CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance propanil[1]

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SUMMARY

Propanil is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002,[3] as amended by Commission Regulation (EC) No 1095/2007.[4] In accordance with Article 10(1) of the Regulation, Italy, being the designated rapporteur Member State (RMS), provided an initial evaluation of propanil in the format of a Draft Assessment Report (DAR), which was received by the EFSA on 28 November 2007. The Commission of the European Communities (hereafter referred to as 'the Commission') examined propanil in accordance with Article 11a 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 11f and 12 of the Regulation.

Following the Commission Decision of 30 September 2008 (2008/769/EC)[5] concerning the non-inclusion of propanil in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Propanil Data Development Consortium made a resubmission application for the inclusion of propanil 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.

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 26 February 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 2 March 2010. The DAR was also distributed for comments. The EFSA collated and forwarded all comments received to the Commission on 20 April 2010.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission requested the EFSA to conduct a focused peer review in the areas of mammalian toxicology, residues, fate and behaviour in the environment and ecotoxicology and deliver its conclusions on propanil.

[1] On request from the European Commission, Question No EFSA-Q-2010-00851, issued on 23 February 2011.
[2] Correspondence: praper@efsa.europa.eu
[3] OJ L 224, 21.08.2002, p.25
[4] OJ L 246, 21.9.2007, p. 19
[5] OJ L 263, 2.10.2008, p.14
[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 use of propanil as a herbicide on rice, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

In the area of identity, physical/chemical/technical properties and methods of analysis no critical areas of concern were identified. Data gaps were identified for one of the specifications, methods of analysis and formulation storage stability and physical properties.

In the area of mammalian toxicology, two data gaps were identified: the determination of the toxicological relevance of one impurity, and information to allow the setting of reference values (ADI and ARfD) for the plant metabolite 3,4-DCA. Since the composition of the batches used in the toxicological studies was not demonstrated to cover the technical specification, this is considered as a critical area of concern.

Based on the metabolism study conducted on rice the residue for monitoring and risk assessment was defined as "all compounds containing the 3,4-DCA moiety, free and conjugated". No MRL was proposed for rice, as the submitted trials were not performed according to the cGAP and a data gap was identified. A critical area of concern was identified in the residue section, as the consumer risk assessment could not be conducted.

The data available on fate and behaviour in the environment are insufficient for the required environmental exposure assessments in line with the agreed EU MED-Rice (2003) guidance; therefore several data gaps were identified during the peer review. It could however be concluded that in situations represented by the scenarios in the EU MED-Rice guidance, the potential for groundwater exposure from the representative use by propanil or the metabolite 3,4-DCA above the parametric drinking water limit of 0.1 µg/L is expected to be low. This conclusion however is based on only the limited data set available. Propanil has a potential for long-range transport through the atmosphere, therefore this was identified as a critical area of concern.

Five data gaps were identified in ecotoxicology section, to further address the acute and long-term risk of propanil to birds, the long-term risk to mammals and the risk to non target-arthropods. The risk of metabolites DCNB, DCAB and TCAB to non-target species should be addressed. Acute risk to birds, long-term risk to birds, long-term risk to mammals, the risk to aquatic organisms and the risk to non-target arthropods were identified as critical area of concerns in the ecotoxicology section.

KEY WORDS

Propanil, peer review, risk assessment, pesticide, herbicide

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BACKGROUND

Legislative framework

Commission Regulation (EC) No 1490/2002,[7] as amended by Commission Regulation (EC) No 1095/2007[8] lays down the detailed rules for the implementation of the third 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 Commission of the European Communities (hereafter referred to as 'the 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 for comments on the Additional Report provided by the designated RMS, and upon request of the 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 1490/2002

Propanil is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007.

In accordance with Article 10(1) of the Regulation, Italy, being the designated rapporteur Member State (RMS), provided an initial evaluation of propanil in the format of a DAR, which was received by the EFSA on 28 November 2007 (Italy, 2006). In accordance with Article 11 of the Regulation, the EFSA dispatched the DAR to the applicant's consultant Rivendell Consulting Ltd. on 3 March 2008 for consultation and comments.

In accordance with the provisions of Article 11a of the Regulation, the Commission examined propanil, 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 11f and 12 of the Regulation.

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

Following the Commission Decision of 30 September 2008 (2008/769/EC)[10] concerning the non-inclusion of propanil in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Propanil Data Development Consortium made a resubmission application for the inclusion of propanil 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 is insufficient** to satisfy the requirements set out in Annex II and Annex III Directive 91/414/EEC in particular with regard to
    - the substantial lack of data to assess the short and long-term risk to birds
    - the substantial lack of data to assess the risk to non-target arthropods

[7] OJ L224, 21.08.2002, p.25
[8] OJ L246, 21.9.2007, p.19
[9] OJ L 15, 18.01.2008, p.5
[10] OJ L 263, 2.10.2008, p.14

- the substantial lack of data to assess the risk to bees, in particular with regard to the metabolite 3,4-DCA

- **concerns were identified with regard to**

  - the operator exposure
  - the long-term risk to aquatic organisms
  - the risk to birds
  - the toxicity to non-target arthropods.

In accordance with Article 18, 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 26 February 2010 (Italy, 2010).

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 2 March 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 Commission on 20 April 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 Commission decided to further consult the EFSA. By written request, received by the EFSA on 20 May 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on propanil 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 Commission on 21 May 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, residues, fate and behaviour in the environment and ecotoxicology and that further information should be requested from the applicant in the areas of physical-chemical propertied, mammalian toxicology and residues.

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, was 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 January – February 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 herbicide on rice, 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 (3 June 2010),
- the Evaluation Table (25 January 2011),
- the reports of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of January 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

Propanil is the ISO common name for 3',4'- dichloropropionanilide (IUPAC).

The representative formulated product for the evaluation was 'Propanil 60' a water dispersible granule (WG) containing 600 g/kg propanil.

The representative use evaluated comprises foliar spraying to control broad leaved weeds in rice. Full details of the GAP 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), Sanco/10597/2003 –rev. 8.1 (European Commission, 2009), and SANCO/825/00 rev. 7 (European Commission, 2004a).

The minimum purity of the active substance as manufactured is 970 g/kg. The technical material contains three relevant impurities 3,4-dichloroaniline, 3,3´,4,4´-tetrachloroazobenzene and 3,3´,4,4´-tetrachloroazoxybenzene and their maximum content in the technical material are 10 g/kg, 2.5 mg/kg and 0.5 mg/kg respectively. A data gap for the relevant impurities was identified to demonstrate that their content in the formulation does not increase on storage. The only specification that was supported by the available batch data was for the applicant Cequisa as given in table C.1.2.1.2a-1 in the revised Additional Report Vol. 4. The RiceCo specification was not supported and data gaps were identified. Data gaps were also identified for information on the analytical columns used for the active substance and impurity methods of analysis as well as the specificity of the method for propanil with regard to its structural isomers (position of the chlorine atoms on the ring).

The main data regarding the identity of propanil and its physical and chemical properties are given in Appendix A.

For the formulation the storage stability studies were incomplete and data gaps were identified for attrition resistance and dustiness before and after storage for both the accelerated and shelf life test. It should also be noted that the container type used in the 2-year study is unknown. The formulation shows persistent foaming problems and therefore it must be demonstrated that in practical use situations this is not an issue. A data gap was also identified for particle size distribution.

An LC-MS/MS method is available to analyse propanil in rice plants. However, as the residue definition for plants is all compounds containing the 3,4-DCA moiety, free and conjugated, a data gap is identified for a new method of analysis. A method for products of animal origin is not required as no MRLs are proposed. However, it should be noted that there is an LC-MS/MS method available. Soil is analysed by GC-NPD for propanil and 3,4-DCA, a data gap has been identified for a confirmatory method. Water is analysed by LC-MS for propanil and 3,4-DCA. The method for air is LC-MS/MS for propanil. A data gap is identified for a method of analysis for 3,4-DCA in air. A method of analysis 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 used in the production of this conclusion: SANCO/221/2000 rev. 10 (European Commission, 2003a), SANCO/222/2000 rev. 7 (European Commission, 2004b) and SANCO/10597/2003 – rev. 8.1 (European Commission, 2009).

Propanil was discussed by the experts in mammalian toxicology in November 2010 (PRAPeR TC 43). The agreed technical specification contains three toxicologically relevant impurities (3,4-DCA, TCAB and TCAOB) and is not covered by the batches used in the toxicological studies (critical area of concern). For one impurity, the determination of the toxicological relevance is still missing (data gap).

Extensively absorbed after oral administration, propanil is widely distributed in the body without potential for bioaccumulation, and mostly excreted via urine. In the acute toxicity tests, propanil was shown to be harmful if swallowed (Xn, R22) and irritating to the eyes (Xi, R36).

In repeated dose studies, changes were observed in the haematological parameters, with pigment deposition in the spleen and kidney, and effects in the liver. In short-term studies, the most sensitive species is the dog with a NOAEL of 7 mg/kg bw/d in a 30-day study. In the 1-year dog study, a LOAEL of 5 mg/kg bw/d has been identified, based on decreased red blood cells, decreased haemoglobin level, increased methaemoglobinemia and presence of haemosiderin in the kidney and liver. No genotoxic potential relevant to humans was detected in the available studies. In long-term studies, the NOAEL for the mouse is 4.39 mg/kg bw/day whereas only a LOAEL of 9 mg/kg bw/d is identified for systemic toxicity in the rat study. Based on an increased incidence of testicular interstitial cell tumours in rats and an increased incidence of lymphomas in several organs in mice, the experts agreed to propose the classification of propanil as **Carcinogenic category 3, R40** Limited evidence of a carcinogenic effect.

In the reproductive toxicity studies, no adverse effect was observed in the fertility parameters or in the embryonic/foetal development. In the two-generation study, both parental and offspring NOAELs are 11 mg/kg bw/day, and both developmental and maternal NOAELs in rats and rabbits are 20 mg/kg bw/day. No specific investigation of neurotoxic effects is required since there is no indication of neurotoxicity in the available studies.

With regard to the plant metabolite 3,4-DCA (with a higher acute toxicity, i.e. *Toxic by inhalation, in contact with skin and if swallowed*, than propanil, *Harmful if swallowed*), a data gap has been identified by the experts for the setting of reference values in order to perform the consumer risk assessment (see also section 3).

The **Acceptable Daily Intake** (ADI) and **Acceptable Operator Exposure Level** (AOEL) are 0.02 mg/kg bw/day, based on the LOAEL in the 1-year dog study and using an increased safety factor of 300 because of the use of a LOAEL. The **Acute Reference Dose** (ARfD) is 0.07 mg/kg bw based on the 30-day dog study and applying a safety factor of 100. The dermal absorption value for the representative formulation is 1% for the undiluted product and 100 % for the dilution.

In the final addendum (Italy, 2011), the operator exposure estimate according to the German model is 70 % of the AOEL with the use of personal protective equipment (gloves during mixing/loading; hood and visor, gloves, coverall and sturdy footwear during application). According to EUROPOEM 2, the worker exposure estimate is 62.5 % of the AOEL with the use of gloves. According to Lloyd and Bell, the exposure estimate for the bystander, located at 8 m from the sprayer and exposed during 5 minutes, is 10 % of the AOEL.

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), and the recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004, 2007).

Metabolism of propanil was investigated in rice grown in pots, under greenhouse conditions. Rice plants at 4-5 leaf growth stage, received on the same day, a soil treatment and a foliar application at a dose rate of 3360 and 3800 g/ha respectively (total 7N rate). The soil application was performed by distribution onto the surface of each pot, of a thin layer of soil previously mixed with ^{14}C-propanil. Pots were flooded the next day after treatments and until harvest. Samplings were performed on immature plants (shoots) and at maturity (straw, rough grain). Rough grains were processed to hulls and brown rice, which was further processed to bran and milled rice (white rice). Significant TRRs were observed at harvest, up to 1.218 mg/kg in straw, 1.551 mg/kg in bran, 0.435 mg/kg in rough rice and 0.234 mg/kg in milled rice.

In all plants parts, most of the radioactivity (60 to 92 % TRR) remained unextracted, and was identified after enzymatic and chemical procedures to be composed of bound residues incorporated into natural products (starch, lignin, hemicellulose etc.). The extracted radioactivity (10-35 % TRR) was shown to be composed of numerous fractions where only two metabolites were identified; 3,4-DCA (*c.a.* 0.3 % TRR in bran and hulls and 7 % TRR in immature shoots) and 3,4-dichloroglucosylamine, accounting for less than 2 % TRR in hulls and straw and up to 4 % TRR in immature shoots. Following alkaline hydrolysis, 20 % of the TRR in straw, rough grain, hulls and bran, was released as 3,4-DCA, suggesting that residues in the extracted fractions are mainly composed of 3,4-DCA free and conjugated and 3,4-DCA analogs. To better understand the metabolic fate of propanil in rice, straw and bran samples were re-analysed 34 months after harvest, using more accurate analytical methods. Parent propanil was confirmed not to be present. Only two metabolites were identified (3,4-DCA and 3,4-dichloroacetanilide, *c.a.* 3 % TRR in straw) and the extracted radioactivity was shown to be mainly composed of a total of 14 unidentified compounds (metabolites A to N), mostly polar in nature and yielding 3,4-DCA after alkaline hydrolysis (*c.a.* 20 % TRR). Even if not supported by reliable storage stability data, this new investigation confirms that propanil is not present in rice samples, where the extracted radioactivity is mainly composed of 3,4-DCA and conjugates of 3,4-DCA accounting for about 20 % of the TRR. The toxicity of the 3,4-DCA metabolite was discussed during the PRAPeR TC 43 meeting on toxicology. Considering that this metabolite has a higher acute toxicity than propanil, the experts agreed that its toxicity is not covered by the reference values set for propanil and further information should be provided. Taking into account this information, the PRAPeR TC 46 meeting on residues proposed to define the residue for monitoring and risk assessment as "all compounds containing the 3,4-DCA moiety, free and conjugated". As the parent propanil is no longer present in plants and the extractable residues mainly composed of the 3,4-DCA metabolite, free and conjugated, it was concluded that the consumer risk assessment should refer to the toxicity of the 3,4-DCA metabolite instead of the propanil toxicity.

No MRL could be proposed, since the submitted residue trials were not conducted according to the cGAP (1000 g a.s./ha), but with a total dose rate ranging from 3960 g/ha to 9395 g/ha (4N to 9N). Based on these overdosed trials where residues in grains were up to 0.33 mg/kg, it was concluded that significant residues are expected to be present in rice at the supported dose rate. A data gap was therefore identified for a full residues trials data set. Storage stability studies were submitted. When analysed for total 3,4-DCA after alkaline hydrolysis, total residues were shown to be stable up to 20 months when stored frozen at -25°C. Processing studies were provided and processing factors were calculated from rough grains to hulls, brown rice, bran and milled rice.

Animal metabolism studies conducted on lactating goat and laying hens were submitted although the calculations based on the residue levels observed in the overdosed trials show animal intakes below the trigger value of 0.1 mg/kg DM. Therefore, no residue definitions were proposed for products of animal origin, since animal intakes will be even lower when considering the supported application rate.

The consumer risk assessment could not be conducted as no toxicological reference values could be set for the metabolite 3,4-DCA and since no MRL could be proposed for rice according to the cGAP.

4. Environmental fate and behaviour

Data on route and rate of degradation in aerobic flooded soil systems were not available for propanil, therefore a data gap was identified to study the degradation of propanil under such conditions. Under aerobic, non-flooded conditions in the dark, propanil exhibits very low persistence, forming three major (>10 % applied radioactivity (AR)) soil metabolites, referred to as 3,4-DCA, DCNB and DCAB. Moreover, metabolite TCAB (dimer of 3,4-DCA) exceeded 5 % AR at more than two consecutive time points in an aerobic soil and was still increasing at the end of another aerobic soil incubation. The rate of mineralisation to carbon dioxide varied between 3.1-36.4 % AR after 30 days or 5.6 % AR after 120 days. Formations of unextractable residues were a sink, accounting for 29.1-63.3 % AR after 30 days or 71.4 % AR after 120 days. No novel metabolites of propanil were formed under anaerobic conditions in soil. However it is noted that based on the available information, the non-extractable

residues accounted for about 71 % AR of the initial dose after 91 days (not extracted by toluene followed by toluene ethyl acetate). The soil photolysis of propanil was investigated using air-dried soil as well as using moistened soil (75 % of field moisture capacity). Insignificant metabolite formation with no degradation of propanil was observed at the surface of the air-dried soil, indicating that photolysis is not a significant process. In the experiment that used moistened soil however a significant degradation was observed, especially in the dark control (assumed to be due to biological degradation). The degradation of propanil in this wet soil resulted in formation of unidentified metabolites. There were some indications that these products or some of them are not identical those metabolites that were identified in the aerobic, non-flooded soil incubations. These results confirmed the need to follow the degradation pathway of propanil under aerobic flooded soil systems (see above). Propanil exhibited very low persistence while metabolite 3,4-DCA exhibited low to high persistence in aerobic, non-flooded soil. Propanil and the metabolite 3,4-DCA exhibited low to medium mobility in soil. No further information or any predicted environmental concentrations (PEC) calculated for the other soil metabolites were available, therefore a data gap was identified.

Regarding propanil and 3,4-DCA, PEC_{soil} were calculated using the longest soil DT_{50} values from the aerobic non-flooded laboratory experiments, as agreed by the experts at the meeting of PRAPeR 84 (a pseudo DT_{50} derived from biphasic kinetics was agreed to be used for the metabolite 3,4-DCA). The calculations followed the common approach assuming even distribution of the chemical in the top 5 cm soil layer and 1.5 kg/L bulk density for the soil.

The available data indicated that hydrolysis or aqueous photolysis may not contribute significantly to the degradation of propanil in shallow aquatic environments. The degradation of propanil in natural aerobic sediment water systems was investigated only in one system. Since the data regarding the sink to mineralization or to the non-extractable residues from the sediment were poorly reported, a data gap was identified to provide this information. A data gap was also identified to investigate the degradation in another sediment water system. No metabolites other than 3,4-DCA, which reached the maximum of 77 % AR in the total system, were measured at significant levels in this single system. The degradation parameters from the available system were derived in the meeting of experts at PRAPeR 84. Based on these data, propanil exhibited low persistence (SFO whole system DT_{50} 2 days at 25°C), while the metabolite 3,4-DCA exhibited moderate persistence (SFO whole system DT_{50} 22 days at 25°C) in this natural aerobic sediment water system. Propanil partitioned to sediment during the study. Due to the relatively fast degradation, the maximum amount in the sediment (9.4 % AR in average) was measured at the first day of the study.

Step 1 PEC values for paddy water, surface water and sediment for propanil and for the metabolite 3,4-DCA as described in the EU MED-Rice guidance document (European Commission, 2003b) were calculated based on the available data set. The PEC values resulting from these calculations can be found in Appendix A. Based on the data on ecotoxicology, refinements of the surface water exposure assessment were necessary for propanil and for the metabolite 3,4-DCA, so a refined modelling using the linked model system RICEWQ-RIVWQ was available. The Member State experts did not accept these higher tier calculations; in particular the representativeness of the used scenario definition in the context of regulatory exposure assessments was questioned. The experts at the meeting of PRAPeR 84 agreed that this scenario, as applied in the available higher tier modelling, very likely results in an underestimation of the surface water concentration compared to what would be expected in a real catchment in rice growing areas in the EU. Therefore a data gap was identified for a more refined exposure assessment that well represents the EU rice growing landscapes.

The potential for contamination of groundwater by simulating the applications of propanil to drained rice paddies was determined using the methods, scenarios and the simple screening calculation (tier 1 PEC_{gw} calculations) specified by EU MED-Rice (2003) guidance. The results indicated that the potential for groundwater exposure from the representative use by propanil or the metabolite 3,4-DCA above the parametric drinking water limit of 0.1 µg/L is low in geoclimatic situations that are represented by the relevant scenarios in EU MED-Rice (2003). These calculations however are based only on the limited data set that was available.

Propanil has a potential for volatilization and the estimated atmospheric half-life is longer than 2 days. Therefore, based on this calculation, there is a potential for short-range and long-range transport through the atmosphere.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, 2002b, 2002c), SETAC (2001) and MED-Rice guidance (European Commission, 2003).

The acute risk to insectivorous and herbivorous birds via dietary exposure was assessed as high at tier 1. Refinements based on focal species mallard duck (*Anas platyrhnchos)* was accepted as a suitable focal species for herbivorous birds. However the RUD and PD were not considered acceptable by the PRAPeR 85 expert's meeting. The use of a PD refinement in an acute assessment was not considered appropriate, while the RUD proposed by the applicant did not correspond to the residue values proposed in the Birds and Mammals guidance document. Therefore a data gap was identified to further address the acute risk to herbivorous and insectivorous birds. The acute risk of the metabolite 3,4-DCA to birds was assessed as low. The short-term risk of propanil to birds was assessed as low at the first tier risk assessment.

The long-term risk of propanil to insectivorous and herbivorous birds was assessed as high at the tier 1. The experts' meeting agreed to use the mallard duck as the relevant focal species for herbivorous birds. However, the PD refinement for mallard duck was not acceptable, due to shortcomings in the study performed (i.e. the habitat was not described and the study was conducted in a single area). The experts concluded that a low long-term risk could not be demonstrated for herbivorous birds. For the insectivorous birds, the black-winged stilt was considered as the relevant focal species. The experts agreed that the RUD to be used in the refinement should be 5.1 for large insects and 29 for small insects, as in the SANCO guidance document (European Commission, 2002c). For herbivorous birds the risk from the metabolite 3,4-DCA was assessed as low at first tier. The long-term risk of 3,4-DCA to insectivorous birds was assessed high. For insectivorous birds concern was raised that the existing toxicity studies may not fully cover the risk from the metabolite. Therefore a data gap was identified to further addressed the long-term risk to herbivorous (from the parent) and insectivorous birds (from the parent and the metabolite), based on relevant focal species and appropriate dietary data.

The acute risk to mammals was assessed as low based on the use of RUD refinement. The long-term risk to mammals via dietary exposure was assessed as high. The applicant proposed to use Norway rat as focal species and PD and RUD refinements, however the experts did not agree with the proposals. Concerns were raised that the existing toxicity studies may not fully cover the risk from the metabolite 3,4-DCA. A data gap was therefore identified for the applicant to further address the long-term risk to mammals from the parent and the metabolite 3,4-DCA.

A risk assessment from secondary poisoning from propanil to birds and mammals was not required since the log P_{ow} for propanil is 2.29. Even though a risk assessment from secondary poisoning was not necessary for 3,4-DCA (log P_{ow} value of 2.7), the secondary poisoning to birds and mammals feeding on sediment-dwelling invertebrates that could be exposed to 3,4-DCA was assessed by the applicant through the long-term risk assessment via diet ingestion. The TER value was below the Annex VI trigger value, indicating a possible risk of secondary poisoning of birds eating contaminated sediment invertebrates present off-field. However according to the guidance document the risk to birds and mammals feeding on sediment dwelling invertebrates need not be addressed based on the low log P_{ow} values for propanil and 3,4- DCA (European Commission, 2002c).

Propanil is very toxic to aquatic organisms. The formulation 'Propanil 60' is very toxic to aquatic organisms even if it was less toxic than the active substance. According to the MED-RICE guidance document, the risk assessment for the rice field crop should be done in two different areas (in-field area and off-field area). The in-field area assessment should be assessed at Member State level. The risk assessment for the off-field areas shows that the acute risk of propanil to fish and chronic risk to sediment-dwellers were assessed as low at MED-Rice step 1a. The acute risk of propanil to aquatic

invertebrates and the risk to higher plants was assessed as low at step 1c whereas a high risk for algae and a long-term risk to fish and aquatic invertebrates was identified.

For 3,4-DCA, a low risk was identified for the algae, aquatic plants, and sediment-dwellers exposed through sediment at step 1a, furthermore a low acute risk to fish was identified at step 1c. However, the risk for invertebrates, the long-term risk for fish, and sediment-dwellers exposed through water was assessed as high. Pending on the data gap identified in the fate and behaviour section, the risk assessment of the metabolites DCNB, DCAB and TCAB to aquatic organisms should be address and a data gap was identified. In conclusion, a high risk of propanil and its relevant metabolite was indicated for aquatic organisms in the off-area area.

Whereas the off-field risk was assessed as low for the two standard test species *A. rhopalosiphi* and *T. pyri*, only the in-field risk was assessed as low for *A. rhopalosiphi* for the representative use on rice. The in-field risk to *T. pyri* was assessed as high. Extended laboratory studies were submitted for *T. pyri*, plus an additional species *Aleochara bilineata* and *Poecilus cupreus*. Results from the extended laboratory studies for *T. pyri* showed 60 % mortality at the highest tested dose (0.25 kg as/ha, lower than the application rate proposed). A low in-field and off-field risk was concluded for *A. bilineata*. For *T. pyri* a low in-field risk could not be identified. Concern was expressed during the PRAPeR 85 experts meeting, that for slow colonising species a lack of off-field effects may not be sufficient to conclude on the potential for re-colonisation due to differences in agricultural practices and situations and a data gap was identified to further address the risk to the most sensitive non-target arthropod species found in rice paddies (see evaluation table expert consultation 5.3).

The risk of propanil and its metabolite 3,4-DCA was assessed as low for earthworms. Pending on the data gap identified in the fate and behaviour section, the risk to soil-dwelling organisms from the metabolites DCNB and DCAB may need to be addressed and a data gap was identified.

The risk to bees, non-target plants and the function of waste water treatment plants was assessed as low for the representative use.

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
propanil	Very low persistence SFO DT_{50} 0.2 – 0.8 days (20°C, pF2 soil moisture)	The risk to earthworms was assessed as low.
3,4-DCA	Low to high persistence [(a)] SFO/DFOP DT_{50} 4.2 – 86.2 days, DT_{90} 14 days – too long to reliably estimate (20°C, pF2 soil moisture)	The risk to earthworms was assessed as low.
DCNB	No data available	No data available. Data gap.
DCAB	No data available	No data available. Data gap.

(a): the class of high persistence is based on the assumption that the DT_{50} for the soil incubation, where the degradation followed biphasic kinetics and no decline was observed in the second phase, were about 300 days.

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 MED-Rice scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
propanil	Medium to low mobility K_{Foc} 239-800 mL/g	No[(a)]	Yes	Yes	Very toxic to aquatic organisms, endpoint driving the aquatic risk assessment: algae EC_{50} = 0.025 mg a.s./L (regulatory concentration including a safety factor of 10 = 0.0025 mg a.s./L). A high risk to the aquatic environment was indicated in the surface water risk assessment.
3,4-DCA	Medium to low mobility K_{Foc} 326-585 mL/g	No[(a)]	No	Yes T, R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.	Very toxic to aquatic organisms, endpoint driving the aquatic risk assessment acute aquatic invertebrates LC_{50} = 0.12 mg a.s./L (regulatory concentration including a safety factor of 100 = 0.0012 mg a.s./L). A high risk to the aquatic environment was indicated in the surface water risk assessment.
DCNB	No data available	No information available. Data gap.	No data.	Yes	No information available. Data gap.

DCAB	No data available	No information available. Data gap.	No data.	Yes	No information available. Data gap.
TCAB	No data available	No information available. Data gap.	No data.	Yes	No information available. Data gap.

(a): Based on the available, limited data set

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
propanil	Very toxic to aquatic organisms, endpoint driving the aquatic risk assessment: algae EC_{50} = 0.025 mg a.s./L (regulatory concentration including a safety factor of 10 = 0.0025 mg a.s./L). A high risk to the aquatic environment was indicated in the surface water risk assessment.
3,4-DCA	Very toxic to aquatic organisms, endpoint driving the aquatic risk assessment acute aquatic invertebrates LC_{50} = 0.12 mg a.s./L (regulatory concentration including a safety factor of 100 = 0.0012 mg a.s./L). A high risk to the aquatic environment was indicated in the surface water risk assessment.
DCNB	No information available. Data gap.
DCAB	No information available. Data gap.

6.4. Air

Compound (name and/or code)	**Toxicology**
propanil	No data on toxicity by inhalation, not required.
3,4-DCA	Toxic by inhalation (T, R23)

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

- For the three relevant impurities evidence must be provided that their content does not increase on storage. If their content does increase on storage then storage stability studies will be required as well as methods of analysis for the relevant impurities in the formulation (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Revised specification and new batch analysis date, to include analysis of the three relevant impurities (RiceCo) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- In the current methods for the active substance and impurities information is required on what columns were used. It should also be demonstrated that the structural isomers of propanil can be separated (RiceCo and Cequisa) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Validated methods of analysis for the impurities in the specification (RiceCo) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Attrition resistance and dustiness before and after storage for both the accelerated and shelf life tests (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- In use study to demonstrate that persistent foam is not an issue (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Particle size distribution (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Method of analysis for all compounds containing the 3,4-DCA moiety, free and conjugated, in plants (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Confirmatory method for soil (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Method of analysis for 3,4-DCA in air (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Assessment of the toxicological (non) relevance for the impurity 2 (relevant for all representative uses evaluated; data have been submitted to the RMS but not evaluated in an addendum; see section 2).
- Toxicological information in order to derive reference vales (ADI and ARfD) for the metabolite 3,4-DCA (relevant for the representative use evaluated on rice; submission date proposed by the applicant: unknown; see section 2 and 3).
- A full residue data set on rice where trials are conducted according to the cGAP is required (relevant for the representative use evaluated on rice; submission date proposed by the applicant: unknown; see section 3).

- Route and rate of degradation studies of propanil in at least two (for rate) representative aerobic laboratory flooded soil systems (relevant for use in rice; submission date proposed by the applicant: unknown; see section 4).

- Assessments of the exposure and subsequent risk assessments are missing for the soil metabolites DCNB (soil, surface water and groundwater), DCAB (soil, surface water and groundwater) and TCAB (groundwater). Substantial data (e.g. soil DT_{50}, K_{oc} or ecotoxicological endpoints) are missing for these assessments (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 4 and 5).

- An aerobic laboratory water-sediment study for propanil on an additional representative water sediment system (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).

- Quantitative information regarding the formed volatile compounds and bound residues measured in the available water-sediment study (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).

- A higher tier exposure assessment for surface water and sediment that well represents the EU rice growing landscapes and the subsequent risk assessment for the aquatic organisms (a high risk of propanil to aquatic organisms was identified at step 1c level of the exposure assessments). These assessments should also consider the potential for short-range transport of propanil and 3,4-DCA (relevant for use in rice; submission date proposed by the applicant: unknown; see section 4 and 5).

- Applicant to further address the acute risk to herbivorous and insectivorous birds (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

- Further consideration of the long-term risk to herbivorous birds (from the active substance) and insectivorous birds (from the active substance and 3,4-DCA) is required based on relevant focal species and appropriate dietary data (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

- Applicant to further address the long-term risk to mammals from the active substance and the metabolite 3,4-DCA (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).

- The applicant to further address the risk to the most sensitive non-target arthropod species found in rice paddies (relevant for all representative 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

- Use of personal protective equipment by the operators (gloves during mixing/loading; hood and visor, gloves, coverall and sturdy footwear during application) and by the workers (gloves) in order to have an exposure level below the AOEL (see section 2).

ISSUES THAT COULD NOT BE FINALISED

- Assessment of the toxicological relevance of the impurity 2.

- The route and rate of degradation of propanil in soil and in natural sediment water systems has not been properly investigated. Substantial data are missing for the environmental exposure

assessments of some relevant soil metabolites. Therefore there is no assessment for groundwater and surface water contamination of any potentially formed or already identified soil or aquatic transformation products that would trigger further evaluation.

CRITICAL AREAS OF CONCERN

- The composition of the batches used in the toxicological studies has not been demonstrated to cover the technical specification.
- The consumer risk assessment could not be conducted as no reference values could be derived for the 3,4-DCA metabolite (which has a higher acute toxicity than propanil). Moreover no MRL could be proposed for rice as the submitted trials were not performed according to the cGAP and significant residues are expected in grain.
- Propanil has the potential for long-range transport through the atmosphere.
- High acute and long-term risk to birds.
- High long-term risk to mammals.
- The risk to aquatic organisms in the off-field area was assessed as high based on the exposure data available (step 1c).
- The risk to non-target arthropods was assessed as high, based on the available data.

REFERENCES

EFSA (European Food Safety Authority), 2011. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance propanil.

European Commission, 1999. Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, 1607/VI/97 rev.2, 10/6/1999.

European Commission, 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. SANCO/3030/99 rev.4, July 2000.

European Commission, 2002a. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev.2 final, 17 October 2002.

European Commission, 2002b. Guidance Document on Aquatic Ecotoxicology Under Council Directive 91/414/EEC. SANCO/3268/2001 rev 4 (final), 17 October 2002.

European Commission, 2002c. Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC. SANCO/4145/2000.

European Commission, 2003a. Guidance document on assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC. SANCO/221/2000-rev 10-final, 25 February 2003.

European Commission, 2003b. Guidance document for environmental risk assessments of active substances used on rice in the EU for annex 1 inclusion. Document prepared by Working Group on MED-Rice. Sanco/1090/2000-rev.1 June 2003.

European Commission, 2004a. Guidance document on residue analytical methods. SANCO/825/00 rev. 7, 17 March 2004.

European Commission, 2004b. Guidance Document on Dermal Absorption. SANCO/222/2000 rev. 7, 19 March 2004.

European Commission, 2008. Review report for the active substance propanil Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 20 May 2008 in support of a decision concerning the non-inclusion of propanil in Annex I of Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance. SANCO/1352/08 – rev. 0, 25 April 2008.

European Commission, 2009. Guidance document on the assessment of the equivalence of technical materials of substances regulated under Council Directive 91/414/EEC. Sanco/10597/2003 –rev. 8.1, May 2009.

Italy, 2006. Draft Assessment Report (DAR) on the active substance propanil prepared by the rapporteur Member State Italy in the framework of Directive 91/414/EEC, July 2006.

Italy, 2010. Additional Report to the Draft Assessment Report on the active substance propanil prepared by the rapporteur Member State Italy in the framework of Commission Regulation (EC) No 33/2008, February 2010.

Italy, 2011. Final Addendum to the Additional Report on propanil, compiled by EFSA, January 2011.

JMPR, 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20–29 September 2004, Report 2004, 383 pp.

JMPR, 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Geneva, Switzerland, 18–27 September 2007, Report 2007, 164 pp.

SETAC (Society of Environmental Toxicology and Chemistry), 2001. Guidance Document on Regulatory Testing and Risk Assessment procedures for Plant Protection Products with Non-Target Arthropods. ESCORT 2.

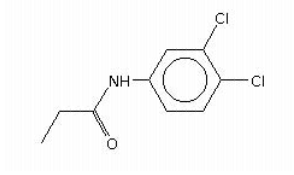
APPENDICES

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

Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	Propanil
Function (*e.g.* fungicide)	Herbicide
Rapporteur Member State	Italy

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	3',4'- dichloropropionanilide
Chemical name (CA)	*N*-(3,4–dichlorophenyl)propanamide
CIPAC No	205
CAS No	709-98-8
EEC No (EINECS or ELINCS)	EINECS 211-914-6
FAO Specification (including year of publication)	Not applicable
Minimum purity of the active substance as manufactured (g/kg)	> 970 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	3,4-DCA 10 g/kg TCAB 2.5 mg/kg TCAOB 0.5 mg/kg Open for impurity 2
Molecular formula	$C_9H_9Cl_2NO$
Molecular mass	218.1
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	91 °C (99.61%)
Boiling point (state purity)	351 °C (99.61%)
Temperature of decomposition	Not relevant

Appearance (state purity)	Brownish crystalline solid (technical material) White crystalline solid (purity ≥ 99%) inoffensive odour
Relative density (state purity)	1.412 at 20°C (99.9%)
Surface tension	70.4 mN/m (20.1°C, 90% saturation concentration)
Vapour pressure (in Pa, state temperature)	1.93×10^{-4} (25°C)
Henry's law constant (Pa m^3 mol^{-1})	4.4×10^{-4}
Solubility in water (g/l or mg/l, state temperature)	pH 6.7: 0.095 g/l at 20°C
	Different pH values not considered: Propanil does not ionise
Solubility in organic solvents (in g/l or mg/l, state temperature)	n-Heptane: 0.39 g/l (20°C)
	Xylene: 34.51 g/l (20°C)
	Ethyl acetate: >598 g/l (20°C)
	Methanol: >650 g/l (20°C)
	Acetone: >664 g/l (20°C)
	Dichloromethane: >631 g/l (20°C)
Partition co-efficient (log P_{OW}) (state pH and temperature)	2.29 (neutral pH, room temperature)
Hydrolytic stability (DT_{50}) (state pH and temperature)	Propanil is hydrolytically stable in the pH range 4 to 9
Dissociation constant	PKa: 19.1 Propanil does not dissociate or protonate in the pH range 5-8

UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	λ_{max} : 251 nm ε = 20037 L x mol^{-1} x cm^{-1} (neutral solution) ε = 18471 L x mol^{-1} x cm^{-1} (acidic solution) ε = 18659 L x mol^{-1} x cm^{-1} (basic solution) λ_{max} : 290 nm ε = 1374 L x mol^{-1} x cm^{-1} (neutral solution) ε = 910 L x mol^{-1} x cm^{-1} (acidic solution) ε = 1033 L x mol^{-1} x cm^{-1} (basic solution)
Photostability (DT_{50}) (aqueous, sunlight, state pH)	23.6 d : continuous irradiation (Suntest Xenon lamp) 52.1 d : natural spring sunlight for Japan and Europe in pond water
Quantum yield of direct phototransformation in water at λ > 290 nm	2.29 x 10^{-4}
Flammability	Not flammable
Explosive properties	Not explosive

Summary of intended uses:

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 as/hL min/max	Water L/ha min/max	kg as/ha min/max		
Rice	Italy, Spain, Portugal, France, Greece	Propanil 60 (Stam 60, Lizar 60, Kome 60)	F	Control of *Echinochloa crus-galli*, sedges and plants from water-plantain family originating from seed.	WG	600	Tractor-mounted/ drawn field crop sprayer with hydraulic nozzles	Between the 1st and 3rd leaf stage of the crop BBCH 11-13 (crop stage at 1st application)	1 - 2	15 days	0.1	500	0.5	60-90	Propanil is applied to drained paddy fields. The field remains drained for ca. 24 h after application, then it is reflooded until harvest or second application. PHI of 90 days has to be considered for a single application. PHI of 60 days has to be considered for two applications. [1], [2], [3], [4], [5], [6].

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse 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
(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) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

[1] High acute and long-term risk to birds.
[2] High long-term risk to mammals.
[3] High risk to non-target arthropods.
[4] The composition of the batches used in the toxicological studies had not been demonstrated to cover the technical specification.
[5] The consumer risk assessment could not be conducted.
[6] High risk to aquatic organisms in the off-field area.

Methods of Analysis

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

Residue definitions for monitoring purposes

Food of plant origin		all compounds containing the 3,4-DCA moiety, free and conjugated
Food of animal origin		Not necessary
Soil		propanil and 3,4-DCA
Water	surface	propanil and 3,4-DCA
	drinking/ground	propanil and 3,4-DCA
Air		propanil and 3,4-DCA

Technical as (principle of method)	GC-FID
Impurities in technical as (principle of method)	GC-FID HPLC-UV GC-MS Open for further methods/validation
Plant protection product (principle of method)	GC-FID

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Open
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	LC-MS/MS, LOQ: 0.01 mg/kg (bovine fat, kidney, liver, muscle, milk and eggs); determined as Propanil . No ILV supplied but not required as no MRLs are proposed.
Soil (principle of method and LOQ)	1) GC-NPD, LOQ: 0.01 mg/kg for Propanil and free 3,4-DCA. Open confirmatory method
Water (principle of method and LOQ)	LC-MS, LOQ: 0.01 µg/l in surface water, 0.05 µg/l in drinking and ground water (Propanil and 3,4-DCA)
Air (principle of method and LOQ)	LC-MS/MS, LOQ: 0.002 mg/m^3 Open for 3,4-DCA
Body fluids and tissues (principle of method and LOQ)	Not required as the active substance is not classified as toxic or very toxic.

Impact on Human and Animal Health

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

Rate and extent of oral absorption:	Readily absorbed (~80%), based on urinary excretion within 24 h.
Distribution:	Widely distributed, highest level in liver
Potential for accumulation:	No potential for accumulation. Very low levels of tissue residues after one week.
Rate and extent of excretion:	Extensive and rapid (≥ 90% within 168h, mainly during the first 24h); mostly via urine (78-87%) and faeces (10%)
Metabolism in animals	Extensively metabolised (≥ 90%). In the proposed metabolic pathway, the primary metabolites are 3,4-dichloroaniline (3,4-DCA) and N-hydroxy-3,4-dichloroaniline. The majority of metabolites are eliminated in urine as polar conjugates.
Toxicologically relevant compounds (animals, plants)	Propanil; 3,4-dichloroaniline (3,4-DCA) and N-hydroxy-3,4-dichloroaniline
Toxicologically relevant compounds (environment)	Propanil

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	960 mg/kg bw	R22
Rabbit LD50 dermal	> 2000 mg/kg bw	
Rat LC50 inhalation	No data - Not required	
Skin irritation	Non irritant	
Eye irritation	Irritant	R36
Skin sensitisation	Non sensitising (M&K test and modified Buehler test, 9 inductions)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Rat, dog, mouse: haematological changes (including increased metHgb); and histopathological changes in liver, kidney and spleen (a.o. iron pigment) Rabbit: haematological changes	
Relevant oral NOAEL	Rat: 23 mg/kg bw/d (90-d) Dog, 30-day: 7 mg/kg bw/d Dog, 1-yr: : LOAEL 5 mg/kg bw/d Mouse: LOAEL 71 mg/kg bw/d (13-wk)	
Relevant dermal NOAEL	Rabbit: 250 mg/kg bw/d (21-d, important deviations)	
Relevant inhalation NOAEL	No data - Not required	

Genotoxicity (Annex IIA, point 5.4)

No genotoxic potential relevant to humans	

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

Target/critical effect	Marginal metHgb increase and slightly decreased RBC parameters (at week 52, in females); haemosiderin in spleen and kidney (rat) Hepatocyte enlargement (mouse)	
Relevant NOAEL	Mice: 4.39 mg/kg bw/d (2-yr) Rat (2-yr): - neoplastic NOAEL : 9 mg/kg bw/d - systemic LOAEL : 9 mg/kg bw/d	
Carcinogenicity	Rat: increased incidence of testicular interstitial cell tumours. Without mechanistic evidence, the relevance to humans could not be ruled out. Hepatocellular adenomas in female rats at high dose were not considered relevant to human risk assessment. Mouse: increased incidence of lymphomas in several organs at the high dose (150 mg/kg bw/d), the relevance to humans could not be ruled out.	Carc Cat.3 R40

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	Parental: decreased body weight gain, food consumption and effects in the spleen Offspring: reduction in pup body weights; delay in balanopreputial separation Reproductive: no adverse effect up to 43 mg/kg bw/d
Relevant parental NOAEL	11 mg/kg bw/d
Relevant reproductive NOAEL	43 mg/kg bw/d
Relevant offspring NOAEL	11 mg/kg bw/d

Developmental toxicity

Developmental target / critical effect	Maternal: mortality and clinical signs (rabbit); decreased body weight gain (rat, rabbit) Developmental: reduced foetal weight (rat, rabbit); delayed ossification (rat)
Relevant maternal NOAEL	20 mg/kg bw/d (rat, rabbit)
Relevant developmental NOAEL	20 mg/kg bw/d (rat, rabbit)

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity Repeated neurotoxicity Delayed neurotoxicity	No data – Not required

Other toxicological studies (Annex IIA, point 5.8)

2-week gavage study in rats with hormone evaluation	Weight and histopathologic changes of reproductive organs were reported in mature and immature rats in the presence of systemic toxicity. Very slight hormonal changes were not clearly related to these alterations.

Medical data (Annex IIA, point 5.9)

	There have been few case reports of Propanil poisonings. Most common symptoms include; chloracne, cyanosis and skin rash. Other symptoms include dark urine and blood (from the formation of methaemoglobin), acetanilide in the urine, chills, cyanosis (also from methaemoglobin), and jaundice. Death from respiratory failure may occur.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	0.02 mg/kg bw/d	1-yr dog	300*
AOEL	0.02 mg/kg bw/d	1-yr dog	300*
ARfD (acute reference dose)	0.07mg/kg	30-d dog	100

* increased safety factor because of the use of a LOAEL

Dermal absorption (Annex IIIA, point 7.3)

In vitro study with Propanil 60 WG, using human and rat skin	1% for the undiluted product. Conservative value of 100% for the dilution, in the absence of reliable data for the highest dilution.

Exposure scenarios (including method of calculation)

	Exposure estimates (in % of AOEL)		
Operator	**Model**	**Without PPE**	**With PPE**
	German	1470	70*****
	UK POEM	4075	1045******
Workers	**Model**	**Without PPE**	**With gloves**
	EUROPOEM 2	625	62.5
Bystanders	According to Lloyd and Bell (1983), the exposure estimate of the bystander at 8m from the sprayer, exposed during 5 minutes, is 10% of the AOEL.		

*****PPE (personal protective equipment): gloves during mix/loading; hood and visor, gloves, coverall and sturdy footwear during application.

******PPE: gloves during mixing/loading and application.

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

Propanil	RMS/peer review
	Xn, R22 Harmful if swallowed Xi, R36 Irritating to eyes Carc. Cat.3, R40 Limited evidence of a carcinogenic effect

Residues

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

Plant groups covered	Cereals (rice)
Rotational crops	Grass, sorghum and soybean; 30, 156 and 365 DAT, 6700 g a.s./ha (6.7N). (not relevant for Italy and Portugal)
Metabolism in rotational crops similar to metabolism in primary crops?	No characterisation performed. No fractions above 0.01 mg/kg in the extractable residues.
Processed commodities	Standard hydrolysis study not provided and not required
Plant residue definition for monitoring	All compounds containing the 3,4-DCA moiety, free and conjugated
Plant residue definition for risk assessment	All compounds containing the 3,4-DCA moiety, free and conjugated
Conversion factor (monitoring to risk assessment)	None

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

Animals covered	Lactating goat and Laying hen
Animal residue definition for monitoring	Not proposed, not necessary according to the representative use on rice
Animal residue definition for risk assessment	Not proposed, not necessary according to the representative use on rice
Conversion factor (monitoring to risk assessment)	Not relevant.
Metabolism in rat and ruminant similar (yes/no)	Not evaluated.
Fat soluble residue: (yes/no)	No

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

Maximum TRR was 0.40 mg/kg in soybean straw at 30 day DAT (*c.a.* 0.05 mg/kg when expressed on a 1N rate basis). No individual compound expected to be above 0.01 mg/kg when considering the 1N dose rate.

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

Propanil residues analysed as 3,4-DCA stable for at least: 91 weeks in rough rice grain and hulls; 77 weeks in rice straw, 70 weeks in rice bran, 68 weeks in polished rice grain, when stored frozen at -25°C.

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 specified the level)	No[a]	No[a]	No[a]
Potential for accumulation (yes/no):	-	-	-
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	-	-	-
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	-	-	-
Liver	-	-	-
Kidney	-	-	-
Fat	-	-	-
Milk	-		
Eggs		-	

[a]: When estimated using the STMR for rice grain of 0.05 mg/kg derived from the overdosed residue trials (4 to 9N), the calculated intakes are <0.1 mg/kg DM for poultry, cattle and pig. Residues in straw are not taken into account as rice straw in not considered as a feed item.

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern/ Southern Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL mg/kg	STMR (b)
Rice	South (Italy, Spain)	6x <0.01, 0.01, 2x 0.02, 2x 0.03, 0.04, 0.05, 2x 0.06, 0.07, 0.08, 0.10, 0.14, 0.16, 0.17, 0.18, 0.20, 0.33 **Trials not conducted according cGAP**	Trials not appropriate to derive MRL, as conducted with a total dose rate of 3960 to 9395 g/ha (4N to 9N). Samples analysed as 3,4-DCA and residue levels expressed as 3,4-DCA.	No proposal	0.05

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 2x 0.11, 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

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

ADI	0.02 mg/kg bw/d
TMDI (% ADI) according to EFSA PRIMo model	The chronic risk assessment could not be conducted, as information on the chronic toxicity of the metabolite 3,4-DCA is missing.
TMDI (% ADI) according to national (to be specified) diets	-
NEDI (% ADI) (specify diet)	-
Factors included in NEDI	Not applicable
ARfD	0.07 mg/kg bw
IESTI (% ARfD)	The acute risk assessment could not be conducted, as information on the acute toxicity of the metabolite 3,4-DCA is missing.
NESTI (% ARfD) according to national (to be specified) large portion consumption data	-
Factors included in IESTI and NESTI	Not applicable

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

Crop/processed crop	**Number of studies**	**Processing factors**		% Transference
		Transfer factor **Mean** (values)	Yield factor	
Rough rice / hulls	4	**2.5** (2.0, 2.0, 2.5, 3.4)		
Rough rice / brown rice	4	**0.74** (0.64, 0.73, 0.75, 0.82)		
Rough rice/ bran	4	**3.7** (2.8, 3.5, 3.7, 4.6)		
Rough rice / polished rice	4	**0.19** (0.11, 0.13, 0.25, 0.27)		

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

Rice	No proposal, as residue trials not conducted according to cGAP

When the MRL is proposed at the LOQ, this should be annotated by an asterisk (*) after the figure.

Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	3.1 –36.4% AR after 30 d (n=4) 5.6% AR after 120 d (n=1)
Non-extractable residues after 100 days ‡	29.1-63.3% AR after 30 d (n=4) 71.4% AR after 120 d (n=1)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	3,4-DCA max. 43.7-80.2% AR at 1 to 3 d (n= 5) 3,4-Dichloronitrobenzene max. 18.1% AR at day 17 DCAB 10% max. 10.0% AR at 12 hours TCAB max. 7.1% AR at day 3

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

Anaerobic degradation

Mineralization after 100 days	3.4% AR volatile at 91 d, 3.6% AR volatile at 182 d
Non-extractable residues after 100 days ‡	70.1-71.8% AR at 91 d, 81.6-85.4% AR at 182 d
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Metabolites: 3,4-DCA max. 77.6-78.8 % at day 14

Soil photolysis

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Several unidentified metabolites were found at significant level under irradiated and/or dark moistened conditions. A data gap has been set for investigation of the route of degradation under aerobic flooded condition in soil. No metabolite at significant level was found in the air-dried samples.

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 / pF2 (%)	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	Error level (χ^2 test) %	Method of calculation
Loamy sand	6.8	20°C / 13.1	0.8	2.8	0.8	χ^2 = 11.2	non linear SFO*

Sandy clay loam	8.0	20°C / 24.0	0.6	1.8	0.6	χ^2 = 3.5	non linear SFO*
Clay loam	8.2	20°C / 52.7	0.2	0.7	0.2	χ^2 = 7.4	non linear SFO*
Sandy loam	6.3	20°C / 24.5	0.4	1.3	0.4	χ^2 = 4.8	non linear SFO*
Sandy loam	7.5	25°C / 16.9% (moisture content %)	0.2	0.6	0.276	χ^2 = 14.8	non linear SFO*
Geometric mean					0.4		

*** Parameter optimisation for SFO kinetics with Excel Solver Add-In**

Metabolite 3,4-DCA	Aerobic conditions						
Soil type	pH	t. °C / pF2 (%)	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	Error level (χ^2 test) %	Method of calculation
Loamy sand	6.8	20°C / 13.1	4.2	14.0	4.2	χ^2 = 10.9	non linear SFO*
Sandy clay loam	8.0	20°C / 24.0	8.3	27.4	8.3	χ^2 = 3.5	non linear SFO*
Clay loam	8.2	20°C / 52.7	4.8	No decline in the 2nd phase	1000**	χ^2 = 8.2	DFOP
Sandy loam	6.3	20°C / 24.5	4.5	111.8	86.2 ***	χ^2 = 8.3	DFOP
Sandy loam	7.5	25°C / 16.9% (moisture content %)	9.6	32.0	13.9	χ^2 = 13.2	non linear SFO*
Geometric mean					33.4		

* Parameter optimisation for SFO kinetics with Excel Solver Add-In
** 1000 days is used in the modelling as no decline was apparent in the 2nd phase
*** DT_{50} of the slow phase

Field studies (state location, range or median with n value)	Not reliable data available
Degradation in the saturated zone:	No data submitted and no data required
pH dependence	No
Soil accumulation and plateau concentration	No data submitted and no data required

Laboratory studies ‡

Parent	Anaerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Silt loam	6.0	25°C/n.a.	2	-	r^2=0.99	linear regression

Metabolite 3,4-DCA	Anaerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Loamy sand	6.8	20°C/ n.a.	26.0/88.0	n.a.	r^2=0.9918	linear regression

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Propanil at 25°C						
Soil Type	t. °C	OC %	Soil pH	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Sand	25	0.3	5.4	0.54	306	1.18
Sandy loam	25	1.65	8.03	2.32	239	0.819
Silty clay loam	25	1.4	7.8	5.79	703	0.826
Silt loam	25	1.7	6.0	8.00	800	0.848
Clay loam	25	5.0	7.0	11.7	398	0.806
Arithmetic mean					489	0.90
pH dependence, Yes or No				No		

3,4-DCA					
Soil Type	OC %	Soil pH	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Clay loam	5.9	8.2	34.5	585	0.81
Sandy clay loam	0.5	8.0	1.63	326	0.81
Loamy sand	0.4	6.8	3.26	543	0.81
Arithmetic mean				484.7	0.81
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 available
Aged residues leaching	no data available
Lysimeter/ field leaching studies	no data available

PEC (soil) for Propanil (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 0.9 d (the longest aerobic soil DT_{50} is 0.8 d) Kinetics: non linear SFO Field or Lab: from aerobic non-flooded laboratory studies worst case
Application data	Crop: Rice Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 plant interception: 25 % crop interception (post-emergence application) Number of applications: 2 Interval (d): 15 Application rate(s): 0.5 kg as /ha

$PEC_{(s)}$ mg/kg Day after last appl'n		Multiple application Actual	Multiple application Time weighted average
Initial	0h	0.500	-
Short term	24h	0.231	0.349
	2d	0.107	0.255
	4d	0.023	0.155
Long term	7d	0.002	0.092
	28d	0.000	0.023
	50d	0.000	0.013
	100d	0.000	0.006

PEC (soil) – metabolite 3,4-DCA

Method of calculation	Molecular weight relative to the parent: 162.2/218.1

	DT_{50} (d): 33.7 d Kinetics: pseudo SFO (calculated from DFOP DT90 111.8/3.32 for soil Bromsgrove) Field or Lab: Representative from aerobic laboratory studies
Application rate	Application rate assumed: 298 g as/ha (assumed 3,4-DCA is formed at a maximum of 80.2% of the applied dose)

$PEC_{(s)}$ mg/kg Day after last appl'n		Multiple application Actual	Multiple application Time weighted average
Initial	0h	0.517	
Short term	24h	0.507	0.512
	2d	0.496	0.507
	4d	0.476	0.497
Long term	7d	0.448	0.482
	28d	0.291	0.393
	50d	0.185	0.323
	100d	0.066	0.219

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 4: Propanil and 3,4-DCA are stable to hydrolysis at 50° C
	pH 7: Propanil and 3,4-DCA are stable to hydrolysis at 50° C
	pH 9: Propanil and 3,4-DCA are stable to hydrolysis at 50° C
Photolytic degradation of active substance and relevant metabolites	Propanil 'Suntest' Xenon light, DT_{50} 23.6 d (estimated) (pond water) Natural Spring Sunlight, 35°N; DT_{50} 52.1 d (pond water)
Readily biodegradable (yes/no)	No

Degradation in water / sediment

Parent	Distribution: max. in water 95.4 % after 0 d; max. sed. 9.4 % after 1 d (average)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys. (day)	Error level (χ^2 test) %	DT_{50}-DT_{90} water	Error level (χ^2 test) %	DT_{50}-DT_{90} sed	Error level (χ^2 test) %	Method of calculation
Silt Loam	7.4	6.4	25	2.0 – 6.7	12.5	-	-	-	-	non linear SFO*

* Parameter optimisation for SFO kinetics with Excel Solver Add-In

3,4-DCA	Distribution: max. in water 37.1 % after 7 d (average); max. sed 42.9 % after 14 d (average)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys. (day)	Error level (r^2)	DT_{50}-DT_{90} water	Error level (χ^2 test) %	DT_{50}-DT_{90} sed	Error level (χ^2 test) %	Method of calculation
Silt Loam	7.4	6.4	25	21.9 – 72.6	0.977	-	-	-	-	non linear SFO

PEC surface water and PEC sediment for Propanil (Annex IIIA, point 9.7)

Propanil Parameters used in MED-RICE, step 1a, step 1b and step 1c	Molecular mass (g/mol) : 218 Water solubility (mg/L) : 225 (at 25 °C) Koc (mL/g) : 489 (mean value) DT_{50pw} in water phase (d): 1000 default $DT_{50\ soil}$ in solid phase (d): 0.4 aerobic study geometric mean) $DT_{50\ sw}$ in water phase (d): 1000 (default) $DT_{50\ sed}$ in solid phase (d): 3.1 Crop interception (%): 25%
Application rate	Crop: Rice Number of applications: 2 Interval (d): 15 Application rate: 0.5 kg a.s./ha for the single application and 1 kg as./ha for the multiple application (no degradation between the applications is assumed). Depth of water body: 0.1 m

PEC$_{(sw)}$ (initial)	**Clayey soil** Single application Actual	**Clayey soil** Multiple application Time weighted average	**Sandy soil** Single application Actual	**Sandy soil** Multiple application Time weighted average
Step 1a (µg/L)	35.350	70.700	35.350	70.700
Step 1b (µg/L)	35.228	70.455	35.228	70.455

PECsw Step 1c µg/L		**Clayey soil** Single application Actual	**Clayey soil** Single application Time weighted average	**Sandy soil** Single application Actual	**Sandy soil** Single application Time weighted average
Initial		5.260	—	8.690	—
Short term	24h	5.256	5.258	8.684	8.687
	2d	5.253	5.256	8.678	8.684
	4d	5.245	5.253	8.666	8.678
Long term	7d	5.235	5.247	8.648	8.669
	28d	5.159	5.209	8.523	8.606
	42d	5.109	5.184	8.441	8.565
	50d	5.081	5.170	8.394	8.541
	100d	4.908	5.082	8.108	8.396

PECsw Step 1c µg/L	**Clayey soil** Multiple application Actual	**Clayey soil** Multiple application Time weighted average	**Sandy soil** Multiple application Actual	**Sandy soil** Multiple application Time weighted average

Initial		10.520		17.3801	
Short term	24h	10.513	10.5163	17.3680	17.3741
	2d	10.505	10.5127	17.3560	17.3680
	4d	10.491	10.5054	17.3320	17.3560
Long term	7d	10.469	10.4945	17.2960	17.3380
	28d	10.318	10.4185	17.0460	17.2125
	42d	10.218	10.3683	16.8814	17.1295
	50d	10.162	10.3397	16.7881	17.0824
	100d	9.815	10.1636	16.2162	16.7914

PECsed **Step 1c** µg/L		**Clayey soil** Single application Actual	**Clayey soil** Single application Time weighted average	**Sandy soil** Single application Actual	**Sandy soil** Single application Time weighted average
Initial		26.473	—	45.077	—
Short term	24h	21.169	23.722	36.045	40.393
	2d	16.927	21.345	28.823	36.346
	4d	10.824	17.497	18.430	29.793
Long term	7d	5.534	13.378	9.423	22.779
	28d	0.051	4.220	0.086	7.186
	42d	0.002	2.819	0.004	4.800
	50d	0.000	2.368	0.001	4.032
	100d	0.000	1.184	0.000	2.016

PECsed **Step 1c** µg/L		**Clayey soil** Multiple application Actual	**Clayey soil** Multiple application Time weighted average	**Sandy soil** Multiple application Actual	**Sandy soil** Multiple application Time weighted average
Initial		52.9454		90.1531	
Short term	24h	42.3372	47.4438	72.0898	80.7851
	2d	33.8544	42.6908	57.6458	72.6920
	4d	21.6472	34.9941	36.8599	59.5864
Long term	7d	11.0684	26.7556	18.8467	45.5582
	28d	0.1011	8.4407	0.1722	14.3724
	42d	0.0044	5.6374	0.0075	9.5991
	50d	0.0007	4.7357	0.0013	8.0638
	100d	0.0000	2.3679	0.0000	4.0320

PEC surface water and PEC sediment – metabolite 3,4-DCA

3,4-DCA Parameters used in MED-RICE, step 1a, step 1b and step 1c	Molecular mass (g/mol) : 162 Water solubility (mg/L) : 92 (at 25 °C) Koc (mL/g) : 484.7 (mean value) $DT_{50\ w}$ in water phase (d): 1000 (default value) $DT_{50\ soil}$ in solid phase (d): 33.4 (worst case) $DT_{50\ w}$ in water phase (d): 1000 (default value) $DT_{50\ sed}$ in solid phase (d): 34.3 (at 20 °C) Crop interception (%): 25%
Application rate	Crop: Rice Number of applications: 2 Interval (d): 15 Application rate: 447 g a.s./ha as modelled. That includes the dose of the two applications, 25% interception and assumes no degradation between the applications. Depth of water body: 0.1 m

PECsw (initial)	**Clayey soil** Multiple application Actual	**Sandy soil** Multiple application Actual
Step 1a (µg/L)	41.7620	41.7620
Step 1b (µg/L)	41.6175	41.6175

PECsw **Step 1c** µg/L		**Clayey soil** Multiple application Actual	**Clayey soil** Multiple application Time weighted average	**Sandy soil** Multiple application Actual	**Sandy soil** Multiple application Time weighted average
Initial		6.0776	-	10.1892	-
Short term	24h	6.0733	6.0755	10.1821	10.1856
	2d	6.0691	6.0733	10.1751	10.1821
	4d	6.0607	6.0691	10.1610	10.1751
Long term	7d	6.0481	6.0628	10.1399	10.1645
	14d	6.0189	6.0482	10.0908	10.1399
	21d	5.9897	6.0335	10.0419	10.1154

	28d	5.9607	6.0190	9.9933	10.0909
	42d	5.9032	5.9899	9.8968	10.0423
	50d	5.8705	5.9734	9.8421	10.0146
	100d	5.6706	5.8717	9.5068	9.8441

PECsed **Step 1c** **µg/L**		**Clayey soil** Multiple application Actual	**Clayey soil** Multiple application Time weighted average	**Sandy soil** Multiple application Actual	**Sandy soil** Multiple application Time weighted average
Initial		34.4423	-	56.6187	-
Short term	24h	33.7533	34.0966	55.4860	56.0505
	2d	33.0780	33.7556	54.3760	55.4898
	4d	31.7678	33.0870	52.2221	54.3908
Long term	7d	29.8991	32.1172	49.1502	52.7965
	14d	25.9551	29.9989	42.6669	49.3143
	21d	22.5314	28.0669	37.0387	46.1384
	28d	19.5593	26.3028	32.1530	43.2383
	42d	14.7395	23.2138	24.2299	38.1605
	50d	12.5393	21.6772	20.6130	35.6345
	100d	4.5651	14.7846	7.5045	24.3039

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

Method of calculation and type of study	Modelling using EU MED-RICE model Molecular mass (g/mol) : 218 Water solubility (mg/L) : 225 (at 25 °C) Koc (mL/g) : 489 (mean value) $DT_{50p\ w}$ in water phase (d): 1000 default $DT_{50\ soil}$ in solid phase (d): 0.4 aerobic study geometric mean) $DT_{50\ sw}$ in water phase (d): 1000 (default) $DT_{50\ sed}$ in solid phase (d): 3.1 Crop interception (%): 25%
Application rate	Crop: rice Application rate: 0.5 kg a.s./ha (1 kg as./ha modelled considering the multiple application) Number of applications: 2 Interval (d): 15
PEC_{gw} (µg/l)	
Average annual concentration step 1	< 0.001 µg/l

PEC (ground water) for metabolite 3,4 DCA (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	Modelling using MED-RICE model Molecular mass (g/mol) : 162 Water solubility (mg/L) : 92 (at 25 °C) Koc (mL/g) : 484.7 (mean value) $DT_{50\ w}$ in water phase (d): 1000 (default value) $DT_{50\ soil}$ in solid phase (d): 33.4 (worst case) $DT_{50\ w}$ in water phase (d): 1000 (default value) $DT_{50\ sed}$ in solid phase (d): 34.3 (at 20 °C) Crop interception (%): 25%
Application rate	Crop: Rice Number of applications: 2 Interval (d): 15 Application rate: 447 g a.s./ha as modelled. That includes the dose of the two applications, 25% interception and assumes no degradation between the applications. Depth of water body: 0.1 m

$PEC_{(gw)}$ (µg/l)	
Average annual concentration step 1	< 0.01 µg/l

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.9)

Direct photolysis in air	No data provided
Quantum yield of direct phototransformation	2.29 x 10^{-4} (direct photolysis in aqueous solution)
Photochemical oxidative degradation in air	DT_{50} 2.829 d (OH radicals 1.5 x 10^{6} 12 hr. day) DT_{50} 3,4-DCA 0.48 days (OH radicals 1.5 x 10^{6} 12 hr. day)
Volatilization	No data submitted

PEC air

Method of calculation	Expert judgement, based on vapour pressure (1.93 * 10^{-4} Pa at 25 °C), Henry's law constant (4.4 *10^{-4} Pa*m3*mol^{-1}) and molecular weight (218.1). Volatilization from soil and water surfaces is expected to be low.

PEC_a	
Maximum concentration	Negligible

Definition of the Residue (Annex IIA, point 7.3)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Soil: Propanil, 3,4-DCA, DCNB, DCAB Ground water: Propanil, 3,4-DCA, DCNB, DCAB, TCAB Surface water and sediment: Propanil, 3,4-DCA, DCNB, DCAB Air: Propanil, 3,4-DCA

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	No data provided
Surface water (indicate location and type of study)	Novara and Vercelli, north west Italy, surface water monitoring study. 36 samples, 12 sampling sites in northern Italy. Collected in June, July and December (1988). 7 peaks of 0.038 – 0.370 µg/L *recent literature data and Italian monitoring data show values >MAC in water bodies of rice-growing regions*
Ground water (indicate location and type of study)	Novara and Vercelli, north west Italy, ground water monitoring study. 72 samples, 24 sampling sites in northern Italy. Collected in June, July and December (1988). 1 peak of 0.040 µg/L
Air (indicate location and type of study)	No data available

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

Active substance	Candidate for R53

Effects on Non-target Species

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 ‡				
Bobwhite quail (*Colinus virginianus*)	Propanil	Acute	LD_{50} = 196	
	Preparation	Acute		
Bobwhite quail (*Colinus virginianus*)	3,4 DCA	Acute	LD_{50} = 99.09	
Bobwhite quail (*Colinus virginianus*)	Propanil	Short-term		LC_{50} 2792
Mallard duck	Propanil	Short-term		LC_{50} 5492
Mallard duck	Propanil	Long-term	NOEL = 11.33	
Mammals ‡				
Rat	Propanil	Acute	LD_{50} = 960	
Rat	Propanil 60 DF	Acute	LD50 = 1500 mg a.s./kg bw/day	
Rat	Propanil	Long-term (two generation)	NOEL: 11	NOEC = 150
Additional higher tier studies ‡				

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

Rice, 0.5 kg a.s./ha, 2 application at 15days interval.

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 – uptake via diet (Birds)				
Insectivorous	Acute	27.04	**7.25**	10
Large herbivorous	Acute	37.49	**5.23**	10
Insectivorous	Short-term	15.08	87.70	10
Herbivorous	Short-term	23.41	56.49	10
Insectivorous	Long-term	15.08	**0.75**	5

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Herbivorous	Long-term	12.41	**0.91**	5
Metabolite 3,4-DCA (application rate 0.085 Kg/ha)[1]				
Insectivorous	Acute	4.60	21.54	10
Large herbivorous	Acute	6.37	15.55	10
Insectivorous	Long-term	2.56	**4.4**	5
Herbivorous	Long-term	2.1	5.4	5
Higher tier refinement – uptake via diet (Birds)				
Propanil				
Insectivorous bird	Acute	Data gap		10
Herbivorous bird	Acute	Data gap		10
Insectivorous bird	Long-term	Data gap		
Herbivorous bird	Long-term	Data gap		5
Metabolite 3,4-DCA				
Insectivorous	Long-term	Data gap		10
Tier 1– uptake via consumption of contaminated water (Birds)				
	Acute			10
Tier 1 – secondary poisoning (Birds) Metabolite 3,4-DCA				
Sediment invertebrate-eating bird	Long-term	15.1	**0.8** *	5
Fish-eating bird	Long-term	Not relevant		5
Tier 1– uptake via diet (Mammals)				
Rat	Acute	118.43	**8.11**	10
Rat	Long-term	39.19	**0.28**	5
Metabolite 3,4-DCA				
Mammals		Data gap		
Higher tier refinement – uptake via diet (Mammals)				
Rat	Acute [2]	51.48	18.6	10
Mammals	Long-term	Data gap		

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1– uptake via consumption of contaminated water (Mammals)				
	Acute		Not relevant.	10
Tier 1 – secondary poisoning (Mammals)				
Sediment invertebrate-eating mammals.	Long-term	19.2	**0.6** *	5
Fish-eating mammals.	Long-term	Not relevant		5

[1] $C_{metabolite} = C_{parent}$ x (% Mass Conversion/100%) = 0.5 Kg/ha x 0.17 = 0.085 Kg/ha.
% Mass Conversion of 3,4-DCA = % conversion (mole basis) of Propanil to 3,4-DCA (23%) multiplied by the mole fraction of 3,4-DCA with respect to Propanil (0.743) = 0.17.
[2] RUD refinement for grasses/cereal shoots (61.73 mg/kg), based on the highest initial residue value (246.91 mg/kg) normalized to 1 kg a.s./ha.

*** The risk from secondary poisoning to birds and mammals need not be addressed because the log P_{ow} were < 3.**

Toxicity data for aquatic species (most sensitive species of each group*) (Annex IIA, point 8.2, Annex IIIA, point 10.2). In bold data used in risk assessment.

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Laboratory tests ‡				
Fish				
O. mykiss	Propanil	96 hr (flow-through)	Mortality, LC_{50}	5.4 mm
Cypronodon variegatus	Propanil	96 hr (flow-through)	Mortality, LC_{50}	**4.6 mm**
P. promelas Larvae at hatch	Propanil	96 hr (flow-through)	Mortality, LC_{50}	14 mm
P. promelas Early life stage	Propanil	35 d (flow-through)	Growth, NOEC	**0.019 mm**
P. promelas Life cycle	Propanil	263 d (flow-through)	Larval growth, NOEC	9.1 mm
O. mykiss	Propanil 60	96 hr (static)	Mortality, LC_{50}	7.0 mg a.s./L mm
Lepomis macrochirus	Propanil 60	96 hr (flow-through)	Mortality, LC_{50}	9.9 mg a.s./L mm
O. mykiss	3,4-DCA	96 hr	Mortality, LC_{50}	**1.9 mm**
Poecilia reticulata	3,4-DCA	42 d life cycle	Survival offspring 1st generation, NOEC	< **0.002** (literature data)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Aquatic invertebrate				
Daphnia magna	Propanil	21 d (flow-through)	Reproduction, NOEC	**0.086 mm**
Daphnia magna	Propanil 60	48 h (static)	Immobilization, EC_{50}	**2.39 mg a.s./L nom**
Daphnia magna	3,4-DCA	48 h	Mortality, LC_{50}	LC_{50}: **0.12 mg/L** (literature data)
Ceriodaphnia quadrangular	3,4-DCA	21 d	Reproduction, NOEC	NOEC: **0.002** (literature data)
Sediment dwelling organisms				
Chironomus riparius	Propanil	28 d (static, spiked water)	Development rate, NOEC	**1.9 mg/L nom**
Chironomus riparius	Propanil	28 d (static, spiked sediment)	Development rate, NOEC	**16 mg/kg mm**
Chironomus riparius	3,4-DCA	28 d (static, spiked sediment)	Development rate, NOEC	7.7 mg/kg mm (initial conc)
Pristina longiseta Oligochaete	3,4-DCA	96 h	Mortality, LC50	**2.5 mg/L** (literature data)
Ophryotrocha diadema Worm	3,4-DCA	31 d	Reproduction, NOEC	**0.003 mg/L** (literature data)
Algae				
Selenastrum capricornutum	Propanil	72 h (static)	Cell density, EC_{50}	0.11 mm
Navicula pelliculosa	Propanil	72 h (static)	Cell density, EC_{50}	**0.025 mm**
Skeletonema costatum	Propanil	72 h (static)	Cell density, EC_{50}	0.028 mg/L mm

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Scenedesmus subspicatus	Propanil 60	72 h (static)	Biomass, E_bC_{50} Growth rate, E_rC_{50}	0.107 mg a.s./l nom 0.30 mg a.s./L nom
Phaeodactylum tricornutum	3,4-DCA	96 h (static)	Growth, EC_{50}	**0.45 mg/L** (literature data)
Higher plant				
Lemna gibba	Propanil	14 d (static renewal)	Fronds number, EC_{50}	**0.11 mm**
Lemna gibba	3,4-DCA	7d (static)	Fronds number, EC_{50}	**5.80 mm** NOEC: 0.722
Lemna gibba	3,4-DCA	49d (semi-static)	Fronds dry weight, NOEC	**0.456 mm** EC_{50}: 2.962
Microcosm or mesocosm tests				

* For 3,4-DCA, only the endpoints relative to the most sensitive organisms are listed.

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

Maximum PEC_{sw} values and TER values for Propanil (off-field[1]) – application to rice at 0.5 kg a.s./ha, 2 applications at 15days interval.

Scenario	PECsw global max (µg/L)	PEC twa, 28d (µg/L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged *(via* sediment)[2]	Sed. dweller prolonged *(via* water)[3]
			C. variegatus	***P. promelas***	***Daphnia magna***	***Daphnia magna***	***Navicula pelliculosa***	***Lemna gibba***	***C. riparius***	***C. riparius***
			96h LC_{50}	35d NOEC	48h EC_{50}	21d NOEC	72h ErC_{50}	14d ErC_{50}	28d NOEC	28d NOEC
			4600 µg/L	19 µg/L	2390 µg a.s./L	86 µg/L	25 µg/L	110 µg/L	16000 µg/Kg	1900 µg/L
MED-Rice										
Step 1a	35.4		129.9	**0.5**	**67.5**	**2.4**	**0.7**	**3.1**	35.5	**53.7**
Step 1b	35.2			**0.5**	**67.9**	**2.4**	**0.7**	**3.1**		
Step 1c	8.7	8.6		**2.2**	275	**9.9**	**2.9**	12.6		
Annex VI Trigger			100	10	100	10	10	10	10	10

[1] According to MED-Rice, for aquatic organism the current trigger value of TERs as prescribed under 91/414 should be applied for the "off-field" environment, not for the "in-field" because the rice paddy falls dry after a certain time period. The in-field risk assessment should be possibly taken into account only for product registration at MS level.

[2] PEC_{sed} has been used

[3] PEC_{sw} has been used

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

Maximum PEC_{sw} values and TER values for the metabolite 3,4-DCA (off-field[1])

Scenario	PEC global max (µg/L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant		Sed. dweller prolonged	Sed. Dweller prolonged
			O. mykiss	*P. reticulata*	*Daphnia magna*	*C. quadrangula*	*P. tricornutum*	*Lemna gibba*		*Chironomus riparius* (via sediment)[1]	*Ophryotrocha Diadema* (via water)[2]
			48h LC_{50}	42d NOEC	48h LC_{50}	21d NOEC	96h EC_{50}	7d EC_{50}	49d NOEC	28d NOEC	31d NOEC
			1900 µg/L	< 2 µg/L	120 µg/L	2 µg/L	450 µg/L	5800 µg/L	456 µg/L	7700 µg/kg	3.2 µg/L
MED-Rice											
Step 1a	21.1		**90.0**	**<0.09**	**5.7**	**0.09**	21.3	275	21.7	264	**0.2**
Step 1b	21.0		**90.4**	**<0.09**	**5.7**	**0.1**					0.2
Step 1c	5.2		365	**< 0.4**	**23.1**	**0.4**					**0.6**
Annex VI Trigger**			100	10	100	10	10	10		10	5

* 28 d-PECtwa to be used in connection with the 34 d-NOEC from the ELS with *P. promelas*.

** If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. 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 MS in relation to product approval

[1] PEC_{sed} has been used

[2] PEC_{sw} has been used

Bioconcentration	Propanil	3,4-DCA
log P_{OW}	2.29	2.7
Bioconcentration factor (BCF)[1] ‡	100 x (supportive information from fish full life-cycle study)	BCF = 45 (fish) BAF= 572, (*Lumbriculus variegatus)*
Annex VI Trigger for the bioconcentration factor		
Clearance time (days) (CT_{50})		
(CT_{90})		
Level and nature of residues (%) in organisms after the 14 day depuration phase		

[1] only required if log $P_{O/W}$ >3.
* based on total ^{14}C or on specific compounds

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.	N/A	N/A
Propanil 60	> 94.26µg a.s./bee	> 100 µg a.s./bee
3,4 DCA	> 1604.96	> 102
Field or semi-field tests		
not required		

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

Rice, 0.5 kg a.s./ha, 2 application at 15days interval.

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	N/A	50
a.s.	oral	N/A	50
Propanil 60	Contact	< 5	50
Propanil 60	oral	< 5.30	50
3,4 DCA	Contact	< 3.64	50
3,4 DCA	oral	<0.23	50

N/A: Not applicable.

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} kg/ha)
Typhlodromus pyri ‡	Propanil 80 DF	Mortality	0.087 kg a.s./ha
Aphidius rhopalosiphi ‡	Propanil 60	Mortality	>13.7 kg a.s./ha

Crop and application rate

Test substance	Species	Effect (LR_{50} kg a.s./ha)	HQ in-field	HQ off-field[1]	Trigger
Propanil 60	*Typhlodromus pyri*	0.087	5.75	1.6	2
Propanil 60	*Aphidius rhopalosiphi*	>13.7	0.04	<0.01	2

[1] 2.77% drift at 1 m

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (kg/ha)[1, 2]	End point	% effect[3]	Trigger value
Typhlodromus pyri	Protonymph	Propanil 80 DF 7d exposure to aged residues Lab study	0.02-0.16 kg a.s./ha	Mortality Reproduction	17.4 (mortality at 0.16 kg/ha, 7d aged residues) 40.1 (reduction in reprodtuction at 0.16 kg/ha, 14 d aged residues)	50 %
Typhlodromus pyri	Protonymph	Propanil 60 7d exposure Extended lab study	0.03-0.250 kg a.s/ha	Mortality Reproduction	60.0 (mortality at 0.250 kg a.s/ha) 16.9 (reduction in reproduction at 0.15 kg a.s./ha)	50 %
A. bilineata	Adult	Propanil 60 30d exposure Lab study, fresh residue	0.27 kg a.s/ha	Reproduction	-1.3	50 %
			11.0 kg a.s/ha	Reproduction	79.6 (reduction in reproduction)	

Species	Life stage	Test substance, substrate and duration	Dose (kg/ha)[1, 2]	End point	% effect[3]	Trigger value
A. bilineata	Adult	Propanil 60 28d exposure Extended lab study, fresh residues	2.37 kg a.s/ha	Reproduction	-0.7	50 %
P. cupreus	Adult	Propanil 60, Laboratory study, fresh residues	13.7 kg a.s/ha	Mortality Feeding Rate	0.0 -6.5	50 %

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation
[3] indicate if positive percentages relate to adverse effects or not
Note: The field rate is calculated = 0.95 kg a.s./ha, the drift rate = 0.026 (kg a.s./ha).

Field or semi-field tests
Indicate if not required

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			
Eisenia fetida	Propanil	Acute 14 days	LC_{50} = 734 mg a.s./kg d.w.soil
Eisenia fetida	Propanil 60WG	Acute 14 days	LC_{50} = 621 mg a.s./kg d.w.soil
	3,4-DCA	Acute	LC_{50} = 180 mg/kg soil d.w.
Other soil macro-organisms			
Soil mite	a.s. ‡		
	Preparation		
	Metabolite 1		
Collembola			
	a.s. ‡	Chronic	NOEC mg a.s./kg d.w.soil (mg a.s/ha)
	Preparation		
	Metabolite 1		
Soil micro-organisms			
Nitrogen mineralisation	Propanil		Effects <25% at 9.12 mg a.s./kg d.w. soil after 28 days. Effects <25% at 91.2 mg a.s./kg d.w. soil after 56 days.

Test organism	Test substance	Time scale	End point[1]
	3,4 DCA		No expected long-term effect
Carbon mineralisation	Propanil		3.7% at 91.2 mg a.s./kg d.w. soil after 29d
	3,4 DCA		No expected long-term effect
Field studies[2]			
Indicate if not required			

[1] the LC50 has to be divided by 2 for risk assessment because log P_{ow} >2.

Toxicity/exposure ratios for soil organisms

Rice, 0.5 kg a.s./ha, 2 application at 15days interval.

Test organism	Test substance	Time scale	Soil $PEC_{ini,s}$ (mg/kg) (after 2nd application)	TER	Trigger
Earthworms					
	Propanil	Acute (14d)	0.5	621	10
	3,4-DCA	Acute (7d)	0.517	174	10
Soil mite	a.s. ‡				
	Preparation				
	Metabolite 1				
Collembola	a.s. ‡				
	Preparation				
	Metabolite 1				

[1] to be completed where first Tier triggers are breached
[2] 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) vegetative vigour	ER_{50} (g/ha) emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Brassica oleracea	Propanil 60	294.2 g a.s./ha	---	16.94	17.36	5

[1] The exposure refers to 2 drift events at 15 days interval, as the sum of PER (1 drift event) plus the residue at 14 days after the first drift event. Drift based on Ganzelmeier drift data (2.77% at 1 m), residues estimated from the results of trial TRC04-18R3, using a DT at 14 days = 77.7.
PER (2 drift events at 15 days interval) = PER (1 drift event) x 1.223.

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 - Propanil	3h EC_{50} = 47.1 mg/l
Activated sludge - 3,4-DCA	3h EC_{50} = 44 mg/l (from literature)

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

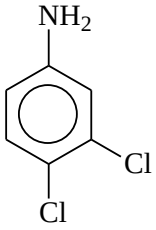
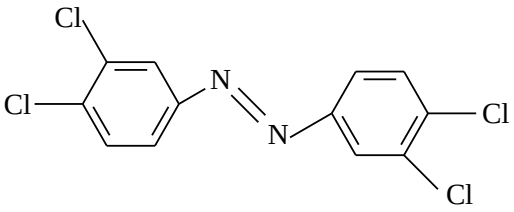
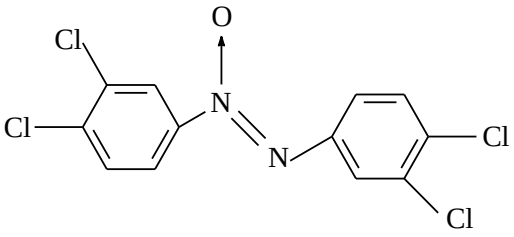
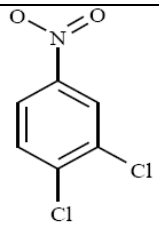
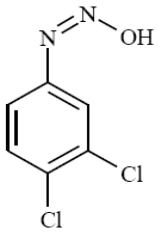
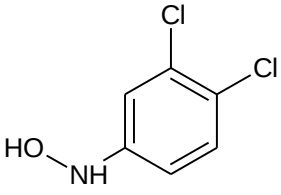
Compartment	
soil	Propanil,
water	Propanil, 3,4-DCA
sediment	Propanil, 3,4-DCA
groundwater	Propanil, 3,4-DCA

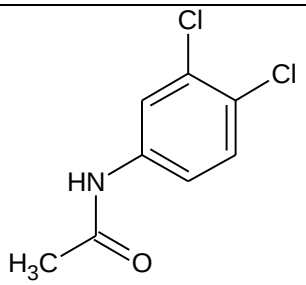
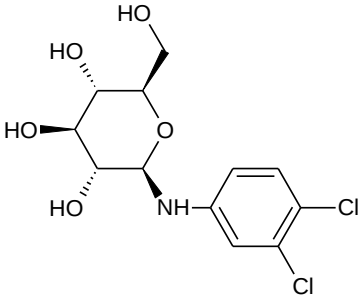
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	R50/53

	RMS/peer review proposal
Preparation	R50/53

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
3,4-DCA	3,4-dichloroaniline	
TCAB	3,3',4,4'-tetrachloroazobenzene	
TCAOB	3,3',4,4'-tetrachloroazoxybenzene	
DCNB	3,4-dichloronitrobenzene	
DCAB *N*-hydroxy-3,4-Dichloroazobenzene	(*Z*)-1-(3,4-dichlorophenyl)-2-hydroxydiazene	
***n*-hydroxy-3,4-dichloroaniline**		

3,4-dichloroacetanilide		
3,4-dichloroglucosylamine *N*-3,4-dichlorophenyl-glucosylamine	*N*-(3,4-dichlorophenyl)-β-D-glucopyranosylamine	

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

ABBREVIATIONS

1/n	slope of Freundlich isotherm
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
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 Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
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
FID	flame ionisation detector
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
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 pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	inter-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
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
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
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

NPD	nitrogen-phosphorus detector or detection
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
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
RICEWQ	Pesticide Runoff Model For Rice Crops
RIVWQ	Chemical transport model for riverine environments
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
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
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year