



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Paclobutrazol
SANCO/10382/2011 final
11 March 2011

Review report for the active substance **paclobutrazol**
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
11 March 2011
in view of the inclusion of paclobutrazol 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 paclobutrazol, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Paclobutrazol is a substance that was covered by the third 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 market¹, with a view to the possible inclusion of this substance in Annex I to the Directive.

Article 11(e) of Commission Regulation (EC) No 1490/2002² laying down detailed rules for the implementation of the third stage of the work programme offered the possibility for the notifier to withdraw, under specific conditions, its support for the active substance. All notifiers withdrew their support and paclobutrazol was not included through Commission Decision 2008/934/EC³.

In accordance with Article 13 of Regulation (EC) No 33/2008⁴, Syngenta Crop Protection, the sole data submitter presented, on 22 May 2009 a request to the United Kingdom, the designated rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

The United Kingdom finalised in November 2009 its examination, in the form of an additional report to the original Draft Assessment Report. This Report was sent to the Commission and the European Food Safety Authority on 20 November 2009 and included a recommendation as to include paclobutrazol in Annex I for the supported uses.

¹ O.J. No L 230, 19.8.1991, p1.

² O.J. No L 224, 21.8.2002, p. 23.

³ OJ No L 263, 2.10.2008, p.18.

⁴ OJ No L 252, 20.9.2008, p. 37.

The EFSA organised the consultation on the draft assessment report and, in accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, on the additional report by all the Member States as well as by Syngenta Crop Protection, being the sole data submitter, on 11 January 2010 by making it available.

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008, the Commission asked EFSA to organise a focused consultation of scientific experts from a certain number of Member States, to review the additional report, draft assessment report and the comments received thereon (peer review) and to deliver its conclusion.

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 of the active substance paclobutrazol⁵. 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 11 March 2011.

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 2011/55/EU**⁶ concerning the inclusion of paclobutrazol in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing paclobutrazol 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

⁵ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance paclobutrazol. EFSA Journal 2010;8(11):1876. [60 pp.] doi:10.2903/j.efsa.2010.1876. Available online: www.efsa.europa.eu/efsajournal.htm

⁶ OJ L 106, 27.4.2011, p. 5–8

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 evaluation is that it may be expected that plant protection products containing paclobutrazol 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 paclobutrazol 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	0.022 mg/kg bw/day
ARfD	0.1 mg/kg bw
AOEL	0.1 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) is lower than 0.03 % of the Acceptable Daily Intake (ADI), (calculated according to EFSA PRIMo rev 2 model). 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 consumption data <0.1% for UK diets).

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 paclobutrazol is given in Appendix I.

At the time of the evaluation no FAO specification was allocated.

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 paclobutrazol

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

Member States shall pay particular attention to the risk to aquatic plants.

Conditions of use shall include risk mitigation measures, where appropriate.

7. List of studies to be generated

Further studies were identified which were at this stage considered necessary in relation to the inclusion of paclobutrazol in Annex I under the current inclusion conditions.

The Member States concerned shall request the submission of confirmatory information, as regards, the specification of the technical material as commercially manufactured, the analytical methods in soil and surface water for the metabolite NOA457654, the residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin, the potential endocrine disrupting properties of paclobutrazol and the potential adverse effects of breakdown products of the different optical structures of paclobutrazol and its metabolite CGA 149907 on the environmental compartments soil, water and air.

Some other endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. The list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusions.

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

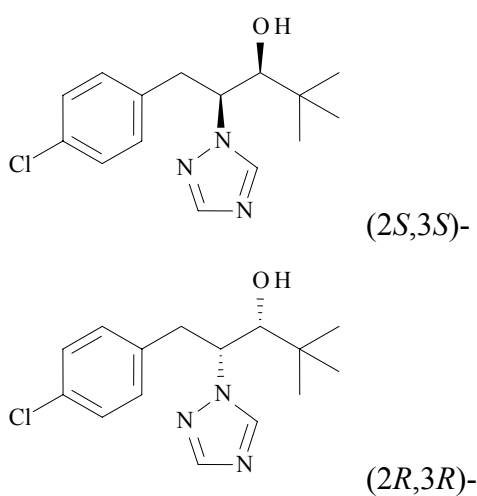
operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

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 paclobutrazol in Annex I of the Directive.

APPENDIX I

Identity
PACLOBUTRAZOL

Common name (ISO)	Paclobutrazol
Chemical name (IUPAC)	<i>(2R,3R)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pentan-3-ol</i>
Chemical name (CA)	<i>(αR,βR)-rel-β-[(4-chlorophenyl)methyl]-α-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol</i>
CIPAC No	445
CAS No	76738-62-0
EEC No	266-325-7
FAO SPECIFICATION	No specification exists at the time of evaluation
Minimum purity	930 g/kg (dry weight basis) 750 g/kg (wet paste) [1:1 ratio of (2S,3S)- and (2R,3R)- enantiomers] open
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)	None
Molecular formula	$C_{15}H_{20}ClN_3O$
Molecular mass	293.8 g/mol
Structural formula	 <p>(2S,3S)-</p> <p>(2R,3R)-</p>

APPENDIX II
List of uses supported by available data
PACLOBUTRAZOL

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	g as/ha min max		
Winter oilseed rape	North and South EU	'Toprex'	F	plant growth regulator	SC	125 g/l paclobutrazol + 250 g/l difenoconazole	Foliar spray	BBCH 16-18 (sept-oct) and 31-51 (feb-mar)	2 1) 1 app in autumn and 2) 1 app in spring.	3 months		200-300	37.5 paclobutrazol 75 difenoconazole and 62.5 paclobutrazol 125 difenoconazole	see appl stage	[1], [2], [3].

[1] The contribution of the residues of the triazole derivative metabolites (TDM) present in primary crops, rotational crops and products of animal origin, to the overall consumer exposure was not considered.

[2] The risk assessment for aquatic organisms was not finalised for geoclimatic situations represented by the FOCUS_{sw} scenarios D2, D3, D4, R1, R2 and R3. A critical areas of concern was identified due to a high-risk to aquatic organisms was identified from paclobutrazol and CGA149907 with a worst case assumption regarding the toxicity and exposure pattern of the enantiomers.

[3] The potential endocrine disruption properties of paclobutrazol could not be finalised based on the available data.

- 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