



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Napropamide
SANCO/12647/2010 final
28 October 2010

Review report for the active substance **napropamide**
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 napropamide 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 napropamide, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Napropamide is a substance that was covered by the third stage of the work programme for review of existing active substances regulated by Commission Regulation (EC) No 451/2000⁽¹⁾ 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⁽²⁾.

At the outcome of that evaluation, napropamide was not included through Commission Decision 2008/902/EC³ as, on the basis of the available information, it had not been demonstrated that the risk to groundwater, aquatic organisms, mammals and fish eating birds, was acceptable. All information as regards this initial evaluation is recorded in the relevant Commission Review Report (document SANCO/112/08 final of 20 May 2008).

In accordance with Article 13 of Regulation (EC) No 33/2008, United Phosphorus, the sole data submitter presented, on 18 December 2008 a request to Denmark, the original rapporteur Member State.

Denmark finalised in June 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 29 June 2009.

¹ OJ No L 55, 29.02.2000, p.25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p.32).

² 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).

³ OJ No L 326, 4.12.2008, p. 35.

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 United Phosphorus being the sole data submitter, on 30 June 2009 by making it available.

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 napropamide (re-issued on 29 April 2010)⁴]. 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 **2010/83/EU**⁵ concerning the inclusion of napropamide in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing napropamide 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

⁴ *EFSA Scientific Report (2010)8(4) – Conclusion on Pesticide peer review – Peer review of the pesticide risk assessment of the active substance napropamide (re-issued on 29 April 2010).*

⁵ OJ L 315, 1.12.2010, p. 29–31

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 napropamide 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 napropamide 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	0.3 mg/kg bw/day
ARfD	not allocated, not necessary
AOEL	0.5 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 70 kg adult is <0.1 % of the Acceptable Daily Intake (ADI), (WHO diet). Additional intake from water is not expected to give rise to intake problems.

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 napropamide is given in Appendix I.

There were no FAO specifications at the moment this report was drafted.

The review has established that for the active substance notified the manufacturing impurity toluene is considered to be of toxicological concern and a maximum level of 1.4 g/kg is established.

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 napropamide

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, where necessary;
- protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones;
- consumer safety where it may be expected that the occurrence in groundwater for NOPA 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 napropamide in Annex I under the current inclusion conditions.

However, the concerned Member States shall request the submission of further information to confirm the surface water exposure assessment as regards the photolysis metabolites and the metabolite NOPA and information concerning the risk assessment for aquatic plants.

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

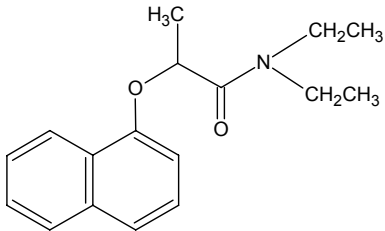
For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a

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 napropamide in Annex I of the Directive.

APPENDIX I**Identity
NAPROPAMIDE**

Common name (ISO)	Napropamide
Chemical name (IUPAC)	(<i>RS</i>)- <i>N,N</i> -diethyl-2-(1-naphthyloxy)propionamide
Chemical name (CA)	<i>N,N</i> -diethyl-2-(1-naphthalenyloxy)propanamide
CIPAC No	271
CAS No	15299-99-7
EEC No	Not allocated
FAO SPECIFICATION	<i>None</i>
Minimum purity	930 g/kg (racemic mixture)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)	max. 1.4 g/kg toluene
Molecular formula	C ₁₇ H ₂₁ NO ₂
Molecular mass	271.36 g/mol
Structural formula	

APPENDIX II
List of uses supported by available data
NAPROPAMIDE

Crop and/or situation (a)	Member State, Country or Region	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					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 (l) min – max	water L/ha min – max	kg as/ha (l) min – max		
Head cabbage	EU, North	Devrinol SC, 450	F	Annual grasses and broad-leaved weeds	SC	450g/l	Application to soil surface, followed by soil incorporation into the top 5-8 cm preplanting and cultivation over 20 cm following harvest	Before sowing/ planting	1	Not applicable	0.5	200	1.0	Not applicable.	
Brussels sprouts	EU, North	Devrinol SC, 450	F	Annual grasses and broad-leaved weeds	SC	450g/l	Application to soil surface, followed by soil incorporation into the top 5-8 cm preplanting and cultivation over 20 cm following harvest	Before sowing/ Planting	1	Not applicable	0.5	200	1.0	Not applicable	
Cauliflower	EU, North	Devrinol SC, 450	F	Annual grasses and broad-leaved weeds	SC	450g/l	Application to soil surface, followed by soil incorporation into the top 5-8 cm preplanting and cultivation over 20 cm following harvest	Before sowing/ Planting	1	Not applicable	0.5	200	1.0	Not applicable	
Broccoli/calabrese	EU, North	Devrinol SC, 450	F	Annual grasses and broad-leaved weeds	SC	450g/l	Application to soil surface, followed by soil incorporation into the top 5-8 cm preplanting and cultivation over 20 cm following harvest	Before sowing/ Planting	1	Not applicable	0.5	200	1.0	Not applicable	
Oilseed rape	EU	Devrinol SC, 450	F	Annual grasses	SC	450g/l	Application to soil surface, followed by	Before sowing/	1	Not applicable	0.6	200	1.2	Not applicable	

Crop and/or situation (a)	Member State, Country or Region	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application			Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks	
					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 (l) min – max	water L/ha min – max			kg as/ha (l) min – max
				and broad-leaved weeds			soil incorporation into the top 5-8 cm preplanting and cultivation over 20 cm following harvest	planting							
<p>* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).</p> <p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>								<p>(i) g/kg or g/L of the technical substance. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxyppyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p>							