Commission Directive 2008/108/EC of 26 November 2008 amending Council Directive 91/414/EEC to include flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat as active substances (Text with EEA relevance)

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(Text with EEA relevance)

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 1490/2002[(3)] lay down the detailed rules for the implementation of the third 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 includes flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat.

(2) For those active substances the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 451/2000 and (EC) No 1490/2002 for a range of uses proposed by the notifiers. Moreover, those Regulations designate the rapporteur Member States which have to submit the relevant assessment reports and recommendations to the European Food Safety Authority (EFSA) in accordance with Article 10(1) of Regulation (EC) No 1490/2002. For flutolanil the rapporteur Member State was Finland and all relevant information was submitted on 13 June 2005. For benfluralin the rapporteur Member State was Belgium and all relevant information was submitted on 16 February 2006. For fluazinam the rapporteur Member State was Austria and all relevant information was submitted on 3 January 2006. For fuberidazole and mepiquat the rapporteur Member State was the United Kingdom and all relevant information was submitted on 5 April 2005.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 3 March 2008 for flutolanil and benfluralin, on 26 March 2008 for fluazinam, on 14 November 2007 for fuberidazole and on 14 April 2008 for mepiquat in the format of the EFSA Scientific Reports[(4)]. These reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 20 May 2008 in the format of

the Commission review reports for flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat.

(4) It has appeared from the various examinations made that plant protection products containing flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat 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 reports. It is therefore appropriate to include these active substances in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances can be granted in accordance with the provisions of that Directive.

(5) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore it is appropriate to require that benfluralin should be subject to further testing for confirmation of the risk assessment for consumers and for aquatic organisms and that fluazinam should be subject to further testing for confirmation of the risk assessment for aquatic organisms and soil macro-organisms and such studies should be presented by the notifiers.

(6) 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.

(7) 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 six months after inclusion to review existing authorisations of plant protection products containing flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat 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 way of 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.

(8) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92[(5)] 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.

(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 adopt and publish by 31 August 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.

They shall apply those provisions from 1 September 2009.

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 flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat as active substances by 31 August 2009.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat 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 of that Directive.

2 By way of derogation from paragraph 1, for each authorised plant protection product containing flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 28 February 2009 at the latest, 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 flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat respectively. 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:

a in the case of a product containing flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat as the only active substance, where necessary, amend or withdraw the authorisation by 28 February 2013 at the latest; or

b in the case of a product containing flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat as one of several active substances, where necessary, amend or withdraw the authorisation by 28 February 2013 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 4

This Directive shall enter into force on 1 March 2009.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 26 November 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission

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
‘193	Flutolanil CAS No 66332-96-5 CIPAC No 524	α,α,α-trifluoro-3′-isopropoxy-o-toluanilide	≥ 975 g/kg	1 March 2009	28 February 2019	PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing flutolanil for uses other than potato tuber treatment, Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any

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

						necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flutolanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection

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						of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate.
194	Benfluralin CAS No 1861-40-1 CIPAC No 285	N-butyl-N-ethyl-α,α,α-trifluoro-2,6-dinitro-p-toluidine	≥ 960 g/kg Impurities: — ethyl-butyl-nitrosamine: max. 0,1 mg/kg	1 March 2009	28 February 2019	PART A Only uses as herbicide may be authorised. PART B In assessing applications to authorise plant protection products containing benfluralin for uses other than lettuce and endive,

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

						Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on benfluralin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food

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

						Chain and Animal Health on 20 May 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of the operators' safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the residues in food of plant and animal origin

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

						— and evaluate the dietary exposure of consumers, the protection of birds, mammals, surface waters and aquatic organisms. In relation to these identified risks, risk mitigation measures, such as buffer zones, should be applied where appropriate. The Member States concerned shall request the submission of further studies on rotational crops metabolism and to confirm the risk assessment for

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						metabolite B12 and for aquatic organisms. They shall ensure that the notifiers at whose request benfluralin has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
195	Fluazinam CAS No 79622-59-6 CIPAC No 521	3-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-2, 6-dinitro-p-toluidine	≥ 960 g/kg Impurities: 5-chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-*o*-toluidine — not more than 2 g/kg	1 March 2009	28 February 2019	PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing fluazinam for uses other than potatoes, Member States shall pay

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

						particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fluazinam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20

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

						May 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of the operators' and workers' safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the residues in food of plant and animal origin and evaluate

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

						— the dietary exposure of consumers, — the protection of aquatic organisms. In relation to this identified risk, risk mitigation measures, such as buffer zones, should be applied where appropriate. The Member States concerned shall request the submission of further studies to confirm the risk assessment for aquatic organisms and soil macro-organisms. They shall ensure that the notifiers at whose request fluazinam has been

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

						included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
196	Fuberidazole CAS No 3878-19-1 CIPAC No 525	2-(2′-furyl)benzimidazole	≥ 970 g/kg	1 March 2009	28 February 2019	PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing fuberidazole for uses other than seed dressing, Member States shall pay particular attention to the criteria in Article 4(1)(b), and

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						shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fuberidazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 shall be taken into account. In this overall assessment Member States must pay

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						particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — long-term risk to mammals and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. In such case the use of adequate equipment ensuring a high degree of incorporation

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						in soil and a minimisation of spillage during application should apply. Conditions of use shall include adequate risk mitigation measures, where appropriate.
197	Mepiquat CAS No 15302-91-7 CIPAC No 440	1,1-dimethylpiperidinium chloride (mepiquat chloride)	≥ 990 g/kg	1 March 2009	28 February 2019	PART A Only uses as plant growth regulator may be authorised. PART B In assessing applications to authorise plant protection products containing mepiquat for uses other than in barley, Member States shall pay particular

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

						attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mepiquat, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008

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

						shall be taken into account. The Member States must pay particular attention to the residues in food of plant and animal origin and evaluate the dietary exposure of consumers.’

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 224, 21.8.2002, p. 23.

(**4**) *EFSA Scientific Report (2008) 126.* Conclusion regarding the peer review of the pesticide risk assessment of the active substance flutolanil (finalised 3 March 2008).
EFSA Scientific Report (2008) 127. Conclusion regarding the peer review of the pesticide risk assessment of the active substance benfluralin (finalised 3 March 2008).
EFSA Scientific Report (2008) 137. Conclusion regarding the peer review of the pesticide risk assessment of the active substance fluazinam (finalised 26 March 2008).
EFSA Scientific Report (2008) 118. Conclusion regarding the peer review of the pesticide risk assessment of the active substance fuberidazole (finalised 14 November 2007).
EFSA Scientific Report (2008) 146. Conclusion regarding the peer review of the pesticide risk assessment of the active substance mepiquat (finalised on 14 April 2008).

(**5**) OJ L 366, 15.12.1992, p. 10.