TECHNICAL REPORT

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Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for 1-naphthylacetamide in light of confirmatory data

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the risk assessment for an active substance in light of confirmatory data requested following approval in accordance with Article 6(1) of Directive 91/414/EEC and Article 6(f) of Regulation (EC) No 1107/2009. In this context EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States, the applicant and EFSA on the confirmatory data and their use in the risk assessment for 1-naphthylacetamide are presented. The current report summarises the outcome of the consultation process organised by the rapporteur Member State France and presents EFSA's scientific views and conclusions on the individual comments received.

Key words: 1-naphthylacetamide, peer review, confirmatory data, risk assessment, pesticide, plant growth regulator

Requestor: European Commission

Question number: EFSA-Q-2015-00147

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Summary

1-Naphthylacetamide was approved on 1 January 2012 under Regulation (EC) No 1107/2009 via Commission Implementing Regulation (EU) No 786/2011. It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on the risk to non-target plants and the long-term risk to birds by 31 December 2013.

In accordance with the specific provision, the applicant, 1-NAD Task Force, submitted an updated dossier in May 2014, which was evaluated by the designated rapporteur Member State (RMS), France, in the form of an addendum to the draft assessment report. In compliance with guidance document SANCO 5634/2009 rev.6.1, the RMS distributed the addendum to Member States, the applicant and EFSA for comments on 24 November 2014. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 2 March 2015. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table.

The current report summarises the outcome of the consultation process organised by the RMS France and presents EFSA's scientific views and conclusions on the individual comments received.

The information provided with the confirmatory data was not sufficient to address the long-term risk to birds. In agreement with the RMS, the need for a bird chronic toxicity study is identified. Regarding the risk to non-target plants, EFSA agrees with the assessment provided by the RMS according to which, in light of the confirmatory data, the risk for non target plants at the maximum recommended application rate is considered to be acceptable with mitigation measures.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

1-Naphthylacetamide was approved on 1 January 2012 under Regulation (EC) No 1107/2009[1] via Commission Implementing Regulation (EU) No 786/2011[2]. EFSA previously finalised a Conclusion on this active substance on 15 February 2011 (EFSA, 2011).

It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on the risk to non-target plants and the long-term risk to birds by 31 December 2013.

In accordance with the specific provision, the applicant, 1-NAD Task Force, submitted an updated dossier in May 2014, which was evaluated by the designated rapporteur Member State (RMS), France, in the form of an addendum to the draft assessment report (France, 2015). AMVAC Chemical UK Limited, applicant under the Regulation (EC) No 1107/2009, did not submit any confirmatory data dossier. In compliance with Guidance Document SANCO 5634/2009 rev.6.1 (European Commission, 2013), the RMS distributed the Addendum to Member States, the applicant and the EFSA for comments on 24 November 2014. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 2 March 2015. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table.

The current report summarises the outcome of the consultation process organised by the rapporteur Member State France and presents EFSA's scientific views and conclusions on the individual comments received.

1.2. Interpretation of the Terms of Reference

On 22 December 2014 the European Commission requested EFSA to provide scientific assistance with respect to the risk assessment of confirmatory data following approval of an active substance in accordance with Article 6(1) of Directive 91/414/EEC and Article 6(f) of Regulation (EC) No 1107/2009. EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States, the applicant and EFSA on the risk assessment of confirmatory data for 1-naphthylacetamide are presented.

To this end, a Technical Report containing the finalised reporting table is prepared by EFSA. The deadline for providing the finalised report is 31 March 2015.

On the basis of the reporting table, the European Commission may decide to further consult EFSA to conduct a full or focussed peer review and to provide its conclusions on certain specific points.

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

[2] Commission Implementing Regulation (EU) No 786/2011 of 5 August 2011 approving the active substance 1-naphthylacetamide, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/941/EC. OJ L 203, 6.8.2011, p. 11–15.

2. Assessment

The comments received on the pesticide risk assessment for the active substance 1-naphthylacetamide in light of confirmatory data and the conclusions drawn by the EFSA are presented in the format of a reporting table.

The comments received are summarised in column 2 of the reporting table. The RMS' considerations of the comments are provided in column 3, while EFSA's scientific views and conclusions are outlined in column 4 of the table.

The finalised reporting table is provided in the Appendix of this report.

Documentation provided to EFSA

1. France, 2015. Addendum to the assessment report on 1-naphthylacetamide, confirmatory data, March 2015. Available online: www.efsa.europa.eu.

2. France, 2015. Reporting table, comments on the pesticide risk assessment of confirmatory data for 1-naphthylacetamide, March 2015.

References

ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

EFSA (European Food Safety Authority), 2009. Guidance on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438, 358 pp. doi:10.2903/j.efsa.2009.1438

EFSA (European Food Safety Authority), 2011. Conclusion on the peer review of the pesticide risk assessment of the active substance 2-(1-naphthyl)acetamide. EFSA Journal 2011;9(2):2020. [58 pp.]. doi:10.2903/j.efsa.2011.2020. Available online: www.efsa.europa.eu

European Commission, 2013. Guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009. SANCO 5634/2009 rev. 6.1

Abbreviations

a.s.	active substance
DAR	draft assessment report
GAP	good agricultural practice
DG SANCO	European Commission Directorate General Health and Consumers
EFSA	European Food Safety Authority
EU	European Union
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
MRL	maximum residue level
NESTI	national estimated short-term intake
OSR	oilseed rape
PBI	Plant-back interval
PEC	predicted environmental concentration
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PRIMo	Pesticide Residue Intake Model
RMS	rapporteur Member State
TMDI	theoretical maximum daily intake

Appendix A – Collation of comments from Member States, applicant and EFSA on the pesticide risk assessment of for the active substance 1-naphthylacetamide in light of confirmatory data and the conclusions drawn by EFSA on the specific points raised

5. Ecotoxicology

Birds and mammals (B.9.1 and B.9.3)				
No.	**Column 1** **Reference to addendum to assessment report**	**Column 2** **Comments from Member States / applicant / EFSA**	**Column 3** **Evaluation by rapporteur Member State**	**Column 4** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the RMS's assessment of confirmatory data**
5(1)	Addendum to Vol. 3 Annex B.9, confirmatory information, B 9.1long-term risk to insectivorous birds	EFSA: EFSA agrees with the assessment provided by the RMS.	RMS (Feb 2015): Thanks - Noted	Noted

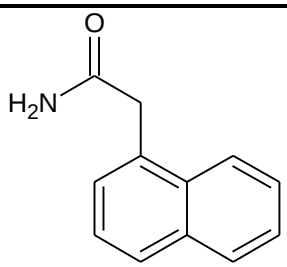
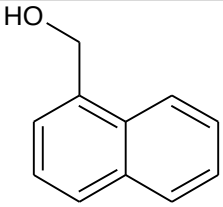
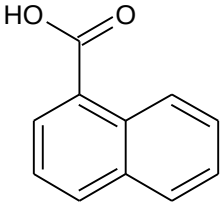
5(2)	Conf. Data Addendum, Vol. 3, B.9.1, Effects on birds	DE: 1-NAD shows a relatively low overall toxicity towards non-target species. Nevertheless, it is difficult to assess whether the submission of a bird reproduction study can be waived or not. We agree with the RMS that the long-term risk assessment to birds still needs to be assessed because an active substance with a short degradation time could still cause reproductive effects. Arguments given by the task force to demonstrate that a long-term exposure of birds is unlikely are not considered sufficient. In the EFSA guidance document on Birds and Mammals (2009) it is stated that an avian reproductive toxicity study and associated risk assessment should not be necessary if it can be demonstrated that exposure will not occur during the reproductive season for birds. But this is not the case for the intended application in orchards. Additionally, checking the reproductive data on mammals, there is evidence that 1-NAD has an intrinsic potential to cause reproductive effects. Thus, it cannot be assumed that 1-NAD is per se harmless. Therefore, DE is of the opinion that the information presented in the confirmatory addendum is not suitable to prove that a safe use is possible.	RMS (Feb 2015): We agree with DE comment. RMS confirms that a bird chronic toxicity study is still needed and considered that this point is still opened	EFSA agreed with the RMS and DE that a bird chronic toxicity study is still needed and considered that this point is still open.

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)				
No.	**Column 1** **Reference to addendum to assessment report**	**Column 2** **Comments from Member States / applicant / EFSA**	**Column 3** **Evaluation by rapporteur Member State**	**Column 4** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the RMS's assessment of confirmatory data**
5(3)	Addendum to Vol. 3 Annex B.9, confirmatory information, B 9.9 non-target plants	EFSA: EFSA agrees with the assessment provided by the RMS.	RMS (Feb 2015): Thanks - Noted	Noted
5(4)	Vol. 3, B.9.9, effects on plants	DE: The RMS presented in the confirmatory addendum summaries of the studies on effects on seedlings emergence and vegetative vigour of plant species. However, the documentation is quite short. We would recommend presenting at least all the details which are essential for the validation of the studies.	RMS (Feb 2015): Validity criteria have been added	Addressed Amendments were provided in the addendum from March 2015

Other comments				
No.	**Column 1** **Reference to addendum to assessment report**	**Column 2** **Comments from Member States / applicant / EFSA**	**Column 3** **Evaluation by rapporteur Member State**	**Column 4** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the RMS's assessment of confirmatory data**
5(5)	Vol. 3, B.9, Background	Notifier: the confirmatory data were officially provided in May 2014 only, because we believed they could be dealt with at MS level during the Step 2 process.	RMS (Feb 2015): No comment - Addressed	Addressed
5(6)	Peer Review of the pesticide risk assessment of the active substance 2-(1-napthyl)acetamide, Appendix A – list of end points	Notifier: the remark no. [2] should be updated following the RMS assessment of the confirmatory data. A proposal could be: [2] The route and rate of degradation in soil including the assessment of the potential for photolysis show that the major metabolites other than 1-NAA (naphtoic acid and 1-naphtalenemethanol) observed in the photolysis study may not be defined as strict photoproducts since they were also observed in the soil aerobic experimentation (dark) and in the dark control samples of the soil photodegradation study.	RMS (Feb 2015): This should not be included in the list of endpoints. It already appears in the addendum	Addressed

5(7)	Peer Review of the pesticide risk assessment of the active substance 2-(1-napthyl)acetamide, Appendix A – list of end points	Notifier: the remark no. [3] should be updated following the RMS assessment of the confirmatory data. A proposal could be: [3] The long term risk to birds for 1-NAD has been conducted using an estimate of bird reproductive NOEC (LD50/10) which is considered acceptable. The TERLT values are greater than the trigger value of 5, indicating an acceptable risk to birds following use of 1-NAD formulation according to the proposed use pattern.	RMS (Feb 2015): This should not be included in the list of endpoints. It already appears in the addendum	Addressed
5(8)	Peer Review of the pesticide risk assessment of the active substance 2-(1-napthyl)acetamide, Appendix A – list of end points	Notifier: the remark no. [4] should be updated following the RMS assessment of the confirmatory data. A proposal could be: [4] The risk to non-target plants is addressed. The observed effects at the maximum application rate of 80 g a.i./ha are below 50% (8% and 11 % for vegetative vigour and seedling emergence, respectively). The TER value is above the trigger of 5 for off-field non target plants at 10 m. The risk for non target plants at the maximum recommended application rate is considered to be acceptable with mitigation measures.	RMS (Feb 2015): This should not be included in the list of endpoints. It already appears in the addendum	Addressed

Appendix B – Used compound code(s)

Code/Trivial name*	Chemical name/SMILES notation**	Structural formula**
1-naphthylacetamide 1-naphthalene acetamide 2-(1-naphthyl)acetamide 1-NAD	2-(1-naphthyl)acetamide NC(=O)Cc2cccc1ccccc12	
1-naphthalenemethanol	1-naphthylmethanol OCc2cccc1ccccc12	
1-naphthoic acid	1-naphthoic acid O=C(O)c2cccc1ccccc12	

* The compound name in bold is the name used in the report.
** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).