91/414/EEC creates a harmonised framework for the authorisation and placing on the market of plant protection products. Active substances to be used as plant protection products are assessed and authorised at Community level and are listed in Annex I to the Directive. Individual plant protection products containing active substances are assessed and authorised by Member States under harmonised rules.

The data submitted by industry have been initially evaluated by a rapporteur Member State, in this case France, and afterwards, on the basis of their draft assessment report, by the Commission and all the Member States within the framework of the Standing Committee on the Food Chain and Animal Health.

In view of the hazardous profile of the substance, the conditions of inclusion provide restrictions to those crops that have effectively been considered during the Community evaluation and for which acceptable use may be expected provided highly prescriptive risk mitigation measures are applied.

The draft Directive was submitted on 3 March 2006 to the Standing Committee on the Food Chain and Animal Health.

3 Member States (68 votes) voted in favour,
19 Member States (205 votes) voted against and
3 Member States (48 votes) abstained

The Committee delivered no opinion. Consequently, pursuant to Article 19 of Directive 91/414/EEC and in accordance with Article 5 of Council Decision 1999/468/EC, the Commission is required to submit to the Council a proposal relating to the measures to be taken, the Council having three months in which to act by a qualified majority.

The draft Directive is not subject to the right of scrutiny of the European Parliament (Article 8 of Council Decision 1999/468/EC).

Proposal for a

COUNCIL DIRECTIVE

amending Council Directive 91/414/EEC to include vinclozolin as active substance

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

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], and in particular Article 6(1) thereof,

Whereas:

(1) Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market[2], establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes vinclozolin.

(2) For vinclozolin the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifier. By Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the Rapporteur Member State for the implementation of Commission Regulation (EEC) No 3600/92[3], France was designated as Rapporteur Member State. France submitted the relevant assessment report and recommendations to the Commission on 24 March 1997 in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.

(3) The assessment report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health.

(4) As regards vinclozolin three matters were submitted to the Scientific Committee on Plants ("the Scientific Committee"). The Scientific Committee was asked to comment on whether there was enough scientific evidence to support the assumption that reproductive effects observed in rats would not occur at significantly lower doses in

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1 OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive … (OJ L …, …, p. …).

2 OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 10).

3 OJ L 107, 28.4.1994, p. 8. Regulation as last amended by Regulation (EC) No 2230/95 (OJ L 225, 22.9.1995, p. 1).

humans i.e. that humans might be significantly more sensitive[4]. The Scientific Committee concluded that the results of these studies do not indicate that humans will be affected by such substances at significantly lower doses, i.e. there is no reason to expect that humans would be more sensitive to vinclozolin than rats. Subsequently, the Committee was requested to comment particularly on the possible increased sensitivity of infants and children to these effects. The Committee observed that the effects induced in rats by vinclozolin during the development period are irreversible. This contrasts with the situation in adult animals where the effects have been shown to be reversible. Furthermore, the effects occur at lower doses during development than in adults. In this context, the Committee concludes that the situation in humans would not be expected to be different from that seen in rats. Finally, it was asked whether the reproductive effects of vinclozolin were mediated via an acute or via chronic exposure response. The Committee stated that, in the case of vinclozolin, it is unlikely that a single dose would induce a developmental effect due to the known mode of action of the substance, the fact that humans are not more sensitive than laboratory animal models and the realistic level of a single exposure. The results of the above works permitted the allocation of an Acceptable Daily Intake (ADI).

(5) In a second question, the Scientific Committee considered the appropriate No Observed Effect Concentration (NOEC) of vinclozolin in birds and wild mammals[5]. The Scientific Committee concluded that the possible long-term risk to birds and mammals could not be excluded. As a result it was considered appropriate to impose risk mitigation measures.

(6) Finally, the Scientific Committee was requested to comment on the biological and ecological significance of the effects observed in the fish life-cycle study with fathead minnow[6]. In the latter case the Committee states that the study made available did not measure or attempt to assess reproductive effects in fish. Consequently, additional studies have been provided by the notifier. These were assessed by the Rapporteur who concluded that the active substance and its metabolites may act as weak anti-androgens and consequently a NOEC level has been determined for them. Based on this level and the application of appropriate management measures, it is considered that the long term risk to fish is acceptable.

(7) Consequently, it is concluded that in the above cases, the recommendations from the Scientific Committee have been taken into consideration in formulating this Directive and the relevant review report.

(8) It has appeared from the various examinations made that plant protection products containing vinclozolin may be expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, with regard to the uses which were

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4 Opinion of the scientific Committee on Plants regarding reproductive effects of vinclozolin in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Opinion expressed on 28 October 1999 - SCP/VINCLO/019-Final dd 19.11.1999).

5 Opinion of the scientific Committee on Plants regarding the evaluation of reproductive effects of vinclozolin in te context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Opinion adopted on 17 March 2000 - SCP/VINCLO/021-Final dd 31.3.2000).

6 Opinion of the scientific Committee on Plants on additional questions from the Commission concerning the evaluation of vinclozolin in the context of Council Directive 91/414/EEC (Opinion adopted on 18 July 2002 - SCP/VINCLO-TER/002-Final).

examined and detailed in the Commission review report, provided that adequate risk mitigation measures are applied. As vinclozolin is a hazardous substance, its use should not be unrestricted. In particular there are concerns about its intrinsic toxic effects, including potential endocrine disrupting properties. There is at present no scientific consensus on the exact extent of the risk. Applying the precautionary principle, and taking into account the current state of scientific knowledge, risk mitigation measures should be imposed in order to achieve the high level of protection of human and animal health and the environment chosen in the Community.

(9) Articles 5(4) and 6(1) of Directive 91/414/EC provide that inclusion of a substance in Annex I may be subject to restrictions and conditions. In this case, restrictions on the inclusion period and on the authorised crops are measures deemed necessary. The restriction of the inclusion period means that Member States will give priority to reviewing plant protection products already on the market containing vinclozolin. In order to avoid discrepancies in the high level of protection sought, the inclusion in Annex I to Directive 91/414/EEC should be limited to the uses of vinclozolin that have been actually assessed within the Community evaluation and for which the proposed uses were considered to comply with the conditions of Directive 91/414/EEC. This means that other uses, which were not or only partially covered by this assessment, must first be subject to a complete assessment, before their inclusion in Annex I of Directive 91/414/EEC can be considered. Finally, due to the hazardous nature of vinclozolin, it is necessary to provide for a minimum harmonisation at Community level of certain risk mitigation measures that are to be applied by Member States when granting authorisations.

(10) The risk mitigation measures in this Directive are considered sufficient to limit the risks resulting from the use of the substance to an acceptable level.

(11) Since it appears possible to identify adequate risk mitigation measures, to be applied within well-described situations and under strict conditions, it would be disproportionate to refuse the inclusion of this active substance in Annex I to Directive 91/414/EEC.

(12) Without prejudice to the conclusion that plant protection products containing vinclozolin may be expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, it is appropriate to obtain further information on certain specific points. The potential endocrine disrupting properties of vinclozolin have been assessed in tests which follow the best currently available practice. The Commission is aware that the Organisation for Economic Cooperation and Development (OECD) is developing test guidelines in order to further refine the assessment of potential endocrine disrupting properties. Therefore it is appropriate to require that vinclozolin should be subjected to such further testing as soon as agreed OECD Test Guidelines exist and that such studies should be presented by the notifier. In addition, Member States should require authorisation holders to provide information on the use of vinclozolin including any information on incidences on operator health.

(13) As with all substances included in Annex I to Directive 91/414/EEC, the status of vinclozolin could be reviewed under Article 5(5) of that Directive in the light of any new data becoming available.

(14) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the directives which have been adopted until now amending Annex I.

(15) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

(16) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of 6 months after inclusion to review existing authorisations of plant protection products containing vinclozolin to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC. Given the hazardous properties of vinclozolin, the period for Member States to verify whether plant protection products containing vinclozolin, alone or in combination with other authorised active substances, comply with the provisions of Annex VI should not exceed three years.

(17) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(18) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 30 June 2007 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 July 2007.

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 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing vinclozolin as an active substance by 30 June 2007. By that date they shall in particular verify that the conditions in Annex I to that Directive relating to vinclozolin are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13.

2. By derogation from paragraph 1, for each authorised plant protection product containing vinclozolin, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning vinclozolin. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

   Following that determination Member States shall for products containing vinclozolin, where necessary, amend or withdraw the authorisation by 31 December 2009.

Article 4

This Directive shall enter into force on 1 January 2007.

Article 5

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President

ANNEX

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EEC:

"No	Common Name, Identification Numbers	IUPAC Name	Purity[7]	Entry into force	Expiration of inclusion	Specific provisions
XX	Vinclozolin CAS N° 50471-44-8 CIPAC N°280	(R,S)3-(3,5-dichlorophenyl)-5-methyl-5-vinyl-1,3-oxazolidine-2,4-dione	960 g/kg	1 January 2007	31 December 2013	PART A Only uses as fungicide on the following crops may be authorised: – rape seed – ornamentals – chicory (root treatment) at rates not exceeding – 0,75 kg active substance per hectare per application for rape seed; – 0,25 kg active substance per hectare per application (spray) and 0,5 kg active substance per hectoliter water per application (dip) for ornamentals; – 0,0175 kg active substance per 1000 kg per application (spray on belt), 0,015 kg active substance per 10 m^2 per application (spray on forcing boxes) and 0,06 kg active substance per hectolitre water per application (dip) for chicory. The following uses must not be authorised: – air application;

[7] Further details on identity and specification of active substance are provided in the review report.

"No	Common Name, Identification Numbers	IUPAC Name	Purity[7]	Entry into force	Expiration of inclusion	Specific provisions
						– knapsack and handheld applications by amateur users; – home gardening. Member States shall ensure that all appropriate risk mitigation measures are applied. Particular attention must be paid to the protection of: – aquatic organisms. Where relevant, an appropriate distance must be kept between treated areas and surface water bodies. This distance may depend on whether or not drift reducing techniques or devices are used; – birds and mammals. Conditions of authorisation shall include risk mitigation measures, such as a judicious timing of the application and the selection of those formulations which, as a result of their physical presentation or the presence of agents that ensure an adequate avoidance, minimise the exposure of the concerned species; – operators , who must wear suitable protective clothing, in particular gloves, coveralls, rubber boots and face protection or safety glasses during mixing, loading, application and cleaning of equipment, unless the exposure to the substance is adequately precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment.

"No	Common Name, Identification Numbers	IUPAC Name	Purity[7]	Entry into force	Expiration of inclusion	Specific provisions
						PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on vinclozolin, and in particular Appendices I and II thereof, shall be taken into account. Member States must ensure that the authorisation holders report at the latest on 31 December of each year on incidences of operator health problems. Member States may require that elements, such as sales data and a survey of use patterns, are provided so that a realistic picture of the use conditions and the possible toxicological impact of vinclozolin can be obtained. Member States shall request the submission of further studies to address the potential endocrine disrupting properties of vinclozolin within two years after the adoption of the Test Guidelines on endocrine disruption by the Organisation for Economic Cooperation and Development (OECD). They shall ensure that the notifier at whose request vinclozolin has been included in this Annex provides such studies to the Commission within 2 years of the adoption of the above test guidelines.

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