COMMISSION DIRECTIVE 2011/34/EU of 8 March 2011
amending Council Directive 91/414/EEC to include flurochloridone as active substance and
amending Commission Decision 2008/934/EC
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 included flurochloridone.


(3) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter the applicant) submitted a new application requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of 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).

(4) The application was submitted to Spain, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2008/934/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(5) Spain evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter ‘the Authority’) and to the Commission on 3 November 2009. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on flurochloridone to the Commission on 14 October 2010 (6). The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 4 February 2011 in the format of the Commission review report for flurochloridone.

(6) It has appeared from the various examinations made that plant protection products containing flurochloridone 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 have been examined and detailed in the Commission review report. It is therefore appropriate to include flurochloridone in Annex I, 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.

(7) 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 the applicant submit further information confirming: the relevance of impurities other than toluene, the compliance of ecotoxicological test material with the technical specifications, the relevance of the groundwater metabolite R42819 (7) and the potential endocrine disrupting properties of flurochloridone.


(9) R42819: (4RS)-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl] pyrrolidin-2-one.
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
The line concerning flurochloridone in the Annex to Decision 2008/934/EC is deleted.

Article 3
Member States shall adopt and publish by 30 November 2011 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 December 2011.

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 4
1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing flurochloridone as an active substance by 30 November 2011.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to flurochloridone 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 flurochloridone 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, where necessary, amend or withdraw existing authorisations for plant protection products containing flurochloridone as an active substance by 30 November 2011.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to flurochloridone 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.

Following that determination Member States shall:

(a) in the case of a product containing flurochloridone as the only active substance, where necessary, amend or withdraw the authorisation by 31 May 2015 at the latest; or

(b) in the case of a product containing flurochloridone as one of several active substances, where necessary, amend or withdraw the authorisation by 31 May 2015 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 5
This Directive shall enter into force on 1 June 2011.

Article 6
This Directive is addressed to the Member States.

Done at Brussels, 8 March 2011.

For the Commission
The President
José Manuel BARROSO
The following entry shall be added at the end of the table in Annex I to Directive 91/414/EEC:

<table>
<thead>
<tr>
<th>No</th>
<th>Common Name, Identification Numbers</th>
<th>IUPAC Name</th>
<th>Purity (*)</th>
<th>Entry into force</th>
<th>Expiration of inclusion</th>
<th>Specific provisions</th>
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</thead>
<tbody>
<tr>
<td>'342</td>
<td>Flurochloridone CAS No: 61213-25-0 CIPAC No: 430</td>
<td>(3RS,4RS;3RS,4SR)-3-chloro-4-chloro-methyl-1-(a,a,a-trifluoro-m-tolyl)-2-pyrrolidone</td>
<td>≥ 940 g/kg. Relevant impurities: Toluene: max 8 g/kg</td>
<td>1 June 2011</td>
<td>31 May 2021</td>
<td>PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flurochloridone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 February 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: 1. the risk for non-target plants and aquatic organisms; 2. the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the applicant submits to the Commission further confirmatory information as regards: 1. the relevance of impurities other than toluene; 2. the compliance of ecotoxicological test material with the technical specifications; 3. the relevance of the groundwater metabolite R42819 (R42819: (4RS)-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl]pyrroldin-2-one); 4. the potential endocrine disrupting properties of flurochloridone. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1) and (2) by 1 December 2011, the information set out in point (3) by 31 May 2013 and the information set out in point (4) within 2 years after the adoption of the OECD test guidelines on endocrine disruption. (*) Further details on identity and specification of active substance are provided in the review report.</td>
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