



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Imazaquin

SANCO/832/08 – rev. 2

07 March 2008

**COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT  
THE VIEWS OF THE COMMISSION SERVICES**

Review report for the active substance **imazaquin**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on  
14 March 2008

in view of the inclusion of imazaquin 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 imazaquin, made in the context 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.

Commission Regulation (EC) No 451/2000<sup>(1)</sup> laying down the detailed rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1490/2002<sup>(2)</sup>, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Imazaquin is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EC) No 451/2000, BASF Agro BV notified to the Commission of their wish to secure the inclusion of the active substance imazaquin in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EC) No 451/2000, the Commission, designated Belgium as rapporteur Member State to carry out the assessment of imazaquin on the basis of the dossiers submitted by the notifier. In Regulation (EC) No 1490/2002 the Commission specified furthermore that the deadline for the notifier with regard to the submission to the rapporteur Member States of the dossiers required under Article 7(2) of

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<sup>1</sup> OJ No L 55, 29.02.2000, p.25.

<sup>2</sup> OJ No L 224, 21.8.2002, p.23. Regulation as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.09.2007, p. 19).

Regulation (EC) No 1490/2002, as well as for other parties with regard to further technical and scientific information was 30 November 2004.

BASF Agro BV submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore BASF Agro BV was considered to be the sole data submitter.

In accordance with the provisions of Article 10(1) of Regulation (EC) No 1490/2002, Belgium submitted on 20 December 2007 to the EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of imazaquin in Annex I to the Directive. Moreover, in accordance with the provisions of Article 10(2) of Regulation (EC) 1490/2002, the Commission and the Member States received also the summary dossier on imazaquin from the notifier.

In accordance with the provisions of Article 11 of Regulation (EC) No 1490/2002 as last amended by Regulation (EC) 1095/2007, the EFSA organised the consultation whether imazaquin fulfills the criteria of Annex V of Regulation (EC) 1095/2007 by all the Member States on 21 January 2008 by making the draft assessment report available.

In accordance with the provisions of Article 11a of Regulation 1490/2002 as last amended by Regulation (EC) 1095/2007 the Commission examined the draft assessment report, the recommendations by the rapporteur Member State and the comments received from other Member States in consultation with experts from a certain number of Member States.

In accordance with the provisions of Article 11b and Article 12 (1) a of Regulation (EC) No 1490/2002 as last amended by Regulation (EC) 1095/2007, the Commission referred on 14 March 2008 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 14 March 2008.

The present review report contains the conclusions of the final examination by the Standing Committee.

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

This review report, including the background document appendices thereto, has been developed in support of the Directive **2008/69/EC**<sup>3</sup> concerning the inclusion of imazaquin in Annex I to Directive 91/414/EEC. The Commission shall request the EFSA to deliver its view on the draft review reports by 31 December 2010 at the latest. When the Member States decide on individual plant protection products containing imazaquin they shall take into account this review report 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. However, when the EFSA has delivered its view on the draft review report, the Commission shall revise it.

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.

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<sup>3</sup> Commission Directive 2008/69/EC (OJ L 172, 02.07.2008, p. 9)

In accordance with the provisions of Article 13 of Regulation (EC) No 1490/2002, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request.

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.

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

The overall conclusion from the draft assessment report, the recommendations by the rapporteur Member State and the result of the examination in accordance with the provisions of Article 11a of Regulation 1490/2002 is that there are clear indications that it may be expected that imazaquin does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, as set out in Annex V of regulation (EC) 1490/2002 2002 as last amended by Regulation (EC) 1095/2007.

These indications are however subject to compliance with the particular requirements in sections 4 and 5 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 imazaquin containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these indications were reached within the framework of the uses which were proposed and supported by the main 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 proposed by the rapporteur Member State:

ADI: 0.25 mg/kg bw/day

ArfD was not allocated.

AOEL: 0.25 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 0.065 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994).

Additional intake from water and products of animal origin are not expected to give rise to intake problems.

Exceedance of the Acute Reference Dose (ARfD) for estimates of acute dietary exposure of adults and toddlers was not calculated as no ARfD was allocated. 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.

It has also been 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, provided that certain conditions are taken into account as detailed in section 6 of this report.

#### **4. Identity**

The identity of imazaquin is given in Appendix I.

As there is no FAO specification, the active substance shall comply with the specification of minimum purity that is given in Appendix I of this report.

It has been established that for the active substance notified by the main data submitter none of the manufacturing impurities considered 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 volume1, page 37 of the DAR and at section 3 of this report. The EFSA will deliver its view on this review report by 31 December 2010 at the latest.

#### **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 imazaquin**

On the basis of the proposed and supported uses (as listed in Appendix II), no 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, varied or withdrawn, as appropriate.

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

Further studies which were at this stage considered necessary were identified in the level 4 of the Draft Assessment Report.

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

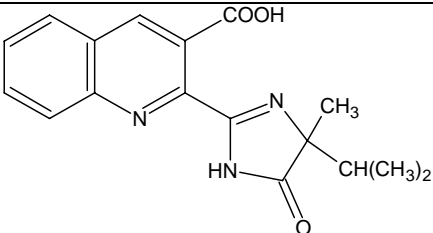
For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential

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 imazaquin in Annex I of the Directive.

**APPENDIX I****Identity****IMAZAQUIN**

<b>Common name (ISO)</b>	Imazaquin
<b>Chemical name (IUPAC)</b>	2-[( <i>RS</i> )-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]quinoline-3-carboxylic acid
<b>Chemical name (CA)</b>	(±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3-quinolinecarboxylic acid
<b>CIPAC No</b>	699
<b>CAS No</b>	81335-37-7
<b>EEC No</b>	none
<b>FAO SPECIFICATION</b>	No FAO specification at time of evaluation
<b>Minimum purity</b>	960 g/kg (racemic mixture)
<b>Molecular formula</b>	C <sub>17</sub> H <sub>17</sub> N <sub>3</sub> O <sub>3</sub>
<b>Molecular mass</b>	311.34 g/mol
<b>Structural formula</b>	

## APPENDIX II

## List of uses supported by available data

## IMAZAQUIN

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Winter wheat Winter barley	EU	Meteor (BAS 114 02 W)	F	Plant growth regulator (prevents lodging)	SL	0.8 g/L <sup>4</sup>	Tractor mounted spray	Leaf sheath lengthening to 1 <sup>st</sup> node detectable  (BBCH 30-32)	1	NA	1 - 0.67	200-300	2	Not relevant <sup>2</sup>	

<sup>3</sup> 0.8 g/L of imazaquin and 368 g/L chlormequat chloride, <sup>2</sup>Last growth stage for application before BBCH 32

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
  - (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
  - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
  - (f) All abbreviations used must be explained
  - (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
  - (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
  - (i) g/kg or g/l
  - (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
  - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
  - (l) PHI - minimum pre-harvest interval
  - (m) Remarks may include: Extent of use/economic importance/restrictions

