



EUROPEAN COMMISSION  
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain  
Unit E.3 - Chemicals, contaminants and pesticides

Haloxyfop-P  
SANCO/12648/2010 final  
28 October 2010

Review report for the active substance **haloxyfop-P**  
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on  
28 October 2010  
in view of the inclusion of haloxyfop-P in Annex I of Directive 91/414/EEC

## 1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of haloxyfop-P, made in the context of a new application by the data submitter after the non-inclusion of this substance. It is noted that the name "haloxyfop-R" which is commonly used but has no official status, has been modified to "haloxyfop-P", the agreed ISO name of the substance.

Haloxyfop-P is a substance that was covered by the second stage of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

At the outcome of that evaluation, haloxyfop-P was not included through Commission Decision 2007/437/EC<sup>1</sup> as, on the basis of the available information, it had not been demonstrated that the risk to groundwater, consumers, mammals and aquatic organisms in particular was acceptable. All information as regards this initial evaluation is recorded in the relevant Commission Review Report (document SANCO/10036/2006 final of 17 October 2006).

In accordance with Article 13 of Regulation (EC) No 33/2008, Dow Agro Sciences, the sole data submitter presented on 4 July 2007 a request to Denmark, the original rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

Denmark finalised in April 2009 its examination, in the form of an additional report to the original Draft Assessment Report. This Report was received by the Commission and the European Food Safety Authority on 3 April 2009.

In accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Dow Agro Science being the sole data submitter, on 8 April 2009 by making it available.

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<sup>1</sup> OJ No L 163, 23.6.2007, p. 22.

The EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review).

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008 the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance haloxyfop-P (re-issued on 9 October 2009)<sup>2</sup>]. This conclusion refers to background document A (draft assessment report and additional report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 21 of Regulation (EC) No 33/2008, the Commission referred a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 28 October 2010.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), these documents are also considered to be part of this review report.

## **2. Purposes of this review report**

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Directive **2010/86/EU**<sup>3</sup> concerning the inclusion of haloxyfop-P in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing haloxyfop-P they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 22 of Regulation (EC) No 33/2008, this review report will be made available for public consultation by any interested parties.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

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<sup>2</sup> *EFSA Scientific Report (2009) 7(10); 1348 – Conclusion on Pesticide peer review – Peer review of the pesticide risk assessment of the active substance haloxyfop-P (issued on 9 October 2009).*

<sup>3</sup> OJ L 317, 3.12.2010, p. 36–38

### **3. Overall conclusion in the context of Directive 91/414/EEC**

The overall conclusion from the evaluation is that it may be expected that plant protection products containing haloxyfop-P will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each haloxyfop-P containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

The following reference values have been finalised as part of this re-evaluation:

ADI	0.00065 mg/kg bw/day
ARfD	0.075 mg/kg bw
AOEL	0.005 mg/kg bw/day

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 52 % of the Acceptable Daily Intake (ADI), (WHO diet). Additional intake from water is not expected to give rise to intake problems.

Estimates of acute dietary exposure of adults and children revealed that the Acute Reference Dose (ARfD) would not be exceeded (according to the UK model: 9% children)

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC.

### **4. Identity**

The main identity of haloxyfop-P is given in Appendix I.

No FAO specifications exist at the time the current report is drafted.

The review has established that for the active substance notified by the data submitter none of the manufacturing impurities are, on the basis of information currently available, of toxicological or environmental concern.

## **5. Endpoints and related information**

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA, and at section 3 of this report.

## **6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing haloxyfop-P**

On the basis of the proposed and supported uses (as listed in Appendix II), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted:

Member States should pay particular attention to:

- operator safety: conditions of use shall prescribe the use of adequate personal protective equipment;
- protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones;
- consumer safety in those conditions where it may be expected that the occurrence in groundwater of metabolites DE-535 pyridinol and DE-535 pyridinone would exceed the trigger value of 0.75 µg/l.

Where appropriate, conditions of authorisation shall include further risk mitigation measures.

## **7. List of studies to be generated**

No further studies were identified which were at this stage considered necessary in relation to the inclusion of haloxyfop-P in Annex I under the current inclusion conditions.

However, the concerned Member States shall request the submission of further information to confirm the groundwater exposure assessment as regards the parent substance and its soil metabolites DE-535 phenol, DEZ-535 pyridinol and DE-535 pyridinone.

Some other endpoints may require the generation or submission of additional data to be submitted to the Member States in order to ensure authorisations for use under certain conditions.

## **8. Information on studies with claimed data protection**

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

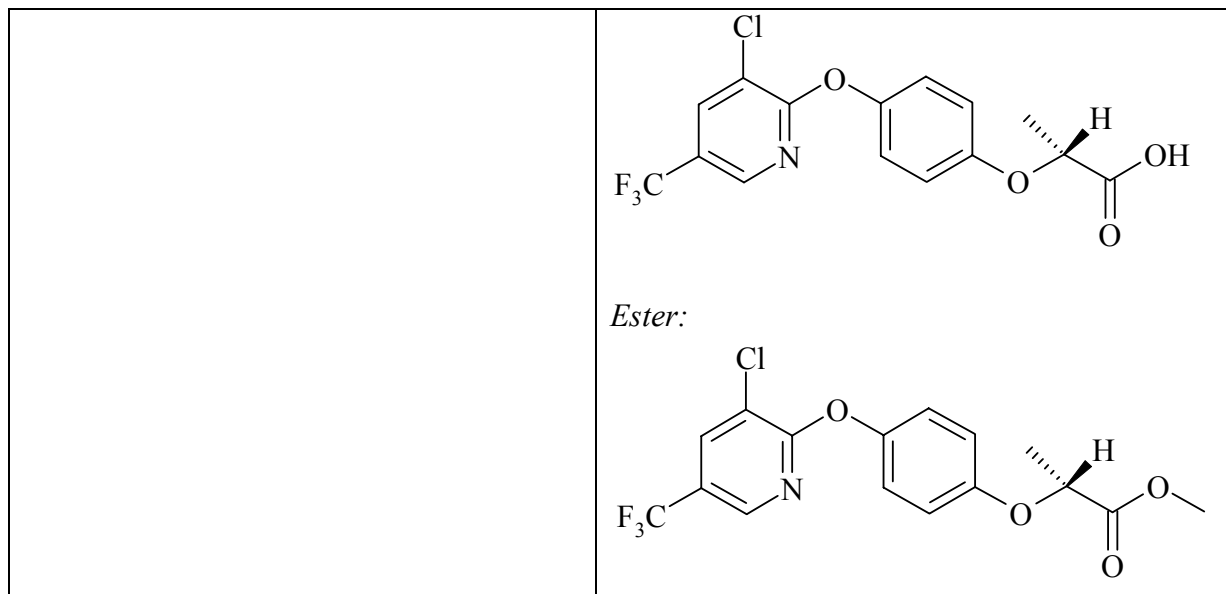
## **9. Updating of this review report**

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for haloxyfop-P in Annex I of the Directive.

## APPENDIX I

Identity  
HALOXYFOP-P

<b>Common name (ISO)</b>	Acid: haloxypop-P. The synonym haloxypop-R is of common use but has no official status. <i>Ester: haloxypop-P-methyl ester. The synonym haloxypop-R-methyl ester is of common use but has no official status</i>
<b>Chemical name (IUPAC)</b>	Acid: (R)-2-[4-(3-chloro-5-trifluoromethyl-2-pyridyloxy)phenoxy]propanoic acid <i>Ester: Methyl (R)-2-[4-(3-chloro-5-trifluoromethyl-2-pyridyloxy)phenoxy]propanoic acid</i>
<b>Chemical name (CA)</b>	Acid: R-(+)- 2-[4-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid <i>Ester: R-(+)-methyl-2-[4-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid</i>
<b>CIPAC No</b>	Acid: 526 <i>Ester: 526.201</i>
<b>CAS No</b>	Acid: 95977-29-0 <i>Ester: 72619-32-0</i>
<b>EEC No</b>	Acid: not applicable <i>Ester: 406-250-0</i>
<b>FAO SPECIFICATION</b>	Acid: none <i>Ester: none</i>
<b>Minimum purity</b>	940g/kg ( <i>content of haloxypop-P-methyl ester</i> )
<b>Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)</b>	<i>No relevant impurities</i>
<b>Molecular formula</b>	Acid: C <sub>15</sub> H <sub>11</sub> ClF <sub>3</sub> NO <sub>4</sub> <i>Ester: C<sub>16</sub>H<sub>13</sub>ClF<sub>3</sub>NO<sub>4</sub></i>
<b>Molecular mass</b>	Acid: 361.7 <i>Ester: 375.7</i>
<b>Structural formula</b>	Acid



## APPENDIX II

### List of uses supported by available data HALOXYFOP-P

Crop and/or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
					Type	Conc. of a.s.	Method kind	growth stage & season	number min max	interval between applications (min)	kg a.s./hl min max	water L/ha min max	kg a.s./ha min max		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)				(l)	(m)	
Carrots VR 0577	S	Gallant Winner (EF-1400)	F	Grasses	EC	104	Mechanical sprayer, broadcast	BBCH 14-46 (Apr-Sep)	1	N/A	0.013-0.0415	200-400	0.052-0.083	30	
Carrots VR 0577	N	Gallant Super (EF-1400)	F	Grasses	EC	104	Mechanical sprayer, broadcast	BBCH 14-50 (Apr-Sep)	1	N/A	0.013-0.0415	200-400	0.052-0.083	56	
Fodder Legumes (Beans, peas dry) VD 0071 VD 0072	N	Gallant Super (EF-1400)	F	Grasses	EC	104	Mechanical sprayer, broadcast	BBCH 13-49 (Apr-Jun)	1	N/A	0.013-0.0415	200-400	0.052-0.083	90	
Rapeseed SO 0495	N	Eloge (EF-1400)	F	Grasses	EC	104	Mechanical sprayer, broadcast	BBCH 12-35 (Sep-Oct)	1	N/A	0.013-0.052	200-400	0.052-0.104	N/S	Autumn application only

Crop and/or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
					Type	Conc. of a.s.	Method kind	growth stage & season	number min max	interval between applications (min)	kg a.s./hl min max	water L/ha min max	kg a.s./ha min max		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)				(l)	(m)	
Soya bean VD 0541	S	Gallant Winner (EF-1400)	F	Grasses	EC	104	Mechanical sprayer, broadcast	BBCH 19-33 (Apr-May)	1	N/A	0.013-0.0415	200-400	0.052-0.083	90	
Sugar beet	N	Gallant Super (EF-1400)	F	grasses	EC	104	Mechanical sprayer, broadcast	BBCH 10-39 (Apr-Jun)	1	N/A	0.013-0.0415	200-400	0.052-0.083	90	
Sugar beet	S	Gallant S (EF-1400)	F	grasses	EC	104	Mechanical sprayer, broadcast	BBCH 10-39 (Mar-May)	1	N/A	0.013-0.0415	200-400	0.052-0.083	90	

<b>Remarks:</b>	*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, <i>e.g.</i> overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described ( <i>e.g.</i> fumigation of a structure)	(i)	g/kg or g/L
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(j)	Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	(c)	<i>e.g.</i> biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	<i>e.g.</i> wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
	(f)	Method, <i>e.g.</i> high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
	(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions