CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance 2-naphthyloxyacetic acid[1]

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SUMMARY

2-naphthyloxyacetic acid is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[3], as amended by Commission Regulation (EC) No 1095/2007[4]. In accordance with Article 21(1) of the Regulation, France, being the designated rapporteur Member State (RMS), provided an initial evaluation of 2-naphthyloxyacetic acid in the format of a Draft Assessment Report (DAR), which was received by the EFSA on 30 October 2007. The European Commission examined 2-naphthyloxyacetic acid in accordance with Article 24a of the Regulation and it was concluded that there were clear indications of harmful effects, leading to the adoption of a decision on non-inclusion in Annex I to Council Directive 91/414/EEC, in accordance with Articles 24f and 25 of the Regulation.

Following the Commission Decision of 26 January 2009 (2009/65/EC)[5] concerning the non-inclusion of 2-naphthyloxyacetic acid in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant L. Gobbi s.r.l. made a resubmission application for the inclusion of 2-naphthyloxyacetic acid in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[6]. The resubmission dossier included further data in response to the issues identified in the conclusions leading to the Decision on non-inclusion, as set out in the Review Report (SANCO/2678/08 – rev.0).

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Italy, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 21 May 2010.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 28 May 2010. The DAR was also distributed for comments. The EFSA collated and forwarded all comments received to the European Commission on 13 July 2010.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the European Commission requested the EFSA to conduct a focused peer review in the areas of mammalian toxicology and ecotoxicology, and deliver its conclusions on 2-naphthyloxyacetic acid.

[1] On request from the European Commission, Question No EFSA-Q-2010-01021, issued on 27 April 2011.
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[3] OJ L 379, 24.12.2004, p.13
[4] OJ L 246, 21.9.2007, p. 19
[5] OJ L 23, 27.1.2009, p.33
[6] OJ L 15, 18.01.2008, p.5

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The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of 2-naphthyloxyacetic acid as a plant growth regulator on tomatoes, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

Data gaps were identified in the section on physical and chemical properties and analytical methods.

No data gaps or critical area of concern were identified in the mammalian toxicology section.

In the residues section a substantial number of data gaps were identified. The residue definitions for risk assessment and for monitoring could not be agreed. Consequently, a consumer risk assessment could not be conducted.

The data available on fate and behaviour in the environment are essentially sufficient to carry out the required environmental exposure assessments at EU level for the representative uses. However, the identification of the major aquatic metabolites was not available. Once this data gap is fulfilled the exposure and risk assessments for these metabolites might need to be updated. The potential for groundwater exposure from the representative uses by 2-naphthyloxyacetic acid above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by the relevant FOCUS groundwater scenarios.

Various data gaps were included in the ecotoxicology section. A data gap was identified to address the risk to bees from 2-naphthyloxyacetic acid, as well as the long-term risk to earthworms. A data gap also remains to address the risk to non-target soil macro-organisms for the representative field uses. Furthermore, the applicant should submit data to address the acute toxicity of 2-naphthyloxyacetic acid to warm-water fish. Finally, a data gap was identified to address the effects of 2-naphthyloxyacetic acid on biological methods of sewage treatment. An in-field no-spray buffer zone of 5 m is required to obtain a low risk for 2-naphthyloxyacetic acid to non-target plants.

KEY WORDS

2-naphthyloxyacetic acid, peer review, risk assessment, pesticide, plant growth regulator

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BACKGROUND

Legislative framework

Commission Regulation (EC) No 2229/2004[7], as amended by Commission Regulation (EC) No 1095/2007[8], lays down the detailed rules for the implementation of the fourth stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC. This regulates for the European Food Safety Authority (EFSA) the procedure for organising, upon request of the European Commission, a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State.

Commission Regulation (EC) No 33/2008[9] lays down the detailed rules for the application of Council Directive 91/414/EEC for a regular and accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC but which were not included in Annex I. This regulates for the EFSA the procedure for organising the consultation of Member States and the applicant(s) for comments on the Additional Report provided by the designated RMS, and upon request of the European Commission the organisation of a peer review and/or delivery of its conclusions on the active substance.

Peer review conducted in accordance with Commission Regulation (EC) No 2229/2004

2-naphthyloxyacetic acid is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004, as amended by Commission Regulation (EC) No 1095/2007.

In accordance with Article 21(1) of the Regulation, France, being the designated rapporteur Member State (RMS), provided an initial evaluation of 2-naphthyloxyacetic acid in the format of a DAR (France, 2007), which was received by the EFSA on 30 October 2007. In accordance with Article 24 of the Regulation, the EFSA dispatched the DAR to the applicant 2-NOA Task Force on 3 March 2008 for consultation and comments. The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 24e, to withdraw support for the inclusion of 2-naphthyloxyacetic acid in Annex I to Council Directive 91/414/EEC.

In accordance with the provisions of Article 24a of the Regulation, the European Commission examined 2-naphthyloxyacetic acid, following which it was concluded that there were clear indications of harmful effects, leading to the adoption of a decision on non-inclusion in Annex I to Council Directive 91/414/EEC, in accordance with Articles 24f and 25 of the Regulation.

Peer review conducted in accordance with Commission Regulation (EC) No 33/2008

Following the Commission Decision of 26 January 2009 (2009/65/EC)[10] concerning the non-inclusion of 2-naphthyloxyacetic acid in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant L. Gobbi s.r.l. made a resubmission application for the inclusion of 2-naphthyloxyacetic acid in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the conclusions leading to the Decision on non-inclusion, as set out in the Review Report (European Commission, 2008), as follows:

the information available was insufficient to satisfy the requirements set out in Annex II and Annex III of Directive 91/414/EEC, in particular with regard to:

[7] OJ L 379, 24.12.2004, p.13
[8] OJ L 246, 21.9.2007, p.19
[9] OJ L 15, 18.01.2008, p.5
[10] OJ L 23, 27.1.2009, p.33

- the substantial lack of toxicology data, with particular reference to long-term toxicity (carcinogenicity) and reproductive toxicity
- the substantial lack of data on plant metabolism
- the substantial lack of data to assess the risk to consumers
- the substantial lack of data to assess the risk to birds and mammals
- the substantial lack of data to assess the risk to aquatic organisms
- the substantial lack of data to assess the risk to non-target arthropods, earthworms and soil micro- and macro-organisms

and concerns were identified with regard to:

- the consumer exposure
- the operator and worker exposure
- the toxicity to aquatic organisms
- the toxicity to birds and mammals
- the toxicity to aquatic organisms
- the toxicity to non-target arthropods, earthworms and soil micro- and macro-organisms

In accordance with Article 18, Italy, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (Italy, 2010). The Additional Report was received by the EFSA on 21 May 2010.

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 28 May 2010. The DAR was also distributed to Member States for comments in view of the fact that it had not previously been distributed for consultation. In addition, the EFSA conducted a public consultation on the Additional Report and the DAR. The EFSA collated and forwarded all comments received to the European Commission on 13 July 2010. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the European Commission decided to further consult the EFSA. By written request, received by the EFSA on 28 July 2010, the European Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on 2-naphthyloxyacetic acid within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 30 September 2010; the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the areas of mammalian toxicology and ecotoxicology, and that further information should be requested from the applicant in the areas of analytical methods, residues, environmental fate and behaviour, and ecotoxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, and the additional information to be submitted by the applicant, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in April 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a plant growth regulator on tomatoes, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011) comprises the following documents:

- the comments received,
- the Reporting Table (revision 1-1; 30 December 2010),
- the Evaluation Table (20 April 2011),
- the report(s) of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR and the Additional Report including its addendum (compiled version of March 2011 containing all individually submitted addenda) (Italy, 2011) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

(2-naphthyloxy)acetic acid (IUPAC) is considered by the International Organization for Standardization not to require a common name. 2-naphthyloxyacetic acid is the name used in the Draft Assessment Report and the Additional Report.

The representative formulated product for the evaluation was '36c - 4.5 %', a soluble concentrate (SL) containing 45 g/kg 2-naphthyloxyacetic acid.

The representative uses evaluated comprise knapsack spraying on tomatoes for fruit setting. Full details of the representative uses can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev. 4 (European Commission, 2000) and SANCO/825/00 rev. 7 (European Commission, 2004a).

The minimum purity of 2-naphthyloxyacetic acid technical material is 995 g/kg. No FAO specification exists.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of 2-naphthyloxyacetic acid or the representative formulation, however a data gap was identified for information on containers of the plant protection product. The main data regarding the identity of 2-naphthyloxyacetic acid and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of 2-naphthyloxyacetic acid and the impurities in the technical material and for the determination of the active substance in the representative formulation. A HPLC-MS/MS method, for which an ILV is outstanding, exists for the monitoring of 2-naphthyloxyacetic acid residues in food of plant origin. It should be noted that, pending on the final residue definition in plant matrices, an analytical method for the determination of the compounds in the residue definition for plants might be identified as a data gap. Pending on the final decision on the residue definition and MRL proposal for animal matrices, a data gap might be identified also for a monitoring method for food of animal origin. Residues of 2-naphthyloxyacetic acid in soil and water can be monitored by HPLC-MS/MS. An analytical method for the determination of 2-naphthyloxyacetic acid residues in the air has been identified as a data gap. A method for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/222/2000 rev. 7, March 2004 (European Commission, 2004b), and SANCO/10597/2003 – rev. 8.1, May 2009 (European Commission, 2009).

2-naphthyloxyacetic acid was discussed at the PRAPeR Experts' Meeting on mammalian toxicology (PRAPeR 86) in February - March 2011. The batches used in the toxicological studies support the technical specification. There are no relevant impurities in the technical specification.

Low to moderate acute toxicity has been observed when 2-naphthyloxyacetic acid was administered by the oral, dermal or inhalation routes. 2-naphthyloxyacetic acid did not produce skin irritation, but severe eye irritation and the potential for skin sensitisation were observed. Classification as "harmful if swallowed", Acute Tox. 4, H302, "may cause an allergic skin reaction", Skin Sens. 1, H317, and "causes serious eye damage", Eye Dam. 1, H318 are proposed regarding the acute toxicity testing.

The target organs in rats upon short-term exposure were the liver with increased weight, hepatocyte centrolobular hypertrophy and changes in biochemical parameters, and kidney toxicity with increased weight, tubular dilation and increased creatinine levels; the NOAEL was 10 mg/kg bw/day in the 90-day oral study. No short-term study was presented on a non-rodent species and no long-term toxicity/carcinogenicity studies were submitted in either rats or mice. 2-naphthyloxyacetic acid is unlikely to have genotoxic or neurotoxic potential.

In a one-generation reproduction toxicity study no effects were observed on the reproductive parameters or on the offspring up to the dose level of 153.8 mg/kg bw/day, and it was considered that there was no need to require a full multi-generation study. In the developmental toxicity study in rat, significant decrease in maternal body weight gain was observed from the first days of treatment and enlarged ureters in foetuses at the high dose of 300 mg/kg bw/day; both the maternal and developmental NOAELs were 60 mg/kg bw/day. In the rabbit developmental toxicity study, no toxicity was observed on the development, while decreased maternal body weight gain was observed over the whole duration of the study at the high dose of 50 mg/kg bw/day; the maternal NOAEL was 10 mg/kg bw/day. A dose-range finding study in rabbits showed the occurrence of maternal mortality at 500 mg/kg bw/day and the NOAEL for this effect was 60 mg/kg bw/day.

Toxicological studies were submitted on a minor rat metabolite 2M, found in urine as fraction U13, however these could not be taken into consideration in the peer review due to the restrictions concerning the acceptance of new studies submitted after the deadline for resubmission. It is noted that, pending on the identification and assessment of plant metabolites in the residue section, toxicological information may be required on plant metabolites.

The acceptable daily intake (ADI) of 2-naphthyloxyacetic acid is set at 0.01 mg/kg bw/day, based on the NOAEL of 10 mg/kg bw/day from the 90-day rat study and applying a safety factor of 1000, considering an extra safety factor of 10 due to the lack of short-term studies with a non-rodent species and the lack of long-term/carcinogenicity studies in rats and mice. The acceptable operator exposure level (AOEL) is 0.03 mg/kg bw/day, based on the same NOAEL from the same rat study with a safety factor of 300 applied, considering an extra safety factor of 3 due to the lack of short-term studies with a non-rodent species; no correction for oral absorption was necessary. The acute reference dose (ARfD) is 0.6 mg/kg bw, based on the developmental toxicity study in rats and on the dose-range finding developmental toxicity study in rabbits, both presenting a NOAEL of 60 mg/kg bw/day for acute effects, with the standard safety factor of 100 applied.

The estimated operator exposure level is below the AOEL for the field uses without considering the use of personal protective equipment (PPE) according to the German model for high crop hand-held applications corresponding to a worst case compared to the representative use on tomatoes at a maximum application rate of 25.2 g 2-naphthyloxyacetic acid/ha. For the greenhouse uses, the estimated operator exposure is below the AOEL only if PPE of gloves and coverall are worn. Worker exposure is estimated to be around 20 % of the AOEL when no PPE is taken into account after one application of 2-naphthyloxyacetic acid; however, when seven applications are considered, it is expected that worker exposure estimates would exceed the AOEL, and a 10 % protection factor (as given by gloves, long-sleeved shirt and long trousers) would be needed to obtain a level of exposure below the AOEL. The estimated bystander exposure is below 1 % of the AOEL for field crop applications; bystander exposure is not relevant to greenhouse applications.

3. Residues

The conclusion in the residue section below is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999).

The metabolism of 2-naphthyloxyacetic acid was studied with radiolabelled substance in tomatoes. Since only the interim report of the metabolism study was available for peer review, pertinent information to conclude on the plant residue definition was still missing. A residue definition, preliminarily proposed as 2-naphthyloxyacetic acid, plus metabolites M1 and M4, expressed as

2-naphthyloxyacetic acid could not be agreed, since the identity of the major metabolites in tomato M1 and M4 was unknown. At a later stage the applicant submitted more detailed data on metabolism and the identity of metabolites, which could not be used in the assessment since results from ongoing studies cannot be considered eligible. Finalisation of the plant metabolism study is necessary in order to agree on the plant residue definition. Therefore, a data gap was identified for the submission of the finalised metabolism study in tomato. In the absence of an agreed plant residue definition it could not be assessed whether the submitted residue trials sufficiently address the residues relevant for consumer risk assessment and for monitoring. Moreover, the residue trials do not seem to sufficiently cover the critical GAP and freezer storage stability has not been sufficiently demonstrated. Therefore data gaps were identified for a sufficient freezer storage stability study and for sufficient critical GAP conforming residue trials in tomatoes. An ongoing freezer storage stability study and the ongoing residue trial could not be considered in the peer review.

The need for tomato processing data is currently open and will be subject to the outcome of the metabolism study, the residue trials and the final residue definition. To date also the assessment of residues in rotational crops is pending on a finalised plant metabolism study and residue definition. Based on the currently available data and information (DT_{90} 147 - 443 days; refer to section 6.1) rotational crop data cannot be waived. Therefore, also the assessment of livestock exposure through potential residues in rotational crops is open, even if the primary crop is not considered relevant for animal feeding.

Given the substantial number of data gaps a plant residue definition could not be agreed, and a livestock and consumer exposure assessment could not be conducted. Hence the consumer risk assessment could not be performed.

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, 2-naphthyloxyacetic acid exhibited moderate to high persistence forming no soil metabolite that would require further assessments. It is noted that the degradation end points were derived either by using all the extracted residues or considering residues that were extracted using relatively harsh extraction methods. Therefore the classification of persistence is based on end points that are considered as worst case. The rate of mineralisation to carbon dioxide varied between 4.8 - 16.3 % AR (applied radioactivity (AR)) after 94 - 121 days. Formation of unextractable residues was a significant sink, accounting for 63 - 69 % AR after 94 - 121 days. There was a soil incubation where the unextractable residues were slightly above 70 % AR after 62 days (end of the experiment), but the rate of mineralization was > 5 % AR in this soil incubation. The degradation in soil under anaerobic conditions was not investigated considering the use pattern (summer applications in tomatoes) of the active substance. It is noted however that the degradation rate under aerobic conditions was several times re-evaluated during the peer review process and was finally concluded that 2-naphthyloxyacetic acid was relatively persistent in some soils. Therefore, it cannot be excluded that significant residues are found in late autumn or in the winter period when soils might be under anaerobic conditions. On the other hand, it is also noted that the degradation end points are considered as worst case. In the study for photolysis on soil, no metabolites were formed at significant amounts. Although formally triggered, it was agreed that the investigation of the dissipation of 2-naphthyloxyacetic acid under field conditions was not necessary. 2-naphthyloxyacetic acid exhibited very high to high mobility in soil. Soil plateau concentration for long-term use in consecutive years and predicted environmental concentrations (PEC) for soil for 2-naphthyloxyacetic acid were calculated based on the worst-case non-normalized soil DT_{50} value derived from the slow phase of DFOP degradation kinetics.

2-naphthyloxyacetic acid is stable to hydrolysis. In an aqueous photolysis study where 2-naphthyloxyacetic acid was dosed, two unidentified, major metabolites coded as DP-3 and DP-4, were formed. In laboratory incubations in aerobic natural sediment water systems, 2-naphthyloxyacetic acid exhibited relatively moderate persistence (SFO DT_{50} 34 - 84 days) in the whole system, forming the major metabolite M6. Metabolite M6 was found only in the sediment up to the level of 12 % AR. The dissipation of 2-naphthyloxyacetic acid from the water phase via partitioning to the sediment was a

slow process. The majority of 2-naphthyloxyacetic acid was found in the water phase of the tested systems at all sampling times. After 100 days, the mineralization was 12.2 - 30.3 % AR. Unextractable residues in sediment accounted for 19.1 – 41.2 % AR at the end of the study (100 days). A data gap for the identification of the major aquatic metabolites (DP-3, DP-4 and M6) was identified. The exposure and risk assessments might need to be updated once this data gap is fulfilled.

The necessary surface water and sediment exposure assessments (PEC) were carried out using the FOCUS (FOCUS, 2001) approach at step 1 and 2 level. Moreover, exposure estimations at FOCUS step 3 level were also provided for 2-naphthyloxyacetic acid, which confirmed that the PECsw and PECsed values obtained at step 2 level are appropriate to be used in the risk assessment. Rough estimations for PECsw and PECsed for the aquatic metabolites DP-3, DP-4 and M6 were also performed using FOCUS step 1 approaches.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS scenarios (FOCUS, 2000) and models (PELMO 3.3.2 and PEARL 3.3.3[11]). The potential for groundwater exposure from the representative uses by 2-naphthyloxyacetic acid above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by the relevant FOCUS groundwater scenarios. It is noted that the soil DT_{50} value used in the simulations was not agreed by EFSA, since some parameters of the kinetic fittings were not found to be reliable (for details see Evaluation Table, Point of clarification 4.1; EFSA, 2011). However, it is not expected that this issue could have a significant impact on the assessment for the groundwater exposure and, in general, the degradation parameters, as they were derived from the soil incubations, might be considered as conservative estimations for these end points.

2-naphthyloxyacetic acid has a low potential for volatilization with an estimated atmospheric half-life shorter than 2 days. Therefore long-range transport through the atmosphere is not expected.

The PEC in soil, surface water, sediment and groundwater, that are appropriate to be used for the assessment for the representative uses assessed, can be found in Appendix A of this conclusion. It is noted that all the PEC calculations considered that maximum seven applications are envisaged in a season.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, 2002b, 2002c), and SETAC (2001).

The risk from the use of 2-naphthyloxyacetic acid to non-target species for the glasshouse uses was considered to be low, due to the lack of exposure to the non-target organisms or it was considered covered by the field uses.

The acute risk to birds via dietary exposure to 2-naphthyloxyacetic acid was assessed as low at tier 1 for the representative field uses as a plant growth regulator in tomatoes. No short-term or long-term toxicity studies for birds were available. To address the short-term and long-term risk residue decline studies on insects and leaves were used as a weight of evidence approach. The experts at the PRAPeR 87 meeting did not consider the weight of evidence approach acceptable. Since the application time is during the flowering of the tomatoes, when birds can be exposed during the breading season, it was considered that the long-term risk should be addressed. Due to the lack of toxicity data for birds the experts considered whether the available toxicity data on mammals could be used as a surrogate for the risk assessment for birds. It was noted that the end point for mammalian short-term toxicity was low (NOAEL of 10 mg a.s./kg bw/day from a 90-day study in rats). In the mammalian toxicology section there were also data available on developmental toxicity in rabbits resulting in a similar end point (based on decreased body weight gain of the parents), as well as a one-generation study in rats, where a NOAEL of 30.4 mg a.s./kg bw/day based on reduced body weight gain was observed. It was

[11] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

noted that in the mammalian toxicology section the experts at the PRAPeR 86 meeting agreed to use the NOAEL of 10 mg/kg bw/day to derive the ADI. The experts at the PRAPeR 87 considered that a new reproduction test with birds would not be needed, and it was proposed that the mammalian end point should be used as a surrogate for birds. When the mammalian short-term (or developmental) end point (NOAEL = 10 mg a.s./kg bw/day) was used for the risk assessment for birds, the TER would be approximately 15.4 and 13.1, for herbivorous and insectivorous birds, respectively. Therefore, the long-term risk for birds was considered to be low.

The acute risk of 2-naphthyloxyacetic acid to mammals via dietary exposure was assessed as low at tier 1 for the representative field uses. The long-term risk to mammals, based on the NOAEL of 10 mg a.s./kg bw/day was assessed as low (TER_{lt} of 26). A risk assessment to earthworm-eating as well as fish-eating birds and mammals (secondary poisoning) was not required since 2-naphthyloxyacetic acid is unlikely to bioaccumulate (log Pow= 2.5).

2-naphthyloxyacetic acid was toxic to fish, daphnids and algae, and very toxic to aquatic plants. For fish and daphnids, acute tests with the formulation and chronic tests with 2-naphthyloxyacetic acid were presented. However, no valid acute toxicity test with warm-water fish was provided in the Additional Report. Therefore a data gap was identified for data to address the acute toxicity of 2-naphthyloxyacetic acid to warm-water fish. A risk assessment for 2-naphthyloxyacetic acid to sediment-dwelling organisms was not required since the toxicity trigger for daphnids was not breeched. All FOCUS step 2 scenarios resulted in TERs above the Annex VI trigger values for all aquatic organisms, therefore the risk from 2-naphthyloxyacetic acid to aquatic organisms was assessed as low, although it is acknowledged that there are some outstanding data due to the lack of an acute toxicity test with warm-water fish. No data to assess the risk for the surface water metabolites DP-3 and DP-4, and the sediment metabolite M6 to aquatic organisms were available. However, the risk assessment for the metabolites was performed assuming a 10 times increased toxicity of the metabolites compared to the active substance. A study with sediment-dwelling organisms with the metabolite M6 was not required, since the toxicity trigger for daphnids was not breeched. Overall, the risk from the metabolites M6, DP-3 and DP-4 was considered to be low. It is noted that a data gap was identified in the environmental fate and behaviour section for the identification of the aqueous photolytic metabolites DP-3, DP-4 and the metabolite M6 found in the sediment of the water sediment study. Therefore the risk assessment might need to be updated once this data gap is fulfilled. No studies deriving a bioconcentration (BCF) value were submitted since the log P_{OW} for 2-naphthyloxyacetic acid is 2.5, and therefore the risk of bioconcentration is considered to be low.

For the risk assessment for bees the applicant provided a comparative evaluation of historical data on the response of bee colonies to reference compounds in the performing laboratory. Even with this, the submitted acute contact and oral toxicity tests with bees presented in the DAR cannot be considered as valid and the lack of results from such studies with bees constitutes a data gap.

The in-field and off-field hazard quotients (HQ) were below the Annex VI trigger value for the two standard test species *Aphidius rhopalosiphi* and *Typhlodromus pyri*. Therefore, the in-field and off-field risk was assessed as low for the two standard test species for the representative field uses on tomatoes.

The acute risk to earthworms was low, however taking into account the high DT_{50} and DT_{90} values in soil and the amount of bound residues (see Appendix A), the long-term risk could not be assessed based on an acute study alone. Results from a reproduction study were considered necessary to finalise the risk assessment for earthworms, therefore a data gap was identified.

The risk to non-target soil macro-organisms and the function of waste water treatment plants (biological methods of sewage treatment) could not be assessed due to lacking data. Therefore data gaps were identified. The risk for 2-naphthyloxyacetic acid to soil non-target micro-organisms was assessed as low.

Based on dose-response studies on five dicotyledonous and four monocotyledonous plants, a risk assessment was provided for *Daucus carota*, which was the most sensitive plant in the vegetative vigour and seedling emergence test. The risk was assessed as high for vegetative vigour based on the first-tier level. However, the risk for 2-naphthyloxyacetic acid to non-target plants was assessed as low with an in-field no-spray buffer zone of 5 m.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
2-naphthyloxyacetic acid	Moderate to high persistence[a] Single first order DT_{50} 16 - 55 days (25°C, 40% MWHC)[b] Biphasic DT_{90} 147 - 443 days (20°C, 40% MWHC)[b]	The acute risk of 2-naphthyloxyacetic acid to earthworms was assessed as low. A data gap was identified for a chronic study on earthworms.

(a): The class of high persistence is based on the assumption that the DT_{50} for the soil incubation, where the degradation followed double first-order in parallel kinetics resulting in a DT_{90} of 443 days, were about 133 days.
(b): The degradation end points were derived either by using all the extracted residues or considering residues that were extracted using harsh extraction methods, therefore these end points are considered as worst case.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
2-naphthyloxyacetic acid	Very high to high mobility K_{Foc} 33 - 110 mL/g	No	Yes	Yes	Very toxic to aquatic organisms, end point driving the aquatic risk assessment: aquatic plants EC_{50} = 3.85 mg a.s./L (regulatory concentration including a safety factor of 10 = 0.385 mg a.s./L). A low risk to the aquatic environment was indicated in the surface water risk assessment.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
2-naphthyloxyacetic acid	Very toxic to aquatic organisms, end point driving the aquatic risk assessment: aquatic plants EC_{50} = 3.85 mg a.s./L (regulatory concentration including a safety factor of 10 = 0.385 mg a.s./L). A low risk to the aquatic environment was indicated in the surface water risk assessment.
DP-3	A low risk to the aquatic environment was indicated in the surface water risk assessment.
DP-4	A low risk to the aquatic environment was indicated in the surface water risk assessment.
M6	A low risk to the aquatic environment was indicated in the surface water risk assessment.

6.4. Air

Compound (name and/or code)	Toxicology
2-naphthyloxyacetic acid	Rat LC_{50} inhalation = 4.87 mg/L air (4 h, nose-only), no classification proposed.

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- Information on containers of the plant protection product (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown, see section 1).
- Analytical method for the determination of 2-naphthyloxyacetic acid residues in the air (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown, see section 1).
- Finalised plant metabolism study in tomato (relevant for all representative uses evaluated; submission date proposed by the applicant: study is ongoing; see section 3).
- A freezer storage stability study (relevant for all representative uses evaluated; submission date proposed by the applicant: study is ongoing; see section 3).
- Sufficient critical GAP conforming residue trials in tomatoes, analysed according to the residue definition (once agreed) for risk assessment and for monitoring, and with a validated analytical method for all components of the residue definition, supported by acceptable storage stability data for all components of the residue definition (relevant for all representative uses evaluated; submission date proposed by the applicant: a residue trial ongoing however study conditions unknown; see section 3).
- Data and information addressing potential residues in rotational crops (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 3).
- Identification of the aqueous photolytic metabolites DP-3, DP-4 and the metabolite M6 found in the sediment of the water sediment study. The exposure and risk assessments might need to be updated once this data gap is fulfilled (relevant for all representative uses evaluated; submission date proposed by the applicant: experimental work already submitted and evaluated by the RMS, but could not be considered in this evaluation; see sections 4 and 5).
- Further information to address the acute toxicity of 2-naphthyloxyacetic acid for warm-water fish (relevant for representative field uses evaluated; submission date proposed by the applicant: a new study on the acute toxicity of 2-naphthyloxyacetic acid to fish (zebra fish) has been made available, however it could not be taken into account in the peer review; see section 5).
- Acute contact and oral toxicity tests with bees are necessary to address the risk to bees (relevant for representative field uses evaluated; submission date proposed by the applicant: a new toxicity study on bees has been provided, however it could not be taken into consideration due to late arrival; see section 5).
- A reproduction study is considered necessary to finalise the risk assessment for earthworms (relevant for representative field uses evaluated; submission date proposed by the applicant: the applicant indicated that a reproduction study on earthworms is in progress; see section 5).
- Tests are necessary to address the risk to non-target soil macro-organisms (relevant for representative field uses evaluated; submission date proposed by the applicant: unknown; see section 5).
- A study to address the effects of 2-naphthyloxyacetic acid on the function of waste water treatment plants is needed (relevant for representative field uses evaluated; submission date proposed by the applicant: unknown; see section 5).

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- The assessments in this conclusion considered that up to seven applications are envisaged to a crop (1 per flower bunch). The assessments therefore do not cover any GAP that considers more than seven applications.
- The estimated operator exposure is below the AOEL for greenhouse uses only if PPE (gloves and coverall) are worn (see section 2).
- Considering seven applications, the estimated worker exposure is below the AOEL only if PPE (gloves, long-sleeved shirt and long trousers) are worn (see section 2).
- The risk from 2-naphthyloxyacetic acid to non-target plants was assessed as low with the use of an in-field no-spray buffer zone of 5 m (see section 5).

ISSUES THAT COULD NOT BE FINALISED

- Consumer risk assessment. A plant residue definition could not be agreed. Subsequently, a livestock and consumer exposure assessment could not be conducted.
- The risk assessment for bees, earthworms (chronic), soil macro-organisms and biological methods of sewage treatment could not be finalised since no data were provided.

CRITICAL AREAS OF CONCERN

None.

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APPENDICES

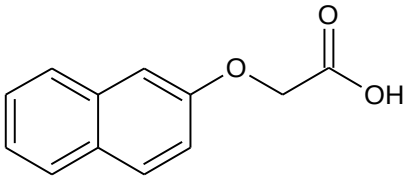
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	2-naphthyloxyacetic acid (no ISO common name)
Function (*e.g.* fungicide)	Plant growth regulator

Rapporteur Member State	Italy
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	(2-naphthyloxy)acetic acid
Chemical name (CA) ‡	(2-naphthalenyloxy)acetic acid
CIPAC No ‡	664
CAS No ‡	120-23-0
EC No (EINECS or ELINCS) ‡	204-380-0
FAO Specification (including year of publication) ‡	None
Minimum purity of the active substance as manufactured ‡	995 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	C_{12} H_{10} O_3
Molecular mass ‡	202.2 g/mol
Structural formula ‡	

‡ End point identified by the EU Commission as relevant for Member States when applying the Uniform Principles

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	155°C (pure 2-naphthyloxyacetic acid, 99.2 %)
Boiling point (state purity) ‡	363.5°C (QSAR, no indication of purity)
Temperature of decomposition (state purity)	No decomposition
Appearance (state purity) ‡	White solid with characteristic odour (pure 2-naphthyloxyacetic acid, 99.2 %)
Vapour pressure (state temperature, state purity) ‡	2.89 x 10^{-6} Pa at 25°C (pure 2-naphthyloxyacetic acid, 99.2 %)
Henry's law constant ‡	1.06 x10^{-4} Pa m^3 mol^{-1} at 20°C and pH >3
Solubility in water (state temperature, state purity and pH) ‡	For pure 2-naphthyloxyacetic acid (99.2 %): At pH>3, Ws= 203 mg/L at 20°C
Solubility in organic solvents ‡ (state temperature, state purity)	Pure 2-naphthyloxyacetic acid (99.2 %)

Solvent	Solubility (g/L)
hexane	6.1.10^{-3}
toluene	0.79
dichloromethane	6.6
methanol	0.14
acetone	160
ethyl acetate	50

Surface tension ‡ (state concentration and temperature, state purity)	54.4 mN/m at 100 mg/L 54.8 mN/m at 200 mg/L
Partition coefficient ‡ (state temperature, pH and purity)	Log $P_{O/W}$ is a calculated value. Log $P_{O/W}$ = 2.50 at pH 3
Dissociation constant (state purity) ‡	pKa = 3.35
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	No spectrum submitted. Data provided: λ max : 227 nm (ε = 40560-48600 mol^{-1} cm^{-1} depending of pH) Shoulder at λ = 270 nm (ε = 1711-4988 mol^{-1} cm^{-1} depending of pH)
Flammability ‡ (state purity)	Not highly flammable (pure 2-naphthyloxyacetic acid, 99.2 %)
Explosive properties ‡ (state purity)	Not explosive (pure 2-naphthyloxyacetic acid, 99.2 %)
Oxidising properties ‡ (state purity)	Not an oxidizer (pure 2-naphthyloxyacetic acid, 99.2 %)

Summary of representative uses evaluated (*2-naphthyloxyacetic acid*)

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hL min max	water L/ha min max	kg a.s./ha min max		
Tomato (non hybrid varieties)	Italy	36c-4.5%	G F	Fruit setting	SL	4.5 %	Knapsack	Flowers (BBCH 63-65) Summer	1 per flower bunch	1-2 weeks	0.0252 25.2 g/hl (5 mL/L)	70-100 L	0.01764 – 0.0252 17.64 – 25.2 g/ha (Glasshouse + Field)	3 or not relevant	For 1 tomato plant max. 7 applications in total are envisaged (however intending only 1 application per tomato fruit) [1] [2]
Tomato (Hybrid varieties)	Italy	36c-4.5%	G F	Fruit setting	SL	4.5 %	Knapsack	Flowers (BBCH 63-65) Summer	1 per flower bunch	1-2 weeks	0.0126 12,6 g/hl (2.5 mL/L)	70-100 L	0.00882 – 0.0126 8.82 – 12.6 g/ha (Glasshouse + Field)	3	For 1 tomato plant max. 7 applications in total are envisaged (however intending only 1 application per tomato fruit) [1] [2]

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl**).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

[1]: Consumer risk assessment could not be conducted.
[2]: The risk assessment for bees, earthworms (chronic), soil macro-organisms and biological methods for sewage treatment could not be finalised.

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	titration
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		open
Food of animal origin		open
Soil		2-naphthyloxyacetic acid
Water	surface	2-naphthyloxyacetic acid
	drinking/ground	2-naphthyloxyacetic acid
Air		2-naphthyloxyacetic acid

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	2-naphthyloxyacetic acid: HPLC-MS/MS (LOQ = 0.01 mg/kg) tomato HPLC-MS/MS (LOQ = 0.01 mg/kg) tomato leaves ILV outstanding open
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	open
Soil (analytical technique and LOQ)	HPLC-MS/MS (LOQ = 10 µg/kg, 2-naphthyloxyacetic acid)
Water (analytical technique and LOQ)	HPLC-MS/MS (LOQ = 0.05 µg/L, 2-naphthyloxyacetic acid)
Air (analytical technique and LOQ)	Data gap
Body fluids and tissues (analytical technique and LOQ)	Not required

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	None

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Approx. 80 % based on urinary excretion, residues in carcass and cage wash. Rapidly absorbed (T_{max} = 30 min – 2 h)
Distribution ‡	Widely distributed
Potential for accumulation ‡	No potential for accumulation
Rate and extent of excretion ‡	Rapidly excreted mostly within 48 h (males) and within 72 h (females), mainly via urine (75 – 80 % within 168 h)
Metabolism in animals ‡	Hydroxilation and glucosilation. The parent is the main compound in urine.
Toxicologically relevant compounds ‡ (animals and plants)	2-naphthyloxyacetic acid
Toxicologically relevant compounds ‡ (environment)	2-naphthyloxyacetic acid

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	1417 mg/kg bw (rat) 1557 mg/kg bw (mice)	**R22** **H302**
Rat LD_{50} dermal ‡	2000 mg/kg bw	
Rat LC_{50} inhalation ‡	4.87 mg/L air (4 h, nose only)	
Skin irritation ‡	Non irritant	
Eye irritation ‡	Severe irritant	**R41** **H318**
Skin sensitisation ‡	Sensitising (M&K)	**R43** **H317**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Rat: Kidney (increased weight, tubular dilation in presence of eosinophilic material, increased creatinine level) Liver (increased weight, hepatocyte centrolobular hypertrophy and increased ALP and SGPT) No data in non-rodent species.	
Relevant oral NOAEL ‡	90-day rat: 10 mg/kg bw/day	
Relevant dermal NOAEL ‡	No data - not required	
Relevant inhalation NOAEL ‡	No data - not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

2-naphthyloxyacetic acid is unlikely to be	

	genotoxic.	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	No data	
Relevant NOAEL ‡	No data	
Carcinogenicity ‡	No data	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental: reduced body weight gain and kidney findings Reproductive toxicity: no effects observed Offspring: no effects observed	
Relevant parental NOAEL ‡	30.4 mg/kg bw/day	
Relevant reproductive NOAEL ‡	153.8 mg/kg bw/day	
Relevant offspring NOAEL ‡	153.8 mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect ‡	Rat: Maternal: Decreased body weight gain Developmental: enlarged ureters Rabbit: Maternal: Decreased body weight gain Developmental: no effects observed	
Relevant maternal NOAEL ‡	Rat: 60 mg/kg bw/day Rabbit: 10 mg/ kg bw/day Rabbit dose-range finding study (acute effects - mortality): 60 mg/kg bw/day	
Relevant developmental NOAEL ‡	Rat: 60 mg/kg bw/day Rabbit: 50 mg/ kg bw/day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data - not required	
Repeated neurotoxicity ‡	No data - not required	
Delayed neurotoxicity ‡	No data - not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data
Studies performed on metabolites or impurities ‡	No eligible data

Medical data ‡ (Annex IIA, point 5.9)

No evidence of health effects on 12 workers of a plant that produces 2-naphthyloxyacetic acid.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.01 mg/kg bw/day	rat 90-day study	1000*
AOEL ‡	0.03 mg/kg bw/day	rat 90-day study	300**
ARfD ‡	0.6 mg/kg bw	Rat developmental & Rabbit dose-range finding developmental studies	100

* Increased safety factor by 10 due to the lack of short-term studies with a non-rodent species and lack of long-term/carcinogenicity studies in rats and mice.
**Increased safety factor by 3 due to the lack of short-term studies with a non-rodent species.

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation: 36c - 4.5 % (50.4 g/L SL)

Concentrate: 3.52 %
Spray dilutions: 10.54 %
in vitro dermal absorption study using human skin

Exposure scenarios (Annex IIIA, point 7.2)

Operator

Hand-held applications (max. application rate of 25.2 g 2-naphthyloxyacetic acid/ha)

Field use	% of AOEL
UK POEM	
Without PPE	222 %
With PPE (gloves when M/L)	218 %
With PPE (gloves when M/L and application)	107 %
German model (high crop hand-held)	
Without PPE	14.2 %
With PPE (gloves when M/L and gloves, coverall and sturdy footwear during application)	1.3 %
Greenhouses	
EUROPOEM and M/L from the German model data	
Without PPE	196 %
With PPE (gloves and coverall)	3.1 %

Workers

After 1 application:
Without PPE: 20.5 % of AOEL after one application
After 7 applications:
Estimated worker exposure is below the AOEL when PPE

	(gloves, long-sleeved shirt and long trousers) are worn.
Bystanders	**Field use:** Exposure considered to be negligible (below 1 % of the AOEL). **Greenhouses:** Bystander exposure is not relevant.

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

2-naphthyloxyacetic acid	According to Directive 67/548/EEC: Xn "Harmful" R22 "harmful if swallowed", R41 "Risk of serious damage to eyes" R43 "May cause sensitisation by skin contact" According to Regulation (EC) No 1272/2008: Warning Acute Tox. 4, H302 "Harmful if swallowed" Skin Sens. 1, H317 "May cause an allergic skin reaction" Danger Eye Dam. 1, H318 "Causes serious eye damage"

Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Tomatoes
Rotational crops	No study submitted
Metabolism in rotational crops similar to metabolism in primary crops?	pending
Processed commodities	
Residue pattern in processed commodities similar to residue pattern in raw commodities?	pending
Plant residue definition for monitoring	open
Plant residue definition for risk assessment	Preliminary proposal: 2-naphthyloxyacetic acid + M4 + M1,expressed as 2-naphthyloxyacetic acid Pending identification of M4 + M1
Conversion factor (monitoring to risk assessment)	open

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	No study submitted; assessment pending
Time needed to reach a plateau concentration in milk and eggs	Not applicable
Animal residue definition for monitoring	pending
Animal residue definition for risk assessment	pending
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Not applicable
Fat soluble residue: (yes/no)	Not applicable

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

No study submitted, assessment pending.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

No studies submitted.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	assessment pending	assessment pending	assessment pending
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	assessment pending	assessment pending	assessment pending
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices: Mean (max) mg/kg		
Muscle	n/a	n/a	n/a
Liver	n/a	n/a	n/a
Kidney	n/a	n/a	n/a
Fat	n/a	n/a	n/a
Milk	n/a		
Eggs		n/a	

Summary of residues data according to the representative uses on raw agricultural commodities and feeding stuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (mg/kg) (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Tomatoes	Italy	no valid studies available according to proposed residue definition and representative GAPs		pending	pending	pending

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.01 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	pending
TMDI (% ADI) according to national (to be specified) diets	pending
IEDI (WHO European Diet) (% ADI)	pending
NEDI (specify diet) (% ADI)	pending
Factors included in IEDI and NEDI	
ARfD	0.6 mg/kg bw
IESTI (% ARfD)	pending
NESTI (% ARfD) according to national (to be specified) large portion consumption data	-
Factors included in IESTI and NESTI	

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
No study submitted; assessment pending	-	-	-	-

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Tomatoes	pending

Environmental fate and behaviour

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	16.3 % at 121 d (n=1) 4.8 - 9.4 % at 94 d (n=2) 10.6 - 15.1 % at 62 d (n=2)
Non-extractable residues after 100 days ‡	67.8 % at 121 d (n=1) 62.7 - 69.0 % at 94 d (n=2) 69.4 - 72.6 % at 62 d (n=2)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No major or non-transient minor metabolites were formed.

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡

No data provided - not required

Soil photolysis ‡

No metabolites requiring further consideration were formed.

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

Parent	Aerobic conditions					
Soil type	pH	t °C / % of MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2) / χ^2 (err)	Method of calculation
Speyer 2.2 Loamy sand	5.5	20°C / 40	16.8/ 247	100.46*	4.1	DFOP
Speyer 2.3 Sandy loam	6.6	20°C / 40	41.7/208	58.12*	1.4	DFOP
Speyer 6S Clay	7.2	20°C / 40	88.2/443	70.89*	6.8	DFOP
Speyer 5M Sandy loam	7.2	20°C / 40	8.5/ 147	65.02*	9.1	DFOP
Soil 1 Loamy sand	6.1	25°C / 40	55 / 183	86.3	12.63	SFO
Soil 2 Sandy loam	5.4	25°C / 40	40/210 [a]	94.3*	4.7	DFOP
Soil 3 Silt loam	8.21	25°C / 40	16 / 52	18.1	3.86	SFO
Soil 4 Clay	5.64	25°C / 40	22 / 72	16.6	3.07	SFO
Geometric mean/median				53.4/68.0		

* slow-phase DFOP

[a] Parameters of the DFOP fit are: M0= 98.3 g=0.273, k1=0.315, k2=0.0095

Field studies ‡

	No data provided - not required

pH dependence ‡ (yes / no) (if yes type of dependence)	No

Soil accumulation and plateau concentration ‡	Plateau maximum PECsoil: 0.053 mg/kg after 4 years

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH ($CaCl_2$)	Kd (mL/g)	Koc (mL/g)	K_F (mL/g)	$K_F$oc (mL/g)	1/n
	0.88	5.1	0.330	37.5	0.287	32.6	0.80
	2.09	5.4	2.43	113	2.37	110	0.76
	0.98	6.4	0.876	89.4	0.747	76.3	0.74
	1.75	7.2	0.843	48.2	0.721	41.2	0.83
Arithmetic mean						65.03	0.78
pH dependence, Yes or No			No				

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	No data provided - not required
Aged residues leaching ‡	No data provided - not required
Lysimeter/ field leaching studies ‡	No data provided - not required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 154.03 days (max. value, phase 2 DFOP not normalised) Kinetics: SFO Lab: representative worst-case from laboratory studies.
Application data	Crop: tomato Depth of soil layer: 5 cm Soil bulk density: 1.5 kg/L % plant interception: 80 % Number of applications: *7* Interval (d): *7* Application rate(s): 25.2 g a.s./ha

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.0071	-	0.043	-
Short term 24h	0.0070	0.0071	0.043	0.043
2d	0.0070	0.0070	0.042	0.043
4d	0.0070	0.0070	0.042	0.043
Long term 7d	0.0069	0.0070	0.042	0.042
28d	0.0063	0.0067	0.038	0.040
50d	0.0057	0.0064	0.034	0.038
100d	0.0047	0.0058	0.027	0.035
Plateau concentration	0.053 mg/kg after 4 years			

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	<10 % degradation after 5 days at pH 4, 7 and 9 at 50°C.
Photolytic degradation of active substance and metabolites above 10 % ‡	Photolytic degradation at pH 7: DT_{50}= 0.37 days in test conditions equivalent to 0.86 days in summer sunlight at 40°N. Met I: DP-3: 12.5 % AR (2.7 d) Met II: DP-4: 30.5 % AR (1 d)
Quantum yield of direct phototransformation in water at Σ > 290 nm	The quantum yield was 2.54 x 10^{-3} (reacted molecules/absorbed photons).
Readily biodegradable ‡ (yes/no)	Not readily biodegradable.

Degradation in water / sediment

Parent	Max. in water 108 % after *0* d. Max. in sed. 22 % after *28* d.									
Water / sediment system	pH water phase	pH sed	t °C	DT_{50}-DT_{90} whole sys	St. (r^2) / χ^2 (err)	DT_{50}-DT_{90} Water[1]	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2) / χ^2 (err)	Method of calculation
Goorven water/sediment system (GV)	6.1	5.9	20°C	84.4 / 280	0.936 4.6	44 */ 269*	0.966 2.1	n.c.	n.c.	SFO
Schoonrewoerdsewiel water/sediment system (SW)	8.3	7.1	20°C	33.6 / 112	0.977 4.4	13.7+ / 131+	0.977 4.6	n.c.	n.c.	SFO
Geometric mean				53.25						

n.c. = not calculated
* HS kinetic
+ FOMC kinetic
[1] dissipation rate

M6	Max. in sed. 12 % after 28 d, not found in the aqueous phase									
Water / sediment system	pH water phase	pH sed	t °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Goorven system	6.1	5.9	20°C	n.d.	-	n.d.	-	n.d.	-	-
Schoonrewoerds ewiel	8.3	7.1	20°C	n.d.	-	n.d.	-	n.d.	--	-

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Goorven system	6.1	5.9	12.2 % AR at 100 d	19.1 % AR at 100 d	19.1 % AR at 100 d
Schoonrewoerds ewiel	8.3	7.1	30.3 % AR at 100 d	41.2 % AR at 100 d	41.2 % AR at 100 d

n.d.= not determined

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Parent	Version control no 1.1. of FOCUS calculator:
Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 202.21 Water solubility (mg/L): 203 K_{OC} (L/kg): 72 at 20°C ($K_F$oc 65 L/kg should have been used) DT_{50} soil (d): 47.38 days geometric mean (the correct geomean value is 53.4 days) DT_{50} water/sediment system (d): 53.25 d DT_{50} water (d): 53.25 d geometric mean whole system DT_{50} sediment (d): 1000 d
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 2.89 10^{-6} at 25°C K_{OM} (L/kg): 41.76 (the correct K_{Foc}/K_{Fom} value is 65.0/37.7 L/kg) 1/n: 0.78
Application rate	Crop: tomato (fruiting vegetable) Crop interception: 70 % (full canopy) Number of applications: *7* Interval (d): *7* Application rate(s): 25.2 g a.s./ha Application window: June - Sep

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	55.2719	-	38.6277	-

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	2.93	-	2.1	-
	24 h	2.87	2.9	2.07	2.08
	2 d	2.84	2.88	2.05	2.07
	4 d	2.77	2.84	2	2.05
	7 d	2.68	2.79	1.93	2.01
	14 d	2.46	2.68	1.77	1.93
	21 d	2.26	2.57	1.63	1.85
	28 d	2.08	2.47	1.5	1.78
	42 d	1.76	2.29	1.27	1.65
	50 d	1.6	2.19	1.15	1.58
	100 d	0.88	1.7	0.64	1.22
Southern EU	0 h	4.07	-	2.92	-
	24 h	4	4.04	2.88	2.9
	2 d	3.95	4.01	2.85	2.88
	4 d	3.86	3.96	2.78	2.85
	7 d	3.72	3.89	2.68	2.8
	14 d	3.42	3.73	2.47	2.69
	21 d	3.15	3.58	2.27	2.58
	28 d	2.9	3.44	2.09	2.48
	42 d	2.45	3.18	1.77	2.29
	50 d	2.23	3.05	1.61	2.2
	100 d	1.23	2.36	0.88	1.7

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6		0 h	0.193	-	0.146	-
		24 h	0.096	0.151	0.143	0.146
		2 d	0.068	0.129	0.139	0.144
		4 d	0.039	0.097	0.132	0.141
		7 d	0.047	0.078	0.120	0.137
		14 d	0.009	0.053	0.103	0.131
		21d	0.005	0.037	0.095	0.123
		28 d	0.003	0.029	0.089	0.117
		42 d	0.002	0.020	0.083	0.108
R2		0 h	0.225	-	0.178	-
		24 h	0.067	0.224	0.130	0.158
		2 d	0.000	0.119	0.114	0.143
		4 d	0.000	0.059	0.100	0.127
		7 d	0.000	0.034	0.089	0.114
		14 d	0.000	0.017	0.077	0.099

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		21 d	0.000	0.012	0.070	0.091
		28 d	0.000	0.012	0.084	0.086
		42 d	0.000	0.010	0.064	0.081
R3		0 h	0.408	-	0.168	-
		24 h	0.073	0.328	0.115	0.155
		2 d	0.001	0.174	0.093	0.144
		4 d	0.000	0.087	0.076	0.132
		7 d	0.000	0.051	0.067	0.123
		14 d	0.000	0.041	0.105	0.117
		21 d	0.000	0.028	0.079	0.115
		28 d	0.000	0.029	0.107	0.113
		42 d	0.060	0.023	0.128	0.109
R4		0 h	0.797	-	0.270	-
		24 h	0.007	0.603	0.152	0.228
		2 d	0.001	0.303	0.118	0.190
		4 d	0.000	0.152	0.091	0.155
		7 d	0.000	0.087	0.075	0.147
		14 d	0.000	0.070	0.119	0.142
		21 d	0.034	0.060	0.149	0.130
		28 d	0.000	0.047	0.106	0.14
		42 d	0.000	0.031	0.081	0.113

M6

Parameters used in FOCUSsw step 1	Molecular weight: 202.21 (parent value) Water solubility (mg/L): 203 (parent value) Soil or water metabolite: water (sediment) DT_{50} water/sediment system (d): 1000 Koc: 10000 L/kg Maximum occurrence observed (% molar basis with respect to the parent) in sediment: 12.1 % Maximum occurrence in soil: 0 % (1 x 10^{-10} used)
Application rate	Crop: tomato (fruiting vegetable) Number of applications: 7 Interval (d): 7 Application rate(s): 25.2 g a.s./ha

FOCUS STEP 1 Scenario	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
	Actual	TWA	Actual	TWA
Global max.	0.20		1.37	

DP-3 Parameters used in FOCUSsw step 1	Molecular weight:134 g/mol* Water solubility (mg/L): 203 (parent value) Soil or water metabolite: water DT_{50} water/sediment system (d): 1000 Koc= 1 L/kg Maximum occurrence observed (% molar basis with respect to the parent) water: 12.5 %
Application rate	Crop: tomato (fruiting vegetable) Number of applications: 7 Interval (d): 7 Application rate(s): 25.2 g a.s./ha * Since the metabolite was not identified by the relevant official deadline in the EU peer review, this value was not validated.

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU & Southern EU	0 h	0.1335		0	
	24 h	0.1332	0.1334	0.0013	0.0007
	2 d	0.1331	0.1333	0.0013	0.001
	4 d	0.1329	0.1332	0.0013	0.0012
	7 d	0.1327	0.133	0.0013	0.0012
	14 d	0.132	0.1327	0.0013	0.0013
	21 d	0.1314	0.1324	0.0013	0.0013
	28 d	0.1308	0.132	0.0013	0.0013
	42 d	0.1295	0.1314	0.0013	0.0013
	50 d	0.1288	0.131	0.0013	0.0013
	100 d	0.1244	0.1288	0.0012	0.0013

DP-4 Parameters used in FOCUSsw step 1	Molecular weight:150 g/mol* Water solubility (mg/L): 203 (parent value) Soil or water metabolite: water DT_{50} water/sediment system (d): 1000 Koc= 1 L/kg Maximum occurrence observed (% molar basis with respect to the parent) water: 30.5 %

Application rate

Crop: tomato (fruiting vegetable)
Number of applications: 7
Interval (d): 7
Application rate(s): 25.2 g a.s./ha
* Since the metabolite was not identified by the relevant official deadline in the EU peer-review, this value was not validated.

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU & Southern EU	0 h	0.3646		0	
	24 h	0.3638	0.3642	0.0036	0.0018
	2 d	0.3636	0.3639	0.0036	0.0027
	4 d	0.3631	0.3636	0.0036	0.0032
	7 d	0.3623	0.3632	0.0036	0.0034
	14 d	0.3606	0.3623	0.0036	0.0035
	21 d	0.3588	0.3614	0.0036	0.0035
	28 d	0.3571	0.3606	0.0036	0.0035
	42 d	0.3536	0.3588	0.0035	0.0035
	50 d	0.3517	0.3578	0.0035	0.0035
	100 d	0.3397	0.3517	0.0034	0.0035

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Models used: FOCUS PELMO 3.3.2 and FOCUS PEARL 3.3.3 Scenarios: Châteaudun + I* Piacenza + I* Porto Sevilla + I* Thiva + I* Crop: Tomato DT_{50lab} 47.38 d (the correct geometric mean of the available 8 values is 53.4 days) Crop interception: 80 % K_{FOC}: arithmetic mean 64.9 mL/g $^1/_n$= 0.78 Vapour pressure: 2.89 x 10^{-6} Pa Water solubility: 203 mg/L Plant uptake: 0.5 Q10: 2.58 * Irrigation is considered
Application rate	Application rate: 25.2 g a.s./ha No. of applications: 7 Interval between applications: 7 days Plant interception: 80 % Time of application: around 60 days after transplantation

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			1	2	3
PELMO 3.3.2 / Tomato	Châteaudun + I*	< 0.001			
	Piacenza + I*	< 0.001			
	Porto	< 0.001			
	Sevilla + I*	< 0.001			
	Thiva + I*	< 0.001			

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			1	2	3
PEARL 3.3.3/ Tomato	Châteaudun + I*	< 0.001			
	Piacenza + I*	0.017			
	Porto	< 0.001			
	Sevilla + I*	< 0.001			
	Thiva + I*	< 0.001			

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Photochemical oxidative degradation in air	DT_{50} of 0.627 hours (0.052 d) derived by the Atkinson model OH (12 h) concentration assumed = 1.5 x 10^{6} OH/cm^3

PEC (air)

Method of calculation	Expert judgement based on: Vapour pressure = 2.89 x 10^{-6} Pa at 25°C Henry's law constant = 1.06 x 10^{-4} Pa.m^3/mol

$PEC_{(a)}$

Maximum concentration	Negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: 2-naphthyloxyacetic acid Surface water: 2-naphthyloxyacetic acid, and metabolites DP-3 and DP-4 Sediment: 2-naphthyloxyacetic acid, and metabolite M6 Ground water: 2-naphthyloxyacetic acid Air: 2-naphthyloxyacetic acid

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Candidate for R 53

Ecotoxicology

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/(day))	End point (mg/kg feed)
Birds ‡				
Coturnix coturnix japonica	2-naphthyloxyacetic acid	Acute	> 2000	-
	Preparation	Acute	-	-
	Metabolite 1	Acute	-	-
	a.s.	Short-term		-
	a.s.	Long-term	10*	-
Mammals ‡				
rat	2-naphthyloxyacetic acid	Acute	1417 (female)	-
	Preparation	Acute	-	-
	Metabolite 1	Acute	-	-
rat	2-naphthyloxyacetic acid	Short-term (90 days)	10	-
rabbit	2-naphthyloxyacetic acid	Developmental test	10 (decreased body weight gain).	
rat	2-naphthyloxyacetic acid	Long-term (1-generation reproduction)	30 (NOAEL parental effects).	-
Additional higher tier studies ‡				
-				

* It was proposed that the mammalian endpoint (NOAEL of 10 mg a.s./kg bw/day) should be used as a surrogate for effects on birds.

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Crop and application rate: Tomatoes (application with a knapsack) open field and greenhouse, 1 application per flower bunch, up to 7 applications per plant, (interval 1-2 weeks), dose per treatment 25.2 g a.s./ha

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
	Acute	Insectivorous: 1.35	Insectivorous: 1467	10
		Herbivorous: 2.31	Herbivorous: 857	
	Short-term	-	-	10
	Long-term	Insectivorous 0.76	13.1	5

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
		Herbivorous: 0.65	15.4	
Higher tier refinement (Birds)				
	Acute	-	-	10
	Short-term	-	-	10
	Long-term	-	-	5
Tier 1 (Mammals)				
	Acute	0.61	2326	10
	Long-term[4]	0.37	26.86	5
Higher tier refinement (Mammals)				
	Acute	-	-	10
	Long-term	-	-	5

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.
[4] Based on the use of a NOAEL of 10 mg a.s./kg bw/day.

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Test substance	Test organism	Test duration	Endpoint	Toxicity (mg test substance/L)
Fish				
36c – 4.5 %	*O. mykiss*	Acute - 96 h (Static)	LC_{50}	52.08 (≈ 2.39 mg a.s./L)
2-naphthyloxy acetic acid	*C. carpio*	Chronic – 28 days, (semi-static)	NOEC	10
Invertebrates				
36c – 4.5 %	*Daphnia magna*	Acute - 48 h (Static)	EC_{50}	≥ 100 (≈ 4.52 mg a.s./L)
2-naphthyloxy acetic acid	*Daphnia magna*	Chronic – 21 days, semi-static	NOEC	6.7
Algae				
2-naphthyloxy acetic acid	*Desmodesmus subspicatus*	72 h (Static)	E_rC_{50} E_YC_{50}	29 7.9
36c – 4.5 %	*Desmodesmus subspicatus*	72 h (Static)	E_rC_{50} E_bC_{50}	> 120 (≈ 5.43 mg a.s./L) > 120 (≈ 5.43 mg a.s./L)
36c – 4.5 %	*Anabaena flos-aquae*	72 h (Static)	E_rC_{50} E_YC_{50}	98.9 (≈ 4.47 mg a.s./L) 1106.8 (≈ 50.1 mg a.s./L)
Aquatic plants				
2-naphthyloxy	*Myriophillum*	14 d (Static)	E_bC_{50} E_rC_{50}	> 7.0 2.0

acetic acid			E_YC_{50}	0.87*
36c – 4.5 %	*Lemna gibba*	7 d (Static)	E_bC_{50} E_rC_{50} $E_{frond\ numb}C_{50}$	569.3 334.3 85.59 (≈ 3.85 mg a.s./L)
Sediment-dwelling organisms				
Not required				

* This study is considered as supplementary information only.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

FOCUS Step1

Crop and application rate: Tomatoes (application with a knapsack) open field and greenhouse, 1 application per flower bunch, up to 7 applications per plant, (interval 1-2 weeks), dose per treatment 25.2 g a.s./ha

Test substance	Organism[2]	Toxicity end point (µg/L)	Time scale	PEC[3] PECsw, ini (µg/L)	TER	Annex VI Trigger[4]
M6	Fish	239	Acute	0.20	1195	100
M6	Fish	1000	Chronic	0.20	5000	10
M6	Aquatic invertebrates	452	Acute	0.20	2260	100
M6	Aquatic invertebrates	670	Chronic	0.20	3350	10
M6	Algae	447	Acute	0.20	2235	100
M6	Higher plants[5]	385	Chronic	0.20	1925	10
DP-3	Fish	239	Acute	0.1335	179.0	100
DP-3	Fish	1000	Chronic	0.1335	7491	10
DP-3	Aquatic invertebrates	452	Acute	0.1335	3386	100
DP-3	Aquatic invertebrates	670	Chronic	0.1335	5019	10
DP-3	Algae	447	Chronic	0.1335	3348	10
DP-3	Higher plants[5]	385	Chronic	0.1335	2890	10
DP-4	Fish	239	Acute	0.3646	656	100
DP-4	Fish	1000	Chronic	0.3646	2743	10
DP-4	Aquatic invertebrates	452	Acute	0.3646	1240	100
DP-4	Aquatic invertebrates	670	Chronic	0.3646	1838	10
DP-4	Algae	447	Chronic	0.3646	1226	10
DP-4	Higher plants[5]	385	Chronic	0.3646	1056	10

Footnotes see under Step 2.

FOCUS Step 2

Crop and application rate: Tomatoes (application with a knapsack) open field and greenhouse, 1 application per flower bunch, up to 7 applications per plant, (interval 1-2 weeks), dose per treatment 25.2 g a.s./ha

Test substance	N/S[1]	Organism[2]	Toxicity end point (µg/L)	Time scale	PEC[3] PECsw, ini (µg/L)	TER	Annex VI Trigger[4]
a.s.	S	Fish	2 390	Acute	4.07	587	100
a.s.	S	Fish	10 000	Chronic	4.07	2457	10
a.s.	S	Aquatic invertebrates	4 520	Acute	4.07	1110	100
a.s.	S	Aquatic invertebrates	6 700	Chronic	4.07	1646	10
a.s.	S	Algae	4470	Chronic	4.07	1098	10
a.s.	S	Higher plants[5]	3850	Chronic	4.07	945	10
a.s.		Sediment-dwelling organisms[6]	Not relevant	Chronic	-	-	10

[1] indicate whether Northern of Southern

[2] include critical groups which fail at Step 1.

[3] indicate whether maximum or twa values have been used.

[4] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to Member States in relation to product approval.

[5] only required for herbicides

[6] consider the need for PEC_{sw} and PEC_{sed} and indicate which has been used

Refined aquatic risk assessment using higher tier FOCUS modelling

FOCUS Step 3

Not presented, as Step 2 calculations result in acceptable TERs.

Bioconcentration			
	Active substance	Metabolite1	Metabolite2
$logP_{O/W}$	2.5		
Bioconcentration factor (BCF)[1] ‡	Not required		
Annex VI Trigger for the bioconcentration factor			

[1] only required if log $P_{O/W}$ >3.

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	Data gap	Data gap
Field or semi-field tests		

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Crop and application rate: Tomatoes (application with a knapsack) open field and greenhouse, 1 application per flower bunch, up to 7 applications per plant, (interval 1-2 weeks), dose per treatment 25.2 g a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	contact		50
a.s.	oral		50
Preparation	contact		50
Preparation	oral		50

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	**Tested substance Tested dose**	**Endpoint**	**Toxicity (g/ha)**
Predatory mites			
Typhlodromus pyri	36c – 4.5 % Dose response test 3.15 to 50.4 g product/ha	Mortality	LR_{50} > 50.4 g product/ha
Typhlodromus pyri	36c – 4.5 % Limit test 100 g a.s./ha	Mortality	LR_{50} > 80 g a.s./ha
Parasitoid			
Aphidius rhopalosiphi	36c – 4.5 % Dose response test 3.15 to 50.4 g product/ha	Mortality	LR_{50} > 50.4 g product/ha
Aphidius rhopalosiphi	36c – 4.5 % Limit test 100 g a.s./ha	Mortality	LR_{50} > 100 g a.s./ha

Crop and application rate: Tomatoes (application with a knapsack) open field and greenhouse, 1 application per flower bunch, up to 7 applications per plant, (interval 1-2 weeks), dose per treatment 25.2 g a.s./ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1] (1m)	Trigger
36c-4.5%.	*Typhlodromus pyri*	> 80 g a.s./ha	1.95	0.124	2
36c-4.5%	*Aphidius rhopalosiphi*	> 100 g a.s./ha	1.56	0.099	2
36c-4.5%	*Typhlodromus pyri*	> 50.4 g product/ha (max. tested rate)	-	-	2

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1] (1m)	Trigger
36c-4.5%	*Aphidius rhopalosiphi*	> 50.4 g product/ha (max. tested rate)	-	-	2

[1] indicate distance assumed to calculate the drift rate

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point[1]
Earthworms			
	36c – 4.5 %‡	Acute 14 days	LC_{50} 1000 mg formulation/kg d.w. soil (45 mg a.s./ha)
	2-naphthyloxyacetic acid	Chronic	Data gap
Other soil macro-organisms			
Soil mite	a.s. ‡	Data gap	
Collembola	a.s. ‡	Data gap	
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡		No effect up to 26.13 mg 36c-4.5% /kg soil dry weight
Carbon mineralisation	a.s. ‡		No effect up to 26.13 mg 36c-4.5% /kg soil dry weight
Field studies[2]			
Not required			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})

[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms

Crop and application rate: Tomatoes (application with a knapsack) open field and greenhouse, 1 application per flower bunch, up to 7 applications per plant, (interval 1-2 weeks), dose per treatment 25.2 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC[1] (accumulation after 10 applications)	TER	Trigger
Earthworms					
	a.s. ‡	Acute	0.053 mg/kg	> 849	10
	a.s. ‡	Chronic	-	-	5
	Metabolite 1	Acute	Not relevant		10
	Metabolite 1	Chronic	Not relevant		5
Other soil macro-organisms					
2-naphthyloxyacetic acid DT_{50} – DT_{90} in soil is 88 – 443 days and 36c – 4.5 % can be applied up to 7 times per season. Therefore the risk for soil non-target macro-organisms should be assessed. Data gap identified.					

[1] indicate which PEC soil was used (e.g. plateau PEC)

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided.

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
carrot	36c – 4.5 %	50.5	-	4.95 a.s. (Ganzelmeier, 5 m)	10.17	> 5
carrot	36c – 4.5 %	-	117.8	4.95 a.s. (Ganzelmeier, 5 m)	23.7	> 5

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

Additional studies (e.g. semi-field or field studies)

-

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	End point
Activated sludge	Data gap
Pseudomonas sp	Data gap

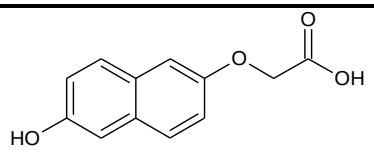
Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	2-naphthyloxyacetic acid
water	2-naphthyloxyacetic acid
sediment	2-naphthyloxyacetic acid
groundwater	2-naphthyloxyacetic acid

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

Active substance	N, R50/53
Preparation	N, R51/53

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
2M (U13)	[(6-hydroxy-2-naphthyl)oxy]acetic acid	
M1	Not identified***	Not identified***
M4	Not identified***	Not identified***
DP-3	Not identified***	Not identified***
DP-4	Not identified***	Not identified***
M6	Not identified	Not identified

* The metabolite name in bold is the name used in the conclusion

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

*** proposed name and structure are already available, but could not be considered in the peer review

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
ALP	alkaline phosphatase
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DFOP	double first order in parallel kinetic
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use

FOMC	first-order multi-compartment model
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high performance liquid chromatography – mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UV	high performance liquid chromatography with ultraviolet detector
HQ	hazard quotient
HS	hockey stick
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
min	minute
M&K	Magnusson and Kligman maximisation test
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level

MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
N	North
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
POEM	Predictive Operator Exposure Model
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
S	South
SD	standard deviation
SFO	single first-order
SGPT	serum glutamic pyruvic transaminase (ALT – alanine aminotransferase)
SL	soluble concentrate
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
T_{max}	Time to maximum plasma concentration
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average

UDS	unscheduled DNA synthesis
UK POEM	United Kingdom Predictive Operator Exposure Model
UV	ultraviolet
W/S	water/sediment
W/s	water solubility
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WHO	World Health Organisation
wk	week
yr	year