

Commission Directive 2008/91/EC of 29 September
2008 amending Council Directive 91/414/EEC to include
diuron as active substance (Text with EEA relevance)

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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 Regulations (EC) No 451/2000⁽²⁾ and (EC) No 703/2001⁽³⁾ lay down the detailed rules for the implementation of the second stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish 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 included diuron. By Commission Decision 2007/417/EC⁽⁴⁾ it was decided not to include diuron in Annex I to Directive 91/414/EEC.
- (2) In accordance with Article 6(2) of Directive 91/414/EEC the original notifier submitted on 26 June 2007 a new application to Denmark, which had been designated rapporteur Member State by Regulation (EC) No 451/2000.
- (3) Denmark assessed the information submitted by the notifier and prepared an additional report on 15 November 2007, recommending the inclusion of the substance in Annex I.
- (4) Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I⁽⁵⁾, entered into force on 25 January 2008. In the case of diuron the rapporteur Member State completed the assessment of the additional information submitted by the notifier before the entry into force of that Regulation, taking into account the same criteria as provided for in Article 15 of that Regulation. Given this situation the Commission evaluated the additional report, and where relevant the draft assessment report, and the recommendation by the Member State in accordance with Article 20 of Regulation (EC) No 33/2008.
- (5) The draft review report was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health, and finalised on 11 July 2008 in the format of the Commission review report for diuron. It concentrated

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on the concerns that lead to the non-inclusion. Those were the unacceptable operator exposure, the inconclusive nature of the assessment of a possible risk for groundwater, due to uncertainties as regards the fate of certain metabolites, and the lack of data demonstrating that the risk to birds and mammals is acceptable.

- (6) As set out in that report the instructions by the notifier now require applications to be made with significantly smaller quantities of diuron. As a result, acceptable levels of operator exposure can be demonstrated, some of them linked to the use of protective equipment. As regards the risk to groundwater, the degradation pattern of certain metabolites has been clarified by the notifier and reviewed by the rapporteur Member State which agreed that when applied to the models for groundwater, the trigger value is not exceeded. Finally, on the basis of the refined assessments that have now been submitted by the notifier, the risk to birds and mammals may be considered as acceptable.
- (7) Consequently, the additional data provided by the notifier permit to eliminate the specific concerns that led to the non-inclusion. No other open scientific questions have arisen. Consequently, the consultation of the European Food Safety Authority was not considered necessary.
- (8) It has appeared from the various examinations made that plant protection products containing diuron may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include diuron in Annex I to that Directive, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.
- (9) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (10) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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 bring into force by 31 March 2009 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.

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

This Directive shall enter into force on 1 October 2008.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 29 September 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission

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ANNEX

The following entry 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 ^a	Entry into force	Expiration of inclusion	Specific provisions
'198	Diuron CAS No: 330-54-1 CIPAC No: 100	3-(3,4-dichlorophenyl)-1,1-dimethylurea	≥ 930 g/kg	1 October 2008	30 September 2018	<p>PART A Only uses as herbicide at rates not exceeding 0,5 kg/ha (areic average) may be authorised.</p> <p>PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on diuron, and in particular Appendices I and II thereof,</p>

^a Further details on identity and specification of active substance are provided in the review report.

						<p>as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none">— the operator safety where conditions of use shall prescribe the use of personal protective equipment, if appropriate,— the protection of aquatic organisms
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a Further details on identity and specification of active substance are provided in the review report.

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						and non-target plants. Conditions of authorisation shall include risk mitigation measures, where appropriate.’
a	Further details on identity and specification of active substance are provided in the review report.					

- (1) OJ L 230, 19.8.1991, p. 1.
- (2) OJ L 55, 29.2.2000, p. 25.
- (3) OJ L 98, 7.4.2001, p. 6.
- (4) OJ L 156, 16.6.2007, p. 32.
- (5) OJ L 15, 18.1.2008, p. 5.