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0. General Comments

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
0(1)	Vol. 1, LOE, Classification and proposed labelling with regard to physical / chemical data	AT: Statement is missing	Monograph being updated by adding the missing statement.	Open point: RMS to amend the list of end points with respect to classification and labelling.
0(2)	Vol. 1, 1.2.7, manufacturer of the active substance	NL: Reference is made to Annex C. The manufacturer of the active substance is however not considered as confidential information	Monograph being amended.	Addressed RMS to consider in a revised DAR or corrigendum.
0(3)	Vol. 1, 1.3.3, type of preparation and code	NL: Oil dispersion (not dispersable) See also 1.4; See also B.1.3.5	Monograph being amended.	Addressed RMS to consider in a revised DAR or corrigendum.
0(4)	Vol. 1, p. 46, list of end points, summary of intended uses	EFSA: For transparency and better comprehensibility, instead of the "summary of intended uses", the list of representative uses evaluated, as mentioned in EPCO Manual E4, should be used.	Headings will be changed according to the guidance document.	Open point: RMS to amend the list of end points with respect to the list of representative uses. See also comment 1(13).
0(5)	Vol. 4, General	EFSA: For transparency and better comprehensibility, RMS should reconsider the use of abbreviations and codes (e.g. in the list on p. 24 only the chemical names are given, but only codes in the table of the	Monograph being amended to clarify to which the codes are related.	Open point RMS to provide a corrigendum or revised Volume 4 to clarify the used codes.

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		batch analysis. Both are mentioned only in the tables starting on page 25; in table on page 39 the used analytical methods are mentioned, but it seems that the respective code is only mentioned in the references relied on in volume 3).		

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(1)	Vol. 1, LOE analytical method for impurities	AT: Principle of the method and LOQ for the relevant impurity Bis-CHYMP is not reported. See also B.5.1.2/B 5.1.4	Vol.1 being amended to include the principle of method and LOQ. Monograph amended to include information for Bis-CHYMP in LOE. Method validation data for Bis-CHYMP in B.5.1 was in section B.5.1.1 and is now moved to B.5.1.2. In the monograph (B.5.1.4) it is stated that impurities are determined only in the technical product and are not formed during formulation or storage.	Open point: RMS to amend the list of end points with respect to method for the determination of Bis-CHYMP. See also comment 1(10).
1(2)	Vol. 1, LOE analytical method for residues in soil and water	AT: A detailed specification of the individual metabolites determined with this method should be listed	Residue definition in soil and water (groundwater, surface water, and drinking water) has been determined to be parent penoxsulam only. All metabolites have been determined to be non-relevant in soil and water. Therefore no analytical method for the determination of metabolites in soil or water is require	Addressed
1(3)	Vol. 1, LOE analytical method for residues in body fluids and tissues	AT: As penoxsulam is not classified as a toxic or highly toxic compound no method for the determination of residues is relevant and this shall be mentioned	Monograph being amended to contain a statement on this matter.	Open point: RMS to amend the list of end points to indicate that a method for blood and tissues (Annex point 4.2.5) is not required.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(4)	Vol. 1, 1.2.3,	NL: IUPAC name is 3-(2,2-difluoroethoxy)-*N*-(5,8-dimethoxy[1,2,4]triazolo[1,5-*c*]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide. See also list of endpoints See also 3.1; See also B.1.2.4	Monograph being corrected.	Addressed List of end points has been amended.
1(5)	Vol. 1, 1.2.6, molecular and structural formula, molecular mass	NL: Data is missing	Monograph being corrected by copying this information at this point.	Addressed RMS to consider in a revised DAR or corrigendum..
1(6)	Vol. 1, 1.2.9, specification of purity	NL: Reference is made to Annex C . The purity of the technical active substance should however be mentioned here. See also B.1.2.9	Monograph being amended.	Addressed RMS to consider in a revised DAR or corrigendum.
1(7)	Vol.1, 2.2.3, Methods for residue analysis	NL: For surface water, ground water and drinking water	Vol. 1, 2.2.3 amended to indicate that the analytical methods are applicable to surface water, ground water, and drinking water.	Addressed RMS to consider in a revised DAR or corrigendum.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(8)	Vol. 1, List of end points, minimum purity of the active substance as manufactured (g/kg)	NL: Minimum purity 980 g/kg (not 980 g/kg ± 3% relative) EFSA: The given value needs to be clarified. Provided that the value should be read as the declared content, the "real" minimum purity shuld be given. AT: Minimum purity of the active substance is missing in Volume 3 and also in Volume 4	Agreed. List of end points being corrected as well as the monograph.	Addressed RMS has amended the list of end points.
1(9)	Vol. 1, List of end points, UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	NL: ë$_{max}$ should be λ$_{max}$.	Agreed. Editing error to be corrected.	Addressed RMS to consider in a revised DAR or corrigendum.
1(10)	Vol. 1, List of end points, Methods of analysis, impurities in technical as (principle of method)	NL: The analytical method for relevant impurity, bis-chymp should also be mentioned in the LOEP.	List of end points being updated to include this method.	See open point in comment 1(1).
1(11)	Vol. 1, List of end points, Methods of analysis, Food/feed of plant origin (…)	NL: Matrices should be mentioned. (Rice)	Agreed. List of end points being updated.	Open point: RMS to amend the list of end points with respect to the validated matrices in food of plant origin.
1(12)	Vol. 1, Level IV	NL: -Oxidizing properties of the ppp properties should be determined	B 2.2.5 EEC method A17 is not relevant to a liquid substance. We agree with the notifier that a waiver can be provided for	Data requirement. Applicant to provide a shelf-life study as well as data on the

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(12)	*continued* Vol. 1, Level IV	according to method EEG A17(B.2.2.5) -2 year stability test in commercial packaging at ambient temperature should be submitted (B.2.2.20) -packaging resitance (B3.5.1.3) -several other studies for the ppp are evaluated as not acceptable or it is concluded that a GLP study should be submitted (see B.2.2)	GF-657. B 2.2.20 Two year packaging study for GF-657 has been completed, upon request. Results are acceptable. B 3.5.1.3 Notifier informed that GLP studies for GF-657 are now available and will be provided upon request. An addendum of the monograph will be provided with the assessment of these studies.	relative density. Applicant stated that the data will be available in June 2006 See also comments 1(20) and 1(21). Data requirement: Applicant to provide data on the oxidising properties of the formulation based on a theoretical assessment or on the EEC method A21. Applicant stated that the data will be available in June 2006 See also comments 1(18) and 1(19).
1(13)	Vol. 1, p. 46, list of end points, summary of intended uses	EFSA: For transparency and better comprehensibility, instead of the "summary of intended uses", the list of representative uses evaluated, as mentioned in EPCO Manual E4, should be used.	Monograph being amended to clarify to which the codes are related.	Addressed RMS to consider in a revised DAR or corrigendum. See also open point in comment 0(4).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(14)	Vol. 1, p. 47, list of end points, analytical methods for the active substance	EFSA: RMS should consider to remove from the table confidential information such as used columns or internal standards.	Methods of analysis to determine the nature and identity of active substances are not to be considered as confidential information (directive 91/414/EEC, art. 14, 7th indent).	Open point: RMS to remove confidential data form the box "Impurities in technical as" from the list of end points It should be noted that the comment refers not to the active substance but to the first sub-heading in the section on "methods of analysis"
1(15)	B.2.1.11 B.2.1.16 B.2.2.12 B.2.2.16 B.2.2.18 B.2.2.24 B.2.2.26 B.2.2.30 B.2.2.33 B.2.2.35 B.2.2.36	DAS: All listed points have no evaluation or conclusion (acceptable,unacceptable, etc.).	Monograph being amended with a statement on their acceptability.	Addressed RMS to provide a revised DAR or corrigendum.
1(16)	B.2.2.14.	DAS: The value should be 0.934 g/**mL**, not g/L	Typing error. Monograph being corrected.	Addressed RMS to provide a revised DAR or corrigendum.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(17)	Vol. 3, B.2.1.13 Solubility in organic solvents	AT: Purity of the active substance is not reported	The nominal purity of the active substance is 98.0% (average for the five batch analysis). Purity being added in the monograph.	Addressed RMS to provide a revised DAR or corrigendum.
1(18)	Vol. 3, B.2.2.5 Oxidizing Properties	AT: The non acceptability of the used method is claimed by RMS but not mentioned in volume 1 level 4 as a data requirement. Therefore it should be stated here that the test has to be performed according EEC A21	Please, refer to comment at point 12.	See second data requirement in comment 1(12).
1(19)	Vol. 3, B.2.2.20 Shelf life	AT: The data gap is stated by RMS however not noted in volume 1 level 4 as a data requirement.	Two year shelf life study has been completed for GF-657. Study will be provided.	See first data requirement in comment 1(12).
1(20)	Vol. 3, B.2.2.22 Persistent foaming	AT: according Guideline 7109/VI/94-Rev. 6. GLP compliance is not necessary EFSA: The indicated requirements for GLP studies are at least arguable. It seems that according to Guidance document 7109/VI/94 rev. 6 ,there is no need to conduct for example the studies on persistent foaming and suspensibility in compliance with GLP.	Agreed. However, according to the notifier, GLP studies are now available and data in the monograph can be updated, if necessary by an addendum.	Addressed See also comment 1(12).

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(21)	Vol. 3, B.2.2.23 Suspensibility	AT: Result (value) is not reported; according Guideline 7109/VI/94-Rev. 6. GLP compliance is not necessary EFSA: The indicated requirements for GLP studies are at least arguable. It seems that according to Guidance document 7109/VI/94 rev. 6 ,there is no need to conduct for example the studies on persistent foaming and suspensibility in compliance with GLP.	Agreed. However, according to the notifier, GLP studies are now available and data in the monograph can be updated, if necessary by an addendum.	Addressed See also comment 1(12).
1(22)	Vol. 3, B.5.3.1 Analytical Method for soil	AT: Specification of soil used for residue analytical method is not reported	Monograph being updated to include the soil specification.	Addressed RMS to provide a revised DAR or corrigendum.
1(23)	Vol. 3, B.2.1.2, boiling point	NL: decomposes before melting should be decomposes after melting or decomposes before boiling	Monograph has been corrected to state decomposes before boiling.	Addressed RMS to provide a revised DAR or corrigendum.
1(24)	Vol. 3, B.5.3.1, analytical method for soil	NL: source and type of soil should be mentioned	Monograph being updated to include the soil specification.	Addressed RMS to provide a revised DAR or corrigendum.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(25)	Vol. 3, B.5.3.2	NL: It is not clear for which type(s) of water the validation results are obtained. Sampling site and characteristics of the surface water should be mentioned.	The types of water for which the methods are applicable have been amended. The sampling sites of the control water samples have been amended.	Addressed RMS to provide a revised DAR or corrigendum.
1(26)	Vol. 3, p. 23ff, References	EFSA: RMS to clarify why the references are given twice and in addition why the references related to volume 4 is listed here.	Copy and paste error. Monograph being amended to include the references at the right place.	Addressed RMS to provide a revised DAR or corrigendum.
1(27)	Vol. 3, p. 125 Analytical method for air in relation to Vol.1, p. 51, list of end points, definition of the residues	EFSA: It should be noted that as long as no residue definition for air is proposed an assessment of the respective analytical method is not possible. Furthermore, the given justification for no setting a residue definition should possibly be reconsidered. The exposure of operators, workers or bystanders during application has not been taken into account.	The residue definition for air has been added. The residue definition is the parent substance only.	Addressed RMS has amended the list of end points.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
1(28)	Vol. 4, C.1.1, Detailed information on the manufacturing process; identity of isomers, impurities and additives in relation to p. 39 of Vol	AT: Purity of starting material is not reported NL: Purity of the raw materials should be mentioned EFSA: Clarification is needed regarding the specified limit of the impurities, where a limit higher than 1 g/kg is proposed, because none of them is reliable taken the submitted batches int account. At least, it must be confirmed that a specified limit above the maximum value found in the batch analyses is acceptable in respect to the toxicological and ecotoxicological assessment.	According information received by the notifier, impurity specification have been proposed in order to account for manufacturing variability expected to occur on a large scale. In fact, as often happens for new active ingredients, batch analysis samples were prepared on a small pilot plant scale and, hence, the results may not reflect actual manufacturing experience. A list of raw materials with specifications being added.	Open point: RMS to report the purity of the starting material in a revised Volume 4 or a corrigendum. Data requirement: Applicant to provide actual batch analysis of the large scale production or a justification that specified limits above the maximum value found in the batch analyses is acceptable in respect to the toxicological and ecotoxicological assessment. Applicant stated that a large scale batch analysis will be available in 2007.
1(29)	Vol. 4, C 1.2 Identity of isomers, impurities and additives	AT: Specification of relevant impurities is missing		Open point RMS to provide the specified maximum value of the relevant impurity in a revised Volume 4 or corrigendum.
1(30)	Vol. 4, C.1.3, Detailed specification of the preparation ➔active	AT: Content of the *pure* active substance is missing in the formulation compositions.	The content of pure active substance is 98%	Addressed RMS to consider in a revised Volume 4 or corrigendum.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	ingredient			
1(31)	Vol. 4, C.1.3, detailed specification of the preparation ➔formulants	AT: CAS numbers of several formulants should be reported in volume 4 (confidential data)	Volume C being amended to include this information.	Open point RMS to provide CAS numbers of formulants in a revised Volume 4 or corrigendum.
1(32)	Vol. 4, C.1.4 Validation data for impurities	AT: Validation data for the relevant impurity Bis-CHYMP are not reported	Monograph being amended to include the validation data.	Open point RMS to provide validation data (incl. the used UV wavelength) for the analytical method used for the determination of the relevant impurity Bis-CHYMP in a revised Volume 4 or corrigendum. See also comment 1(33).
1(33)	Vol. 4, C.1.4.2, analytical method	NL: UV detection at 360 nm for BIS-CHYMP, doesn't correspond with §5.1.1 where UV-detection at 260 is mentioned.	The monograph being corrected to reflect the correct detection wavelength of 360 nm.	See open point in comment 1(32).

Comments received on reporting table, section Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1- B.5)

Reference to reporting table	MS / Notifier	Comment	EFSA response
1(12) Vol. 1, Level IV	DAS	A 2 year shelf life study has been completed and will be provided. by the end of June 2006 An oxidizing properties waiver will be completed and submitted for GF-657 by the end of June 2006. Based on the information available for the active ingredient and individual components, the formulation is considered to be non-oxidizing. The relative density can be calculated from the reported density value. Relative density is the density of the test substance at 20°C (0.937 g/mL) divided by the density of water at 4°C (1.000 g/mL). Thus the relative density is 0.937.	noted and indicated in the reporting table It should be noted that it is not sufficient that the information is given only the comments to the reporting table.
1(18) Vol. 3, B.2.2.5 Oxidizing Properties	DAS	Applicant to provide a shelf-life study as well as data on the relative density by the end of June 2006	noted
1(19) Vol. 3, B.2.2.20 Shelf life	DAS	Applicant to provide data on the oxidising properties of the formulation based on a theoretical assessment or on the EEC method A21 by the end of June 2006	noted

Comments received on reporting table, section Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1- B.5)

Reference to reporting table	MS / Notifier	Comment	EFSA response
1(28) Vol. 4, C.1.1, Detailed information on the manufacturing process; identity of isomers, impurities and additives in relation to p. 39 of Vol	DAS	A complete batch analysis study on production batches will be performed in 2007. Current production batches meet the specifications provided in the dossier.	noted and indicated in the reporting table
Analytical methods	NL	We agree with all the points in the reporting table, including the data requirements set in column 4	noted
Consultation report	NL	The data requirement on oxidising properties of the ppp is missing in chapter 3 (review report no 1(12)), and also data requirement 1(28) is missing (regarding the specifications of the technical material). No further comments.	noted
Phys chem. section	NL	We agree with all the points in the reporting table, including the data requirements set in column 4	noted

2. Mammalian toxicology

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(1)	Vol. 1, List of End Points, ADME	NL: In the box 'toxicologically significant compounds' it is stated: 'none'. This probably should be 'parent compound' or 'parent compound and metabolites'	Agreed. Should read "parent compound". DAR being amended.	Addressed.
2(2)	Vol. 1, List of End Points, Reproductive toxicity	NL: Reproductive NOAEL is 30 mg/kg bw/day. But this is the parental NOAEL. The reproductive NOAEL > 300 mg/kg bw/day.	Agreed. List of end-points being corrected. DAR being amended.	Addressed.
2(3)	Vol. 1, List of End Points, Summary	NL: The drinking water limit can be removed from the list of end points.	Agreed.	Addressed. RMS to provide a revised List of End Points.
2(4)	Vol. 1, 2.3.5 and Vol. 3, B.6.10, Drinking water limit	DE: Remark: Since according to EU rules and practice the drinking water limit for active compounds is set at 0.1 µg/l, it is not appropriate to derive a substance-specific maximum level that is higher by 2290 times.	DWL is usually calculated based on tox-endpoint (ADI). However, in compliance with EU-DW Directive the acceptable criteria for exposure is 0.1ug/l. Confirming that DWL >>EU-DW ensures large margin of safety to population (DAR being amended to include this explanation)	Addressed.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(5)	Vol. 1, 3.1, AOEL	DE: Proposal: It was noted that in the section "Background to the proposed decision" a long-term AOEL is proposed that is not mentioned in other parts of the DAR and that is not necessary – generally and in particular when the conditions of application for this a.i. are taken into consideration. Thus, this suggestion should be deleted.	Agreed. The level III being amended accordingly.	Open point RMS to provide a revised Vol.1, level 3. AOEL to be confirmed in an experts' meeting.
2(6)	Vol.1, App.3, List of end points	EFSA: please amend the following : - reproductive toxicity : indicate the NOAELs for the parents, for the offspring and for the reproductive effects - please move the results of acute and chronic neurotoxicity studies in the box Neurotoxicity - exposure scenarios : add numerical values (% of systemic AOEL)	List of end-points being corrected. Duplicate entry – reproductive NOAELs have been added, and neurotox results moved in DAR. % AOEL being added under exposure scenarios.	Addressed.
2(7)	Vol. 3, B.6.12 Dermal absorption	AT: When setting the dermal absorption rate of penoxsulam, the content of a.i. located in the skin was not regarded by the RMS as "absorbed".	EFSA: typing error. It is 0.04 %.	Dermal absorption rate was modified as for Addendum 1 (enclosed to the DAR), and is considered acceptable.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(7)	*continued* Vol. 3, B.6.12 Dermal absorption	However, considering the continuous decrease of this depot with time accompanied by a continuous increase of amount detected in urine, faeces, carcass and cage wash, in particular for the spray dilution, the amount deposited in the skin should be considered as bioavailable. Therefore dermal absorption rates (based on the values after 24 hours) should be corrected to approx. 12 % for the concentrate and approx. 18 % for the spray dilution. NL: The presentation of the results is limited. Based on the 2 tables, it is not clear whether there are serial non-detects or not. However, exposure was worst-case (24 hours) and the values of 2%/24 hours for the undiluted formulation and 0.4%/24 hours for the diluted formulation are supported. EFSA: the 24h value of absorption for the diluted formulation is 0.04%. However it is not the same in the list of end points (0.4%). Please clarify.		Open point RMS to provide a separate addendum 1 with revised dermal absorption. Dermal absorption to be discussed in an experts' meeting. New open point According to the agreed AOEL and dermal absorption, a confirmation/revision of the exposure estimates will be needed.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
2(8)	Vol. 3, B.6.10, Summary of mammalian tox, ARfD	NL: No ARfD was derived and NL agrees. However, the argumentation in the DAR is very limited, since the acute oral LD50 is just one of the criteria for the ARfD. Some further argumentation why the ARfD is not applicable would be appreciated.	DAR amended to indicate the argumentation which are related toxicological and general toxicological profile (Subchronic dose & developments profile).	Open point RMS to provide an addendum with the argumentation related to the ARfD. ARfD to be confirmed in an experts' meeting.
2(9)	Vol. 3, B.6.5, Long-term toxicity and carcinogenicity, Oral study in rats	DE: Data requirement: Historical control data of the performing laboratory on large granular lymphocytic leukaemia in Fisher rats as well as the cited publications should be made available to all MS	Range of historical control data from the performing laboratory are stated in the dossier. Notifier available to provide copies of cited publications.	Data requirement Notifier to provide a position paper on the relevance of large granular lymphocytic leukaemia in Fisher rats treated with penoxsulam. Open point Carcinogenicity of penoxsulam to be discussed in an experts' meeting.
2(10)	Vol. 3, B.6.12, dermal absorption	EFSA: the 24h value of absorption for the diluted formulation is 0.04%. However it is not the same in the list of end points (0.4%). Please clarify.	Typing error. It is 0.04 %. Corrected in endpoints list.	Addressed. See comment 2(7).
2(11)	Vol.3, B.6.15, List of information, tests and studies	EFSA: please amend the list of references according to the guidance document (i.a. including open literature in the table)	List of reference being amended.	Addressed. RMS to provide a revised list of references.

Comments received on reporting table, section Mammalian toxicology (B.6)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
2(9) Vol. 3, B.6.5, Long-term toxicity and carcinogenicity, Oral study in rats	DAS	Range of historical control data from performing laboratory is included in the dossier. Notifier to provide position a position paper on the relevance of large granular lymphocytic leukemia as well as cited publications by 30 Jun 2006.	Noted.
	NL	NL agrees with the answers provided by the RMS, the open points and with the points to be discussed in an expert meeting.	Noted.
List of endpoints	NL	NL: The drinking water limit can be removed from the list of end points.	Noted.

3. Residues

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(1)	Vol 1, level 3, end points	NL: TMDI = 0,0039% of standard European diet. TMDI = 0,022% as depicted in the end point list refers to the worst case Portuguese diet.	Correct. However RMS is of the opinion that the worst case should be referred in the list of end points. (DAR is already containing the worst-case)	Open point RMS to include TMDI according to WHO/FAO European diet and worst case national diet in the listing of end-points
3(2)	Vol. 3, B.7.1-1 Plant metabolism-Rice	EFSA: Comparability of the metabolism study with the cGAP should be clarified. The possible consequences of a later application in practice on the qualitative and quantitative findings in the metabolism study should be discussed.	Panicle initiation (the latest application timing) is roughly one month later than the application used in the rice metabolism study (5-6 leaf stage). The later application would still take place approximately 3 months prior to harvest, depending upon rice variety and environmental conditions. The majority of the plant growth (and therefore biological growth dilution) will take place after panicle initiation. In neither case would penoxsulam be applied to grain, leaving translocation as the only source of exposure to rice grain. While we don't know how much translocation would take place at the later application time, very little residues (<1 ppb) were observed in the mature grain with the earlier application.	Open point RMS provide an addendum on consideration of possible impacts of a later application in practice on the qualitative and quantitative findings in the rice metabolism study

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(3)	Vol. 3, B.7.1-1 Plant metabolism-Rice	EFSA: Total storage time of samples until finalisation of analysis is not very clear from the study. A repeated analysis was done" several weeks" after the initial analysis to prove storage stability. It should be clarified whether storage stability tests are available to cover the whole time of the experiment when samples were stored prior to analysis.	Initial analysis took place for all immature samples within 2 weeks of harvest. Mature rice and straw samples were analyzed within 2 months of harvest. Therefore, storage stability tests are unnecessary.	Addressed RMS to transfer statement into a corrigendum to DAR or to revise DAR
3(4)	Vol. 3, B.7.1-1 Plant metabolism-Rice	EFSA: The meaning of the straw samples numbering TP-1/TP-2 and Ph-1/Ph2, respectively, in table B.7.1-2 should be explained. Are these replicates or samples originated from different application mode (0.1 kg ai/ha vs 2x0.05 kg ai/ha)?	These are replicate analyses of the same samples and are not from different application modes.	Addressed RMS to transfer statement into a corrigendum to DAR or to revise DAR
3(5)	Vol. 3, B.7.1-1 Plant metabolism-Rice	EFSA: The decline of parent in straw seems evenly over time and comparable for both labels with the exception of Ph-labelled straw harvested 30 DTA, where residues are significant higher. Is there any explanation for this observation?	Differences between the two labels at 30 DAT are likely due to biological variability.	Addressed RMS to transfer statement into a corrigendum to DAR or to revise DAR

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(6)	Vol.3, B.7.2.1-1 Metabolism in goat	EFSA: The recoveries of radioactivity from goat metabolism should be clarified. It is stated in the DAR that >99% of recovered radioactivity was found in urine and faeces. Ca 6-11% and 7-15% of the daily dose have been recovered in urine and faeces, respectively. Thus the total recovery rate in the study seems rather low (max 26% of administered dose). Is there any reasonable explanation for this observation? A low recovery may also affect the validity of the study.	Approximately 6-15% of the applied radioactivity was recovered in the urine and faeces *daily*. In other words, ~6% of the dose was recovered in the urine on Day 1, 8% on Day 2, 9% on Day 3, 6% on Day 4 and 9% on Day 5 for a total of 38% of the applied radioactivity recovered in the urine. The daily recoveries for the faeces were: Day 1 7%, Day 2, 13%, Day 3, 13%, Day 4, 12% and Day 5, 15% for a total of 60% of the applied radioactivity. The radioactivity recovered cumulatively from each day's collection of urine and faeces is about 99%.	Addressed RMS to transfer statement into a corrigendum to DAR or to revise DAR
3(7)	Vol.3, B.7.2.1-2 Metabolism in hen	EFSA: It is stated in the findings that with exception of day 6 no detectable residues in eggs were found. However, this is in contradiction with the results displayed in the respective table 7.2.2-1 (all egg samples < LOD) and should be clarified.	All egg samples were less than the LOD. The monograph being revised to reflect this.	Addressed RMS to provide a revised table in a corrigendum to DAR or revise DAR

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(8)	Vol.3, B.7.3 Residue definition	EFSA: This paragraph elucidates the proposed residue definition for monitoring and it's appropriateness for enforcement purposes. Do these definitions also apply for risk assessment purposes or which are the proposed definitions for RA?	The proposed residue definition was intended to apply to both monitoring and risk assessment. Text in the monograph being revised with this clarification. Not necessarily, for risk assessment only those metabolites deemed of toxicological relevance are included with the parent.	Open point RMS to propose a residue definition for risk assessment in an addendum
3(9)	Vol.3, B.7.6 Residue trials	EFSA: For the reported results from residue trials it was distinguished between non-detects and values < 0.01 (LOQ). For the sake of clarity the limit of detection should be reported for these trials.	The limit of detection was set at 0.002 mg/kg, 20% of the LOQ of 0.01 mg/kg. This additional information being added to the monograph.	Addressed RMS to transfer statement into a corrigendum to DAR or to revise DAR
3(10)	Vol.3, B.7.6 Residue trials	EFSA: The comment concerns the parameters applicable to the analytical method employed in reside trials. For the linearity over concentration range the unit was reported as □g/ml and should be clarified.	The correct units are: µg/ml and the monograph being corrected.	Addressed RMS to transfer statement into a corrigendum to DAR or to revise DAR
3(11)	Vol.3, B.7.6.1 Storage stability	EFSA: It was concluded that residues are stable up to 197 days; however, further analysis after 24 month was scheduled. Do the current storage stability studies cover the storage time spent for the residue trials samples or	Some samples were held in frozen storage for a period exceeding 197 days. The maximum period of frozen storage prior to sample analysis was 688 days for some of the immature plant samples. Notifier provided an	Open point RMS to summarise additional storage stability data covering a period of 24 month in an

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(11)	*continued* Vol.3, B.7.6.1 Storage stability	what is the need for further investigations? Dow AgroSciences: Subsequent analysis of samples from this study confirmed that residues of penoxsulam in rice grain, straw and immature forage (plants) were stable in frozen storage for s period of at least 732 days (24 months).	update concerning stability after 24 months of frozen storage. Results confirmed that residues of penoxsulam were stable in rice grain, straw and immature forage (plants) for at least 24 months (732 days). Therefore, data from the storage stability study demonstrated stability of penoxsulam in residue trial samples over the maximum period of frozen storage encountered in the residue studies. This additional information was incorporated into the monograph.	addendum
3(12)	Vol.3, B.7.8 Livestock feeding study	EFSA: The view of RMS whether or not rice straw is used as a feeding stuff isn't consistent throughout the DAR. On one hand it is considered as a feeding stuff (metabolism studies), on the other hand it's not. Clarification is needed.	Rice straw is not used as a livestock feedstuff. The metabolism section (Conclusions following Vol.3, B.7.2.2) of the DAR corrected to remove a reference to rice straw as being used as a livestock feedstuff. This correction should remove the inconsistency in the DAR.	Addressed RMS to transfer statement into a corrigendum to DAR or to revise DAR
3(13)	Vol.3, B.7.9.1 Rotational crops	EFSA: The table (referred to as table B.7.9-1) with the TRR values found in the confined rotational crop study in the different RAC is lacking. For the sake of transparency this data should be presented.	Monograph being changed to add the concerned table.	Open point RMS to present total radioactive residues (TRR) in rotational crops in an addendum

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(14)	Vol.3, B.7.9.1 Rotational crops	EFSA: Apparently two new metabolites (BST and BSTCA) were identified in the crop rotation study, which were not found in the primary metabolism. The structure of these metabolites displayed in figure B.7.9-6 seems to be identical, clarification is needed on their real structure. Are these metabolites up-taken from the soil? If they are metabolised from 5-OH-DE-638 as stated by RMS, why weren't they found in the primary metabolism?	BST and BSTCA are soil metabolites and were likely taken up from the soil. The structure for the BST was corrected.	Open point RMS to discuss the role of metabolites BST and BSTCA not found in primary but in rotational crops in an addendum The structure for BST to be corrected in a corrigendum to DAR or revised DAR
3(15)	Vol.3, B.7.9.1 Rotational crops	EFSA: It is noted that the shortest pre-planting interval investigated is 90 days. EFSA supports the RMS proposal of a 90 days crop rotation restriction.	Agreed.	Addressed A proposal of a crop rotation restriction arose from the evaluation of the representative use and should be highlighted also in Vol.1 Level 1-3 of the DAR
3(16)	Vol.3, B.7.13 Import tolerances	EFSA: Was there already an import tolerance for penoxsulam/rice requested as one was proposed in the DAR?	Yes, an import tolerance of 0.01 mg/kg was requested.	Addressed
3(17)	Vol.3, B.7.15 Intake assessment	EFSA: The intake figures for Europeans are rather old. The most current version of GEMS/food (FAO/WHO) consumption data should be used for the assessment. However, the data	A new consumer exposure assessment being performed using the updated intake figures as an addendum to the monograph.	Open point RMS to perform a new consumer exposure/risk assessment in an

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
3(17)	*continued* Vol.3, B.7.15 Intake assessment	used in the calculation do not consider the intake by toddler/young children as the most vulnerable group. Even it will not alter the conclusion, the consumer risk assessment should be updated and reflect the current agreed standard.		addendum by taking into account the most recent GEMS/food diet figures and also consumption figures for young children
3(18)	Vol.3, B.7.15 Intake assessment	EFSA: It is noted that an exposure assessment via air is usually not part of the residue section. Also exposure via drinking water is normally not considered due to the European drinking water limit of 0.1 µg/L. An estimate for drinking water containing 229 µg/L penoxsulam as presented in the DAR doesn't correspond with the European standard and is rather confusing.	Agreed: monograph being updated by deleting this item. Note: by deleting this point, it should not be considered further as a data-gap.	Addressed Unless the European drinking water limit of 0.1 µg/L is not exceeded by the active substance or its metabolites no such exposure assessment is currently required

Comments received on reporting table, section Residues (B.7)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
	NL	NL agrees with the answers provided by the RMS and with the open points.	Noted.

4. Environmental fate and behaviour

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(1)	Vol.1, level 2, 2.5.1, definition of the residue	NL: the residue definition for air should be the parent by default and the residue definition for sediment is missing.	Agreed. The residue definition for air and sediment have been added. The residue definition for both compartments is the parent substance only.	Addressed RMS to consider in an amended DAR or corrigendum
4(2)	Vol.1, Annex 3, list of endpoints	NL: In the route of degradation box no metabolites are reported whereas the major metabolites should have been reported here.	Agreed. The list of endpoints has been amended.	Addressed
4(3)	Vol.1, Annex 3, list of endpoints	NL: Route of degradation-supplemental studies: Reported is 'no relevant metabolites', whereas major metabolites should have been reported.	Agreed. The list of endpoints has been amended.	Addressed
4(4)	Vol.1, Annex 3, list of endpoints	NL: Soil adsorption tests were performed for 17 soils. In Vol.3 it is stated that the sediment is not used and data from non European soils are treated as supplementary information. However, all values are included in the end points list without any extra information. Also the average value is based on all data and this is not correct. Non-European soils and sediment should not be used for the assessment (average value).	Agreed. The list of endpoints has been amended.	Data requirement Applicant to provide argumentation on their selection of Koc values used to calculate a mean value for use in PEC calculations. The applicant confirmed this argumentation will be provided by the end of June 2006. A position paper is required.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(5)	Vol.1, Annex 3, list of endpoints	NL: A column leaching study was evaluated and should be included in the list of endpoints as it was an acceptable study. An aged residue study and a lysimeter study were not submitted and are not required.	Agreed. The list of endpoints has been amended.	Addressed
4(6)	Vol.1, Annex 3, list of endpoints	NL: photolytic degradation: information about the major metabolites must be included in the list of endpoints.	Agreed. The list of endpoints has been amended.	Addressed
4(7)	Vol.1, Annex 3, list of endpoints	NL: degradation in water/sediment: major metabolites must be reported in the list of endpoints both for the water phase and for the sediment (5-OH). Now in the box relevant metabolites it is reported none, this is not correct.	Agreed. The list of endpoints has been amended.	Addressed
4(8)	Vol.1, Annex 3, list of endpoints	NL: PEC sediment: it is stated that the method of calculation is according to the GD 1090/2000. This is not the case, different equations are used.	The equations are different but the final result is the same. The DAR being amended in line with 1090/2000 rev1.	Addressed RMS to consider in an amended DAR or corrigendum

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(9)	Vol.1, Annex 3, list of endpoints	NL: residue definition: the residue definition for sediment is missing. The residue definition for air should be parent by default.	Agreed. The residue definition for air and sediment have been added. The residue definitions for both compartments is the parent substance only.	Open point Endpoints for definition of the residue to be updated to include a list of all major residues that require risk assessments as well a relevant residues for monitoring.
4(10)	Vol. 1, 2.5.1, groundwater Vol. 3, B.8.2.5. PECgw metabolites	EFSA: Vol.1 p. 11. The groundwater values written for BSTCA (and possibly 5-OH) should be updated in light of clarifications requested below, (vol. 3 comment) Vol. 3 p. 52. There is a need for the rapporteur to clarify, or get the notifier to clarify the basis for the metabolite PECgw calculations. In particular EFSA cannot agree the use of the formation % proposed (19%) for the metabolite BSTCA. It is also not clear what paddy water DT50 was used to calculate $TWA_{pw,t(close)}$ for both 5-OH and BSTCA.	The amount of BSTCA metabolite was still increasing at end of anaerobic study. The PECgw for this metabolite will be re-calculated and DAR amended	Data requirement Applicant to clarify all assumptions used to calculate metabolite PECgw, to include clear information on how $TWA_{pw,t(close)}$ for both 5-OH and BSTCA were estimated and to present new calculations that use a realistic worst case formation fraction of BSTCA. The applicant has confirmed that the information requested and the new calculations will be provided by the end of June 2006. An updated modelling report is appropriate.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(11)	Vol. 1, Endpoints, route of degradation (aerobic) in soil, mineralisation after 100 days	EFSA: Add for phenyl and triazolopyrimidine ring radiolabels	Agreed. The list of endpoints has been amended.	Addressed
4(12)	Vol. 1, Endpoints, route of degradation (aerobic) in soil, Non extractable residues after 100 days	EFSA: Add for phenyl and triazolopyrimidine ring radiolabels	Agreed. The list of endpoints has been amended.	Addressed
4(13)	Vol. 1, Endpoints, route of degradation (aerobic) in soil, Relevant metabolites	EFSA: Add 5-OH (max 15-40%AR at 14-58 days) and BSTCA (max 29-53%AR at 14-120 days)	Agreed. The list of endpoints has been amended.	Addressed
4(14)	Vol. 1, Endpoints, route of degradation in soil, Supplemental studies, anaerobic degradation	EFSA: Add for phenyl and triazolopyrimidine ring radiolabels and list the major metabolites: 5-OH (max 33%AR at 14 days) and BSTCA (max 19%AR at 120 days)	Agreed. The list of endpoints has been amended.	Open point 'for phenyl and triazolopyrimidine ring radiolabels' still needs to be added to the endpoints to put the mineralization and NER values in context.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(15)	Vol. 1, Endpoints, route of degradation in soil, Supplemental studies, soil photolysis	EFSA: Add for phenyl and triazolopyrimidine ring radiolabels and list the major metabolites: 2 amino-TP (max 10.4%AR at 37 days) and BSTCA (max 11.1%AR at 30 days) also add: moist soil first order DT50 19 days at 25°C summer sunlight at 40°N (r^2=0.9)	Agreed. The list of endpoints has been amended.	Open point 'for phenyl and triazolopyrimidine ring radiolabels' and 'moist soil first order DT50 19 days at 25°C summer sunlight at 40°N (r^2=0.9)' still need to be added to the endpoints.
4(16)	Vol. 1, Endpoints, rate of degradation in soil, method of calculation	EFSA: Add that linear first order kinetics was for the parent compound and that non linear Modelmaker compartment modelling was used for the metabolites 5-OH and BSTCA.	List of endpoints being amended accordingly.	Open point 'non linear first order Modelmaker compartment modelling' still need to be added to the endpoints in the context of the metabolites
4(17)	Vol. 1, Endpoints, rate of degradation in soil, laboratory studies	EFSA: For parent aerobic the range needs correcting to 2**2**-58 days. For parent anaerobic please add the soil DT50 of 8.8 days. The DT50 for the major metabolites need adding (5-OH and BSTCA for aerobic studies and 5-OH for anaerobic studies).	Agreed. The list of endpoints has been amended.	Open point The DT50 for the major metabolites (5-OH and BSTCA for aerobic studies and 5-OH for anaerobic studies) still need to be added to the endpoints.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(18)	Vol. 1, Endpoints, rate of degradation in soil, Degradation in the saturated zone	EFSA: Please amend to: data not submitted, not required.	Agreed. The list of endpoints has been amended.	Addressed
4(19)	Vol. 1, Endpoints, rate of degradation in soil, Field studies	EFSA: please clarify that the DT50/90 currently quoted are for rice paddy water and that DT50 in the underlying paddy soil was < 1 day.	Agreed. The list of endpoints has been amended.	Addressed
4(20)	Vol. 1, Endpoints, rate of degradation in soil, soil accumulation and plateau concentration	EFSA: Please amend to: data not submitted, not required	Agreed. The list of endpoints has been amended.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(21)	Vol. 1, Endpoints, soil adsorption/desorption Vol. 3, B.8.2.1 Batch sorption	EFSA: For parent penoxsulam in the endpoints and on p 26 vol. 3, Table B.8.1.2-2, the kf value for the Amagon soil would appear to be incorrect, (is not consistent with the mean Kd and Koc quoted for this soil). Please check and amend as appropriate. In the endpoints please add the 1/n value associated with each Kf quoted.	Agreed. The Kf value for the Amagon soil has been verified as correct. The list of endpoints has been amended to include the 1/n values associated with each Kf value.	Applicant has stated in its comments that the Kf and 1/n values for the Amagon soil reported in the original study were incorrectly calculated. Data requirement Applicant to provide an audited corrigendum to the original report to correct the Kf, 1/n and Kfoc values for the Amagon soil. Provision by the end of June 2006 would be appreciated. 1/n values have been added to the endpoints so this aspect of the original comment is addressed..
4(22)	Vol. 1, Endpoints, soil adsorption/desorption	EFSA: Please add the Kd and Koc values for the major soil metabolites 5-OH and BSTCA and provide a statement that the adsorption behaviour of these metabolites appears to be pH independent.	Agreed. The list of endpoints has been amended.	Addressed
4(23)	Vol. 1, Endpoints, Mobility in soil, column	EFSA: Please add the endpoints from this study that is available and noted	Agreed. The list of endpoints has been amended.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	leaching	as acceptable in Vol.3 p29-30 .		
4(24)	Vol. 1, Endpoints, Mobility in soil, aged residues leaching and Lysimeter/field leaching studies	EFSA: Please amend to: data not submitted, not required	Agreed. The list of endpoints has been amended.	Addressed
4(25)	Vol. 1, Endpoints, PEC soil, method of calculation PEC soil for metabolites is required	EFSA: For parent please add to this box the assumptions used i.e.: No crop interception, Koc 94 L/kg, DT50 8.8 days (soil phase of anaerobic study worst case compare to the field study where the DT50 was <1 day). PEC should also be added for the 2 major soil metabolites (global max values calculated should be sufficient) Of course in the method of calculation box the assumptions used (formation %, Koc,) should be identified.	List of end points being amended accordingly. End points amended List of end points being amended accordingly. End points amended	Open point RMS to check that Koc were not used to calculate the metabolite PEC. If they were used the values should be added to the method of calculation box.
4(26)	Vol. 1, Endpoints, Route and rate of degradation in water, photolytic degradation.	EFSA: Please list the major metabolites produced and their max formation % (TPSA, 2-amino-TP, 5-OH-2-amino-TP, BSA) Please tabulate the available DT50 for these photolytic metabolites.	Agreed. The list of endpoints has been amended.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(27)	Vol. 1, Endpoints, Route and rate of degradation in water, Degradation in water/sediment.	EFSA: Please list the DT50 that are available for the 5-OH metabolite and distribution between water and sediment of the major metabolites (5-OH and BSTCA)	Agreed. The list of endpoints has been amended.	Addressed
4(28)	Vol. 1, Endpoints, PEC surface water, method of calculation. PESsurface water for metabolites is also required	EFSA: For parent please add to this box the assumptions used i.e.: based on paddy water concentrations from field studies that were comparable to step 1c calculations that assumed, no crop interception, Koc 94 L/kg and DT50 6.6 days (anaerobic whole system value). PEC should also be added for the major water metabolites (5-OH, BSTCA, BSA, TPSA, 2-amino-TP, 5-OH-2-amino-TP, global max values calculated for each would be sufficient). Of course in the method of calculation box the assumptions used (step 1b, formation %, DT50, Koc,) should be identified.	End points amended End points amended	Open point RMS to check that Koc were not used to calculate the metabolite PEC. If they were used the values should be added to the method of calculation box.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(29)	Vol. 1, Endpoints, PEC sediment, method of calculation. PECsediment for metabolites, 5-OH, BSTCA, PCA-5-OH, BSTCA –OH is required.	EFSA: For parent please add to this box the assumptions used i.e.: based on paddy water concentrations from step 1b calculations that assumed , no crop interception, Koc 94 L/kg and DT50 23 days (aerobic whole system value). PEC sediment for metabolites need including in the endpoints. In the DAR these were only reported in the ecotoxicology section (Section B.9.2.11 p. 86). Please transfer these to the fate and behaviour endpoints sheet and note that the % formation in the sediment water study for BSTCA in this ecotox section is incorrect (0.3%AR) so for BSTCA the PEC calculated should be corrected to account for slightly higher 2.2%AR present in the sediment of the sediment water study.	End points amended. End points amended.	Addressed

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(30)	Vol. 1, Endpoints, PEC groundwater, method of calculation.	EFSA: Please add to this box the assumptions used i.e.: step1 no crop interception, parent: Koc 94 L/kg and DT50 5.3 days (anaerobic water phase value, comparable to that seen in the water phase of the field study). 5-OH: formation 33%, DT50 needs clarification, possibly whole system value 5.1 days (anaerobic water phase value?, worst case compared to field study where water concentrations were not detectable, <3µg/L) and Koc 59 L/kg BSTCA: formation 19%, DT50 unknown, needs clarification (anaerobic water phase value. Note there is an issue with this, see point 1 above.) and Koc 174 L/kg	End points amended. For 5-OH and particularly BSTCA, please see comment at point 4 (10) above.	Open point After data requirement at 4(10) has been addressed the endpoints will need appropriately updating with the necessary information in the method of calculation box.
4(31)	Vol. 3, B.8.3.2, PECsoil off-crop	NL: the mean DT_{50},lab was used for calculation whereas the most conservative, i.e. the highest, value should have been used.	Agreed. DAR being amended	Addressed RMS to consider in an amended DAR or corrigendum

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
4(32)	Vol. 3, B.8.3.3, PECsoil metabolites	NL: the mean DT_{50},lab was used for calculation of the PEC for BSTCA whereas the most conservative, i.e. the highest, value should have been used.	Agreed. DAR being amended	Addressed RMS to consider in an amended DAR or corrigendum
4(33)	Vol. 3, B.8.5.3, PECsediment	NL: the equations used for the calculation of PECsed are different from the ones mentioned in SANCO/1090/2000. Why? Why is the calculation not according to this GD?	Please refer to comment at point 8. DAR being amended.	Addressed RMS to consider in an amended DAR or corrigendum
4(34)	Vol. 3, B.8.8.3, residue definition for surface water	NL: the residue definition for sediment is missing.	Agreed. The residue definition for sediment has been added. The residue definition is the parent substance only.	Addressed RMS to consider in an amended DAR or corrigendum
4(35)	Vol.3, B.8.8.4, residue definition for air.	NL: the residue definition for air should be the parent by default.	Agreed. The residue definition for air has been added. The residue definition is the parent substance only.	Addressed RMS to consider in an amended DAR or corrigendum
4(36)	Vol. 1, Appendix 3, List of end points: Photolytic degradation	AT: Four major photoproducts were found in photolysis study: TPSA, BSA, 2-amino-TP, 5-OH-2-amino-TP. These metabolites were not mentioned in endpoint list. Additionally the photolytic degradation (e.g. DT50) of major metabolites have to be stated.	Agreed. The list of endpoints has been amended.	Addressed.
4(37)	Vol. 1, Appendix 3, List	AT: For the distribution in water/sediment system no relevant metabolites were mentioned. However major	Agreed. The list of endpoints has been	Addressed.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	of end points: Route and degradation in water	metabolites (5-OH-DE-638 and BSTCA) were found in water and sediment phase of water/sediment study and should be stated in endpoint list.	amended.	

Comments received on reporting table, section Environmental fate and behaviour (B.8)

Reference to reporting table	MS / Notifier	Comment	EFSA response
4(4) Vol.1, Annex 3, list of endpoints	DAS	Applicant to provide argumentation on their selection of Koc values used to calculate a mean value for use in PEC calculations either in a compendium format or amending the DAR by the end of June 2006	Date of provision of the information noted and included in the reporting table.
4(4)	NL	We agree on the Data requirement that the Applicant is to provide argumentation on their selection of Koc values used to calculate a mean value for use in PEC calculations. The endpointslist has been made clear by RMS.	Noted.
4(10) Vol. 1, 2.5.1, groundwater Vol. 3, B.8.2.5. PECgw metabolites	DAS	Applicant to clarify all assumptions used to calculate metabolite PECgw, to include clear information on how $TWA_{pw,t(close)}$ for both 5-OH and BSTCA were estimated and to present new calculations that use a realistic worst case formation fraction of BSTCA either in a compendium format or amending the DAR by the end of June 2006	Date of provision of the information and new calculations noted and included in the reporting table.
4(10)	NL	We agree on the data requirement that Applicant is to clarify all assumptions used to calculate metabolite PECgw, to include clear information on how $TWA_{pw,t(close)}$ for both 5-OH and BSTCA were estimated and to present new calculations that use a realistic worst case formation fraction of BSTCA.	Noted
4(17)	NL	We agree that the DT50 values for the major metabolites still have to be added to the LoEP.	Noted

Comments received on reporting table, section Environmental fate and behaviour (B.8)

Reference to reporting table	MS / Notifier	Comment	EFSA response
4(21) Vol. 1, Endpoints, soil adsorption/desorption Vol. 3, B.8.2.1 Batch sorption	DAS	Examination of the raw data used to determine the Freundlich coefficients for the Amagon identified that a formula had been reversed. The correct Kf value of 0.30 is consistent with the single concentration Kd value of 0.39. The endpoints document has been amended with the correct Kf and 1/n values for the Amagon soil. Note that the soil sorption results for the Amagon soil have not been used in the exposure assessment calculations, therefore this correction does impact any PEC calculations.	Noted. For formal reasons a data requirement will remain. However it has been reworded from the original 'Applicant to address the reported discrepancy between the adsorption measured in the Amagon soil of 40mL/g (Kdoc value) and 382mL/g (Kfoc value 1/n=1.09).' in light of this comment. Please provide the RMS an audited corrigendum to the original report. Provision by the end of June 2006 would be appreciated.
4(21)	NL	We agree that the discrepancy between measured Kdoc and Kfoc should be clarified.	Noted
4(25)	NL	Open point: It seems that calculation of the PECmax for the metabolites has been based on the results of the parent corrected for formation rate and molecular weight. If the has been the case the data as presented in the LoEP are correct. In this case these calculations can be accepted for global max. PEC.	Noted.
4(28)	NL	Open point: see comment at 4(25)	Noted

Comments received on reporting table, section Environmental fate and behaviour (B.8)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
4(30) Vol. 1, Endpoints, PEC groundwater, method of calculation.	DAS	This data requirements will be fulfilled as consequence of Vol. 1, 2.5.1, groundwater & Vol. 3, B.8.2.5. PECgw metabolites resolution	Noted
4(30)	NL	We agree with the comment of EFSA and the open point formulated regarding the LoEP	Noted
	NL	For the fate and behaviour part of the substance the other open points mentioned in the reporting table are not of major importance. All Dutch comments have been treated adequately. We don't have any comments on the consultation report regarding fate and behaviour.	Noted

5. Ecotoxicology

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(1)	Vol. 1, List of End Points, Effects on other arthropod species	NL: In the heading please replace "Effect" by "Adverse effect". It should be clearly stated (e.g. in a footnote) that the "–" sign means a positive effect on fecundity.	List of end points being amended as suggested.	Addressed, however 'Effect' is the wording normally used in the heading. A footnote has been added as suggested.
5(2)	Vol. 1, Point 2.1.3: " When PENOXSULAM is used in a rice field, growers will be encouraged to use in this paddy additional herbicides (if required) with modes of action other than ALS inhibition (either in tank mix or in sequential programs). When resistance to an ALS inhibitor is suspected or confirmed in a field, it is recommended not to apply PENOXSULAM alone,	FR: such recommendations seem not to be relevant in the frame of the DAR for a particular active substance. We suggest to delete it.	Agreed. It is dealing with the practices related to the authorizations of products by Member States and not to the risk assessment.	Addressed. RMS to consider in a revised DAR/corrigendum.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
cont. 5(2)	but only in a program which includes an herbicide with another mode of action (eg. triclopyr, bentazone, propanil, etc.…) to control the suspected resistant weed."			
5(3)	Vol 1, listing of endpoints, long term risk assessment to mammals. This comment also refers to volume 3, point B.9.3.	FR: a justification for not taking into account of the NOAEL of 25 mg as/kg bw/d in the rabbit is necessary.	The maternal body weight effects observed in the rabbit developmental study may be considered to be relevant to long term mammalian risk assessment. Therefore, the mammalian risk assessment being amended to take into account the NOAEL=25 mg/kg/d in the rabbit developmental study.	Open point: RMS to present the revised assessment in a revised DAR/corrigendum. List of end points has been amended.
5(4)	Vol.1, list of endpoints	EFSA: Please add a proposal for classification and labelling with regard to ecotoxicological data.	The list of endpoints being amended to include the classification and labelling proposal.	Addressed, however the correct wording should be: N: Dangerous for the environment R50/53: Very toxic to aquatic organisms, may cause long term-adverse effects in the aquatic environment

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(5)	Vol. 1, List of endpoints, TERs for birds	EFSA: Since off-crop scenarios are covered by the rice-paddy scenarios, which all have TERs above the trigger, it is not necessary to include the off-crop values for standard species in the list of endpoints. It would be fine with a footnote that explains that the TER values have been calculated based on the sum of dietary and drinking water ETE A box with a short explanation on how the risk assessment for the metabolites were conducted would be useful. Then it is not necessary to present TER values for all scenarios for the metabolites.	The endpoints being amended as suggested.	Addressed. List of end points has been amended.
5(6)	Vol. 1. List of endpoints, Toxicity/exposure ratio for aquatic organisms	EFSA: Annex VI triggers of 10 and 1 are indicated with a reference to SANCO/1090/2000. In the final report of June 2003 these triggers are not mentioned. The in-field risk assessment should be performed at MS level taking into consideration specific local conditions, agricultural practices and particular aspects of environmental protection. Hence for the in crop assessment no specific	Agreed, the endpoints will be amended	Addressed. List of end points has been amended.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(6)	*continued* Vol. 1. List of endpoints, Toxicity/exposure ratio for aquatic organisms	triggers should be indicated, rather it should be stated that this is to be considered at Member State level taking into account the above mentioned local conditions.		
5(7)	Vol. 3, B.9.2.11, Effects in aquatic organisms; exposure, hazard and risk assessment	NL: On page 83 (Refined risk assessment for aquatic plants) the endpoint for aquatic plants was taken as the ErC50 from the microcosm study. According to the Guidance document on Aquatic Toxicology the endpoint in microcosm studies is taken as the NOEC. It should be considered whether in this particular study the NOEC should be the endpoint. Also, it should be better underpinned why the growth rate was chosen as the endpoint instead of the number of fronds.	The study should be considered as a single species study performed with more realistic exposure conditions, as it is aimed to refine the EC50 value of Lemna. A single species study with a modified exposure regime may be used to refine the risk assessment, provided the initial PEC is used and there is no modification of the trigger TER value of 10 (as stated in Guidange document on Aquatic Toxicology, SANCO/3268/2001 and HARAP). The duration of the test was 14 days longer than the standard test (in accordance to point 5.4.2.1 of the guidance document SANCO/3268/2001) in order to allow a certain environmental fate to take place and also in order to take account of	Open point: The risk to aquatic plants to be discussed in an experts' meeting. See also 5(9, 13, 16)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(7)	*continued* Vol. 3, B.9.2.11, Effects in aquatic organisms; exposure, hazard and risk assessment		the recovery. Growth rate generate more relevant information on recovery potential than frond count. The refined TERlt exceeds the uncertainty factor of 10, associated with protection of untested species.	
5(8)	Vol. 3, Point 9.2.1-1, Acute toxicity to fish-rainbow trout	DE: The mean body length of the rainbow trout used in the test (2.9 cm) was not in accordance with OECD guideline 203 (5.0 ± 1.0) and EEC method C.1 (6.0 ± 2.0 cm). Although this deviation is not believed to have an impact on the result or the validity of the study, it should be mentioned in the summary.	DAR being amended to account the suggested change.	Addressed. RMS to consider in a revised DAR/corrigendum.
5(9)	Vol. 3, Point 9.2.11, Summary of effects in aquatic organisms – Exposure, hazard and risk assessment	DE: For refinement of the risk assessment on aquatic plants a higher tier meso-/microcosm study is needed. The chronic 28-day study with *Lemna* is a single species test under semi-natural condition that cannot be considered as a higher tier meso/microcosm	We are not fully agree. Please refer also to comment to Point 9.Tthe objective of the higher tier Lemna study was not intended to be a meso/microcosm one; we are of the opinion that it is not necessary to test the whole aquatic plant community as the first step in the refinement of the risk assessment for	Open point See 5(7)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(9)	*continued* Vol. 3, Point 9.2.11, Summary of effects in aquatic organisms – Exposure, hazard and risk assessment	study. This study can only provide an appropriate endpoint for a refined assessment on effects on the tested species *Lemna* but not on the whole aquatic plant community. Therefore the risk assessment on aquatic plants has not be completed yet, and no safe use has been demonstrated so far.	aquatic plants. According the Guidance Document on Aquatic Toxicity (SANCO/3268/2001) and HARAP guidance, a single species study in which a modified exposure regime is tested to more realistic exposure conditions, including relevant environmental fate processes, may be used to refine the risk assessment, provided the initial PEC is used and there is no modification of the TER trigger. Both of these above said provisions were followed in the refined risk assessment, showing any unacceptable risk to aquatic plants and the demonstrating a safe use of the product.	

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(10)	Vol. 3, Point B.9.6.2, Effects on earthworms	DE: In table B.9.6.2/2 (TER-calculation for the risk assessment for earthworms) the corresponding reference (formulation or active substance) is wrongly indicated. In addition, the toxicity value is an LC_{50} and not an EC_{50} as stated in table B.9.6.2/2. However, these shortcomings do not change the outcome of the ERA.	Typographic error. Being corrected. .	Addressed. RMS to consider in a revised DAR/corrigendum.
5(11)	Vol. 3, Point B.9.10, Effects on biological methods of sewage treatment	DE: A valid study is reported here, indicating no risk of the test substance. However, this result is not mentioned at all in the list of endpoints.	List of end points being amended to add this information.	Addressed. List of endpoints has been amended.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(12)	Volume 3, annex B. General comment	FR: the risk assessment is based on tractor application technology only, it does not cover aerial applications mentioned as possible treatment technology under volume 1, point 1.4.3: " DE-638 can be applied …through adapted aeroplanes for aerial applications in the regions where this practice is allowed". It should be stated clearly that this practice is not covered by the EU assessment.	Aerial application is not allowed at all in Italy and in many other Member States. However some Member State, in particular conditions, may require the application of product by the aerial way. However, we agree that the current EU assessment do not cover this practise and this issue should be addressed at Member State level.	Open point: RMS to clearly indicate in the list of intended uses that the assessment only covers tractor application technology.
5(13) *cont.* 5(13)	Volume 3, annex B, point B.9.2.11 table B.9.2.11/4, vascular plants Standard ErC50: 0.587 mg product/L (0.0126 mg a.s./L) and conclusions from risk assessment page 81: "The growth rate was selected as the endpoint for use in the refined risk	FR: the study also mentions an EC50 based on frond number, of 0.00499 mg a.s./L. This value was disregarded also in the first tier risk assessment. It is suggested that recovery is taken into account if available data indicate that recovery is expected in general. To our opinion, a general recovery may not be expected from the information on Lemna only (which potential from recovery is high compared to other vascular species. This potential for recovery should be	See comment. Please refer also to comment to Point 9. The frond number is not a population level endpoint with ecological relevance to populations. Infact, this is a similar situation with the algal toxicity bioassays, where it may be considered that effects on individual algal cells are not relevant to population level risk assessment, but rather effects on populations of cells. The persistence of populations in the natural environment depends also upon the dynamic parameter of the growth rate of the population which is a factor that	Open point See 5(7)

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
	assessment because this parameter measures the effect on the population and indicates the long-term potential for recovery of the population."	discussed prior to be used into the risk assessment.	counterbalances the death rate of the population. Actually, the individual counts of organisms, fronds or algal cells are static measures of the population size at a particular time and, hence, do not reflect the ongoing growth rate of the population, which is necessary to maintain the species in the environment. Therefore, effects on the growth rate of the population are considered as necessary, as relevant, in the risk assessment of adverse effects of exposure to pesticides on the long term persistence of the species in the environment.	
5(14)	Vol.3, B.9.11 References relied on	EFSA: For the reference IIA 8.1.2/02 a "b" is missing after 2000	Reference list being corrected.	Addressed
5(15)	Vol. 3, page 79	EFSA: The table 10.2-4a seems to have a wrong number. Please amend to Table B.9.2.11/5	The concerned table being corrected.	Addressed. RMS to consider in a revised DAR/corrigendum.

No.	Column 1 Data point based on draft assessment report or comments from MS	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (i) Co-rapporteur, and (ii) Rapporteur	Column 4 Data requirement or Open Point (if data point not addressed or fulfilled) (Annex point)
5(16)	Vol. 3, B.9.2.11, page 83 Refined risk assessment for aquatic plants	EFSA: A justification for why the endpoint based on frond number was disregarded for the risk assessment is needed.	Please refer to comments to Point 9 and point 15.	Open point See 5(7)
5(17)	Vol. 3, B.9.5 Effects on other arthropod species	EFSA: A study on a foliage dwelling species is lacking. Two crop relevant species in addition to the standard species are required.	Off-field HQ values for indicator species are <2 . The indicator species T.pyri, which was affected in In-crop Tier I, was found to be unaffected in extended laboratory study. One additional foliage dwelling species, C.carnea, was found to be unaffected in a standard laboratory test. Therefore, no additional study are deemed as necessary (SANCO/10329/2002).	Addressed
5(18)	Vol.3 B.9.2.11, p. 86 Tables B.9.11/12 and 13	EFSA: Maximum mass % applied radioactivity for BSTCA in these tables should be 2.2.	Agreed. The value and accompanying risk assessments being amended.	Addressed. RMS to consider in a revised DAR/corrigendum.
5(19)	Table B.9.2.9.4/1	is corrupted. It prints out in a single column over a couple of pages.	RMS will provide a new electronic version of the monograph after all the necessary amendments are performed, after the EWG.	Addressed. RMS to consider in a revised DAR/corrigendum.

Comments received on reporting table, section Ecotoxicology (B.9)			
Reference to reporting table	MS / Notifier	Comment	EFSA response
	NL	NL agrees with the answers provided by the RMS, the open points and with the points to be discussed in an expert meeting.	Noted