TECHNICAL REPORT

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Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for metam 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 metam are presented. The current report summarises the outcome of the consultation process organised by the rapporteur Member State Belgium and presents EFSA's scientific views and conclusions on the individual comments received.

Key words: metam, peer review, confirmatory data, risk assessment, pesticide, nematicide, fungicide, herbicide, insecticide

Requestor: European Commission

Question number: EFSA-Q-2015-00509

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Summary

Metam was approved 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, on 1 July 2012 by Commission Implementing Regulation (EU) No 359/2012, amending the Annex to Commission Implementing Regulation (EU) No 540/2011. It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on methyl isothiocyanate as regards: (1) the assessment of the long-range atmospheric transport potential and related environmental risks; (2) the potential groundwater contamination by 31 May 2014.

In accordance with the specific provision, the applicant, Taminco BVBA, submitted an updated dossier in May 2014, which was evaluated by the designated rapporteur Member State (RMS), Belgium, 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 20 January 2015. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 1 September 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, Belgium, and presents EFSA's scientific views and conclusions on the individual comments received.

Appropriate information was provided on the environmental fate and behaviour of methyl isothiocyanate consequent to representative uses of products containing its precursor metam-sodium regarding environmental risks consequent to long-range atmospheric transport potential. Updated FOCUS scenario groundwater exposure modelling and information from groundwater monitoring exercises have been provided regarding methyl isothiocyanate consequent to uses of products containing its precursor metam-sodium.

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1. Introduction

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

Metam was approved in accordance with Regulation (EC) No 1107/2009[1] of the European Parliament and of the Council concerning the placing of plant protection products on the market, on 1 July 2012 by Commission Implementing Regulation (EU) No 359/2012,[2] amending the Annex to Commission Implementing Regulation (EU) No 540/2011[3]. EFSA previously finalised a Conclusion on this active substance on 8 August 2011 in the EFSA Journal 2011;9(9):2334 (EFSA, 2011).

It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on methyl isothiocyanate as regards: (1) the assessment of the long-range atmospheric transport potential and related environmental risks; (2) the potential groundwater contamination by 31 May 2014.

In accordance with the specific provision, the applicant, Taminco BVBA, submitted an updated dossier in May 2014, which was evaluated by the designated rapporteur Member State (RMS), Belgium, in the form of an addendum to the draft assessment report (Belgium, 2015a). 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 EFSA for comments on 20 January 2015. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 1 September 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, Belgium, 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 metam are presented.

To this end, a technical report containing the finalised reporting table is being prepared by EFSA. The deadline for providing the finalised report is 30 September 2015.

On the basis of the reporting table, the European Commission may decide to further consult EFSA to conduct a full or focused 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 359/2012 of 25 April 2012 approving the active substance metam, 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. OJ L 114, 26.4.2012, p. 1–7.

[3] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.187–188.

2. Assessment

The comments received on the pesticide risk assessment for the active substance metam 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 Appendix A of this report.

Documentation provided to EFSA

1. Belgium, 2015a. Addendum to the assessment report on metam, confirmatory data, January 2015, revised in September 2015. Available online: www.efsa.europa.eu.

2. Belgium, 2015b. Reporting table, comments on the pesticide risk assessment for metam in light of confirmatory data, September 2015.

References

EFSA (European Food Safety Authority), 2011; Conclusion on the peer review of the pesticide risk assessment of the active substance metam. EFSA Journal 2011;9(9):2334. [97 pp.]. doi:10.2903/j.efsa.2011.2334. Available online: www.efsa.europa.eu/efsajournal.htm

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2010. Guidance for evaluating laboratory and field dissipation studies to obtain DegT50 values of plant protection products in soil. EFSA Journal 2010;8(12):1936, 67pp. doi:10.2903/j.efsa.2010.1936. Available online: www.efsa.europa.eu/efsajournal.htm

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
DG SANCO	European Commission Directorate General Health and Consumers
AR	applied radioactivity
DT_{50}	period required for 50 % dissipation (define method of estimation)
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GIS	geographic information system
PEC	predicted environmental concentration
RMS	rapporteur Member State

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

0. General

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
0(1)	Addendum to B8	FR: No specific comment. We agree with the assessment of the RMS.	**RMS**: thank you for the support.	Noted
0(2)	Addendum to B8	ES: General comment: agrees with RMS conclusion	**RMS**: thank you for the support.	Noted

4. Environmental fate and behaviour

Route and rate of degradation in soil (B.8.1)

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
4(1)	B.8.1.1.1 Aerobic degradation in soil, normalisation	**NL**: NOT used methodology included in guidance currently not into place and at the time of conducting the study not noted, to evaluate the $degT_{50}$ values. Agree with RMS BE this should not be done and the PECgw calculations should be based on the geometric mean of the available studies. Agree with BE that a correct slightly longer geomean DT_{50} in	**RMS:** RMS notes that NL agrees with RMS proposal. **Notifier**: /	Addressed

Route and rate of degradation in soil (B.8.1)

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
		combination with the correct slightly more conservative arithmetic mean Koc can result in acceptance of the current values		
4(2)	B.8.1.1.1 Study by Lowrie, 2014	**SE:** The total recovery of applied radioactivity decreased over the study in all four soils and the two application rates tested, as shown in tables E-1 to E-8. In some experiments to remarkably low values around 20% AR. This is generally not acceptable. It is postulated that the loss was attributable to loss of $^{14}CO_2$ but this has not been convincingly demonstrated. The DT_{50}s determined are very uncertain, and should not be used for groundwater modelling. In the previous study evaluated in the DAR (Hall et al, 2004) the total recovery remained at acceptable levels over 21 days of incubation at 20°C. In comparison there were apparently technical problems in the new study (Lowrie, 2014). The methods used and the results from the additional	**RMS:** RMS agrees that for some experiments the mass balance decreased up to 20%AR. However, generally speaking, as shown below in the Table 4(2)-1, the overall recovery remained reasonably high (for a volatile substance) up to day 4, then it decreased sharply. The Table shows also that the number of sampling points available until day 4 was sufficient in order to have a reasonable view of the degradation pattern of MITC (which rapidly degrades). By conclusion, as the tested compound is volatile, as the DegT50 of MITC is determined from the sum of the soil phase and the volatile phase, and as MITC rapidly degrades, RMS considers that in this particular case, the mass balance is not an issue. Therefore, RMS considers that DT50's are still valid. Table 4(2)-1: overall recovery at day 4 and number of sampling points until day 4. soils / rate / Recovery (% AR) at day 4 / Nb of sampling points S777 / 115.5 / 72.2 / 5	Addressed

Route and rate of degradation in soil (B.8.1)				
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experiment in Lowrie (2014) (mentioned on page 13) have not been provided in sufficient detail to convince that all losses could be attributed to $^{14}CO_2$.

S777	173.2	63.6	5
S778	115.5	90.1	5
S778	173.2	107.7	5
S779	115.5	74.9	5
S779	173.2	78.4	5
S780	115.5	75.3	5
S780	173.2	90.0	5

Notifier: There is no indication that the low recoveries were due to unaccounted losses of parent MITC and therefore the DT_{50} values reported are valid. Confirmation of the robustness of the DT_{50} values is provided by the very good kinetic fits with the SFO model to MITC degradation data with Chi^2 error (χ^2) <6.2 and correlation coefficient (r^2) >0.91 regardless of recoveries. The evidence is clear in the report that MITC was rapidly and extensively degraded to carbon dioxide.

It is agreed that there is some uncertainty as to the identification of the volatile component lost from the flasks. However, it is clear that the problems encountered are likely to have been caused by the use of an elevated application rate, when compared to the previous study. The rate of degradation of MITC was still very fast, with a concomitant significantly elevated volume of released carbon dioxide (the only significant breakdown product observed in studies). It is reasonable to conclude that the

Route and rate of degradation in soil (B.8.1)				
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			unaccounted for volatile material (in some treatments) was carbon dioxide, and its loss from the system does not impact on the calculation of DT_{50}s for MITC.	
4(3)	B.8.1.1.1 Study by Lowrie, 2014	**SE:** The method of application in Lowrie (2014) is not clearly stated in the Addendum. According to EFSA J 2011;9(9):2334 experts were not convinced that the previous study provided a realistic representation of the fate and behaviour of metam and MITC since in the field volatilisation would be minimised by compacting soil or with plastic film. The new study by Lowrie (2014) could be questioned for the same reason. Especially since use of gas-tight plastic film is a condition for use when metam is applied by drip irrigation (Reg (EU) 359/2012).	**RMS:** RMS agrees with the Notifier's answer. **Notifier**: The degradation study (as for the previous study by Hall et al, 2004) was designed to determine the rate of degradation of MITC in the bulk soil matrix, which is in accordance with recent EFSA guidance. This is appropriate as all the current risk assessment models require this endpoint, and do not simulate surface effects. In this study, MITC was restricted to the volume of the flask – the study was not conducted as a flow-through investigation – with concomitant rapid equilibration of the distribution of MITC between the soil compartment and the limited headspace above the soil in the flask. This closed system, without airflow, mimics the sealing of soil by compaction or plastic film. This design ensured that all the MITC in the flask was exposed to the soil compartment on an ongoing basis, and, hence, the resulting derived DT_{50} values are for degradation in the bulk soil matrix, as required.	Addressed
4(4)	Confirmatory data addendum Vol. 3, B.8.1, route and rate of degradation in soil, pages 9-15	**EFSA**: The RMS has provided a transparent evaluation of new laboratory soil incubations where dose rates of MITC were higher than in the reliable experiments that were the basis for the agreed endpoints in the EFSA conclusion. We agree with	**RMS:** RMS notes that EFSA agrees with the new DegT50 endpoints derived from the new incubation tests. As suggested, RMS has updated the List of Endpoints with the appropriate geomean DegT50 values (see List of Endpoints – revised in September 2015). The appropriate geomean DegT50 values are those reported by the Notifier here below.	Addressed An appropriate supplement to the fate list of endpoints of the published EFSA conclusion, incorporating the new reliable lab soil DT50 for MITC was prepared by the RMS (revision dated September 2015).

Route and rate of degradation in soil (B.8.1)				
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		the new DegT50 endpoints that the RMS has derived from these new incubations. Member State competent authorities and the Commission might appreciate it if these new endpoints, could be summarised in an addendum to the list of endpoints or an updated list of endpoints. If an update to the list of endpoints is provided a geomean DT50 (and not bias corrected geomean) for each dosing rate would be the appropriate value to be included, (to be the agreed EU endpoints that it would be appropriate to use in future modelling assessments that might be required for national product authorisation evaluations).	**Notifier**: Low geomean 2.1 days Medium geomean 3.2 days High geomean 3.9 days	

PEC in surface water and in ground water (B.8.6)				
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4(5)	B.8.6.1 Predicted environmental	**NL**: the $DegT_{50}$ value related to dose rate was used (low,	**RMS:** As concluded during the peer review of the	Addressed

PEC in surface water and in ground water (B.8.6)				
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	concentrations in groundwater (PECgw), section 2	middle,high). For each a geomean of 4 soils is available. These geomean values do not differ to a large extend even at a 4x higher dose rate. As in theory DT_{50} values should not be dose dependent, we wonder why not a single geomean would be a suitable value for calculations. The methods as described in Appendix A of the EFSA (2010) Guidance to obtain $DegT_{50}$ values in soil could be used to test if there is significant difference between the populations of $DegT_{50}$ values and if it is justified to use different $DegT_{50}$ values better than one geomean.	Metam and as reported in the EFSA Conclusion (EFSA Journal 2011;9(9):2334), the literature review showed a relationship between the concentration of MITC in soil and its rate of degradation (MITC degrading slowly at higher concentration rates). Therefore, the use of an overall geomean in PECgw is not appropriate. **Notifier**: It is agreed that the vaues do not differ by a great extent. However, using the EFSA spreadsheet indicates that the low conc $DegT_{50}$ values are significantly lower than both the medium and high conc $DegT_{50}$ values, although the medium/high values are not different. (Low geomean 2.1 days Medium geomean 3.2 days High geomean 3.9 days Medium/high geomean 3.5 days)	It might be expected that DT_{50} of a total soil sterilent would be concentration dependent. A trend for this was identified previously and agreed by the peer review. The statistical test suggested by the NL confirmed that there was a difference, at least between the lower dose and the two higher doses.
4(6)	B.8.6.1 Predicted environmental concentrations in groundwater (PECgw), overall conclusion	**NL**: we don't understand the remarks in table -34. If for band application the highest dose rate with the accompanying DT_{50} is used and this is relevant for the use applied for it seems to us the calculations are acceptable. The simulated dose rate is supported by the DT_{50} study.	**RMS:** RMS considers that as the FOCUS models are sensitive to the application rates, the use of a reduced rate (resulting from the band application) would underestimate the PECgw.Therefore, RMS has some reservation on the Notifier's simulations carried out with a reducing-dose resulting from banded application. RMS acknowledges that the remarks in column 7	Addressed Appropriate clarifications were made on pages 47-51 of the amended addendum dated September 2015.

PEC in surface water and in ground water (B.8.6)				
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		We agree with RMS that use of a reduced application rate for band application is not justified. Please clarify the remarks in column 7 of the table as these seem to say the opposite for some crops.	need to be clarified. As such, further clarification is given in column 7 in the amended Addendum (please refer to amended Addendum – version of September 2015). **Notifier**: /	
4(7)	B.8.6, section 4: Groundwater monitoring campaign	**SE**: The groundwater monitoring campaign was obviously thoroughly conducted. Still, in our opinion the results from the campaign can only be used as weak indications of low risk. One apparent weakness is the lack of confirmation of use of metam at the field scale in most of the areas, another is the lack of analysis of the age of the groundwater. We do not agree with the the RMS conclusion (page 78) that the results of the campaign demontrates safe use of metam. Age of water abstracted not exceeding the duration of the historical use is stated as criteria no. 5 for the study, but no analyses of the age of the waters were reported	**RMS:** Notifier provides further explanation below. The Notifier carried out a monitoring campaign in the Member States of the Southern Zone only. In total, 88 sites were retained for the groundwater monitoring campaign. RMS is of the opinion that there are reasonable evidence that metam products have been used in the vicinity of the monitored wells and that these well sites represent relatively vulnerable locations. If needed, further member state specific questions regarding situation specific or temporal considerations should be undertaken as post-registration activities. **Notifier**: We agree that the GW monitoring campaign was thoroughly conducted and contend that it does confirms safe usage. With respect to metam usage see answer A1 and with respect to the age of groundwater see answer A2 in attached document. For convenience, the content of the Notifier's answer A1 and answer A2 are inserted below.	Addressed The RMS has provided a transparent evaluation of the information provided by the applicant. The RMS conclusions are reasonable. As is always the case with monitoring information, there is uncertainty in relating the monitored sites back to the representative uses that are being assessed. There is reasonable evidence presented that metam products have been used in the vicinity of the monitored wells and that these well sites represent relatively vulnerable locations.

PEC in surface water and in ground water (B.8.6)				
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			"**A1:** While this is technically correct, as field by field level usage statistics are not presented, these comments suggest that nothing was presented or possibly that what was presented is insufficient to assess the suitability of the monitoring location against those criteria. We contend that this is not the case, with strong evidence presented: (i) Extent – Metam is typically used on high value crops whose production is often limited to small intensive production areas determined by suitable soils, plentiful rainfall/irrigation and the presence of good food chain infrastructure. These locations have typically been producing these high value crops for decades and in most places the associated usage period of metam is also measurable in decades. Consequently, in most sampling locations significantly large tracts of arable land upstream of the sampling point had historically been treated on several occasions with metam, for example, in the map below all of the arable land (centre pivot circles) inside the red boundary has been treated every few years for the past 10-20 years. These treatment extents and usage histories were informed by discussions with metam sales representatives who have been selling the product to growers as well as discussions with Farmer Cooperatives, Grower Groups and individual farmers. Although this is not field level usage information, we contend that it is equally powerful and useful.	

PEC in surface water and in ground water (B.8.6)				
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			 In locations where the upstream area was smaller OR there was some uncertainty about the areas treated based on farmer interviews, a comparison of area treated using sales statistics with total crop area from agricultural census statistics is presented, e.g. "*Metam sodium application i [redacted] provinces is usually done through sprinkler, seldom through soil injection with a dose of 1200 kg/ha/year. Based on sales data and typical application rates in [redacted] province, approximately 800 ha of crop are treated with Metam each year. This represents about 0.55 % of the arable land and 83 % of the crops potentially treated with Metam in the area.*" Frequency: The typical metam practice in the area is generally established e.g. "*For all plots where Metam Sodium is used, this latter is employed every 3 or 4 years, for almost 10 or 15 years. Metam Sodium is*	

PEC in surface water and in ground water (B.8.6)				
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			used when carrots are grown, one year over 3 or 4. During the other 2 or 3 years, another crop is grown, which doesn't need Metam Sodium." Rate: The typical metam practice in the area is generally established albeit the label rate might reasonably be assumed in areas where one is not quoted e.g. "*Metam sodium application is usually done through sprinkler in closed tunnel, drip fumigation or soil injection with a dose of 1200/1800 kg/ha."* We would also like to re-iterate that the best possible data has been collected and collated within a real world context. Trying to collect and tabulate field by field metam usage records would only be feasible where a clear source area has been defined (which is not the case for most of the sampling locations). Trying to define a source zone and/or collecting field level usage statistics would have made the cost of the study disproportionately expensive (4 to 5 times the cost which is already substantial). It may also have resulted in farmers not co-operating with the study as pesticide application records are highly sensitive information and (i) many do not keep official records for longer than 2 to 5 years (there is no legal requirement to do so but they are still able to indicate which fields have been treated, over what period and at what rate) which is pertinent to a compound that is used once every 2 to 5 years and (ii) they would not have provided them voluntarily for fear of opening themselves up to legal action/prosecution should the groundwater have been found to be contaminated.	

PEC in surface water and in ground water (B.8.6)				
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			We contend that the real world evidence presented is strong enough to allow registration, as safe usage has been demonstrated for large numbers of vulnerable hydrogeological situations in different parts of the EU and that further member state specific questions regarding situation specific or temporal considerations should be undertaken as post-registration activities in those member states." "**A2:** This statement is technically correct in that no dating of groundwater was attempted in this study. The decision to not undertake dating of groundwater was a function of a number of factors including the degree of uncertainty associated with such a study and the very high cost. That said, this criterion was included in the list of site characteristics and considered by the hydrogeological consultants in each of the member states when they selected the final sampling sites. It was their reasoned opinion that typical groundwater recharge times relative to the decades of intensive usage of metam in the recharge zones made it probable that the sampling targeted water recharged during the period of metam usage. In the majority of cases sampling targeted relatively shallow groundwater situated in sands, gravels and highly fractured rock aquifers where the recharge period was believed to be substantially shorter than the decades of metam usage. Clearly the uncertainty of the monitoring results owing to this factor increases with depth to groundwater and for vadose zones which are characterised by low primary porosity and hydraulic conductivity. Both of these factors are explicitly	

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			accounted for in the DRASTIC vulnerability index which clearly indicates that the sampled population defined by the boreholes is representative of the broad climatic and hydrogeological situations within the member states where metam is used and re-registrations are being sought. While the vulnerability assessment was restricted to member states where metam is used and re-registrations are being sought we do not believe that this biases the vulnerability assessment. These member states reflect a large sample of the total area of the central and southern zones of the EU (and the EU28 itself). We contend that this proportion is sufficiently large that it represents a reasonable population of the total EU sample, making it valid. We contend that the real world evidence presented is strong enough to allow registration as safe usage has been demonstrated for large numbers of vulnerable hydrogeological situations in different parts of the EU and that further member state specific questions regarding situation specific or temporal considerations should be undertaken as post-registration activities in those member states."	
4(8)	Vol. 3, B.8.6, Sec. 4 groundwater monitoring campaign	**DE**: The use of metam in the catchment areas of the monitoring wells, is, in most (or all?) of the provided monitoring studies, adressed in a more general way. Even if a historical use over certain years might be plausible from the study summaries, no real data are available on a field scale which	**RMS:** Notifier provides further explanation below. The Notifier carried out a monitoring campaign in the Member States of the Southern Zone only. In total, 88 sites were retained for the groundwater monitoring campaign. RMS is of the opinion that there are reasonable evidence that metam products have been used in the vicinity of the monitored wells and that these well sites represent relatively vulnerable	Addressed See column 4 entry at comments 4(7) and 4(9).

PEC in surface water and in ground water (B.8.6)				
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		give evidence of the application of certain metam amounts in the different years before monitoring sampling. This rather rare information on the pressure of metam use is, in our opinion, difficult to conclude a none-risk/safe use of MITC for groundwater based on one single sampling occasion. This is underlined by the results of FOCUS groundwater modelling, which show a wide range of concentrations for MITC in the leachate strongly depending on the application amount, the crop and the application time. Further the fast degradation and low adsorption of MITC in soil would let assume that leaching and entry of MITC in groundwater in relevant concentration may temporarily occure, if the application of metam coincides with groundwater recharge. Hence, the one monitoring campaign and the corresponding information about the metam use do not adequately answer the question, for which application conditions in combination with soil and	locations. If needed, further member state specific questions regarding situation specific or temporal considerations should be undertaken as post-registration activities. **Notifier**: It is accepted that field by field level usage statistics are not presented, however, we contend that strong evidence has been presented with respect to pertinent metam usage. See answer A1 in attached document. For the comment on the FOCUS groundwater modelling, and the temporal variations see answer A3 in attached document For convenience, the content of the Notifier's answer A3 is inserted below. "**A3.** The comments relating to the FOCUS models seems to ignore the fact that MITC is a very volatile compound and that very volatile compounds are acknowledged as being poorly represented by the current suite of EU regulatory pesticide fate models. It is our contention that their representation of the real world for metam/MITC is so poor that measurement of losses to groundwater in the real world was the best means of assessing risk to groundwater. In the case where losses of pollutants to groundwater are associated with episodic recharge events, these are often associated with corresponding periods of shallow groundwater levels (e.g. see Haria	

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		climate conditions a safe use can be demonstrated in the EU.	et al, 2003; Chilton et al., 2005). We contend that the sampling network established adequately characterizes shallow vulnerable groundwater systems. Depth to groundwater and vadose zones porosity and hydraulic conductivity are key factors - both of these factors are explicitly accounted for in the DRASTIC vulnerability index which clearly indicates that the sampled population defined by the boreholes is representative of the broad climatic and hydrogeological situations within the member states where metam is used and re-registrations are being sought. However, we agree that the single monitoring occasion does not provide a definitive answer as to temporal variations in MITC concentrations in groundwater. This was acknowledged in the groundwater synthesis report along with the conclusion that the evidence presented was strong enough to allow registration as safe usage has been demonstrated for large numbers of vulnerable hydrogeological situations and that further member state specific questions regarding situation specific or temporal considerations could be undertaken as post-registration activities in those member states."	
4(9)	Vol. 3, B.8.6, Sec. 4 groundwater monitoring campaign	**DE**: The extraction depth of the groundwater wells shows a high range between 1 m in monitoring wells in [redacted] and 220 m in [redacted] Such differences would need to be addressed in the assessment relating to the travel time of MITC, the ages of the of the	**RMS:** Notifier provides further explanation in comment 4(10), answer A2. In total, 88 sites were retained for the groundwater monitoring campaign. RMS is of the opinion that there are reasonable evidence that metam products have been used in the vicinity of the monitored wells and that these well sites represent relatively vulnerable locations. If	Addressed See column 4 entry at comment 4(7). Though many samples were not taken across different seasons at individual sites, the inclusion of a number of different vulnerable sites might be considered to compensate for this to some extent.

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		aquifers and the historical use of metam. Such differences and consequences for the interpretation of monitoring results are rarely discussed in the Addendum.	needed, further member state specific questions regarding situation specific or temporal considerations should be undertaken as post-registration activities. **Notifier**: See answer A2 in attached document.	
4(10)	Vol. 3, B.8.6, Sec. 4 groundwater monitoring, vulnerability assessment	**DE**: To demonstrate the ranking of intrinsic vulnerability of the chosen monitoring regions in the EU, the vulnerability analysis should be based on the whole EU area and not only of the areas of the member states with monitoring results. Large parts of the EU are missing in the GIS vulnerability analysis of the notifier which may negatively influence the range of the calculated vulnerability score. As a consequence, the results might be biased and it seems not possible to conclude that a safe use could be demonstrated more or high vulnerable areas in the EU.	**RMS:** RMS agrees that the vulnerability assessment was not based on the whole EU area. However, the vulnerability assessment was carried out by comparing the vulnerability index of the sites of the monitoring campaign with the vulnerability index of the rest of Europe where, according the Notifier, there is currently an authorization for metam. RMS agrees with the Notifier that these member states reflect a large sample of the total area of the central and southern zones of the EU. In total, 88 sites were retained for the groundwater monitoring campaign. RMS is of the opinion that there are reasonable evidence that metam products have been used in the vicinity of the monitored wells and that these well sites represent relatively vulnerable locations. If needed, further member state specific questions regarding situation specific or temporal considerations should be undertaken as post-registration activities. See also Notifier's answer in comment 4(10). **Notifier**: See answer A2 in attached document	Addressed It is acknowledged that the vulnerability scores calculated did not include information for large parts of the EU. There are also many other choices that have to be made in a vulnerability analysis that influence the results. A transparent assessment has been made of what was done. Therefore decision makers need to consider the uncertainty in the vulnerability assessment and its geographical coverage, alongside all the other information available on groundwater exposure potential

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4(11)	Confirmatory data addendum Vol. 3, B.8.6, PEC in groundwater, pages 16-55	**EFSA**: The RMS has provided a transparent evaluation of the PEC in groundwater. The RMS conclusions are reasonable.	**RMS:** noted. **Notifier**: /	Addressed
4(12)	Confirmatory data addendum Vol. B.8.6, PEC in groundwater, groundwater monitoring campaign pages 55-78	**EFSA**: The RMS has provided a transparent evaluation of the information provided by the applicant. The RMS conclusions are reasonable. As is always the case with monitoring information, there is uncertainty in relating the monitored sites back to the representative uses that are being assessed. There is reasonable evidence presented that metam products have been used in the vicinity of the monitored wells and that these well sites represent relatively vulnerable locations.	**RMS:** noted. **Notifier**: /	Addressed

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
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**
4(13)	B.8.8. Risk for long-range transport via air	**SE:** The assessment using EUSES appears to have been carried out properly, and	**RMS:** Agrees. The suggested conclusions are inserted in the amended Addendum (version of September 2015).	Addressed Additions were made on page 84 of the amended addendum dated September

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
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		addresses the request for confirmatory data. As indicated in the Addendum there is no agreed criteria for interpretation of assessment of long-range transport. From the results in Table 8.8-4 it can be concluded that: 1) long-range transport of MITC can be expected to occur, and 2) the concentrations in different media in remote areas as a result of long-range transport are likely to be 2-3 orders of magnitude lower than at the regional scale. In addition to the risk assessment presented in the Addendum we suggest that these conclusions be stated more clearly.	**Notifier**: /	2015.
4(14)	Confirmatory data addendum Vol. 3, B.8.8, fate and behaviour in air, pages 79-83	**EFSA**: The RMS has provided a transparent evaluation of the information provided by the applicant. We consider that the risk assessment probably addresses the data requirement set by the Commission, with appropriately estimated exposure concentrations of MITC being significantly lower than the ecotoxicological endpoints agreed by the peer	**RMS:** Noted. **Notifier**: /	Addressed

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
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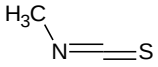
		review as appropriate for use in within field and edge of field risk assessments.		

Appendix B – Used compound code(s)

Code/trivial name*	Chemical name/SMILES notation**	Structural formula**
MITC	Methyl isothiocyanate or isothiocyanatomethane CN=C=S	

* 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).