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CONCLUSION ON PESTICIDE PEER REVIEW

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

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SUMMARY

Terbuthylazine 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 the Regulation, at the request of the Commission of the European Communities (hereafter referred to as 'the Commission'), the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the United Kingdom, being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicants' decision, in accordance with Article 11e, to withdraw support for the inclusion of terbuthylazine in Annex I to Council Directive 91/414/EEC.

Following the Commission Decision of 5 December 2008 (2008/934/EC)[5] concerning the non-inclusion of terbuthylazine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicants Syngenta Crop Protection AG and Oxon Italia SpA made a resubmission application for the inclusion of terbuthylazine 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 DAR.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, the United Kingdom, 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 3 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 applicants for comments on 4 February 2010. The EFSA collated and forwarded all comments received to the Commission on 22 March 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, environmental fate and behaviour, and ecotoxicology and deliver its conclusions on terbuthylazine.

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[1] On request from the European Commission, Question No EFSA-Q-2010-00797, issued on 20 December 2010.
[2] Correspondence: praper@efsa.europa.eu
[3] OJ L224, 21.08.2002, p.25
[4] OJ L 246, 21.9.2007, p. 19
[5] OJ L 333, 11.12.2008, p.11
[6] OJ L 15, 18.01.2008, p.5
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The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of terbuthylazine as a herbicide in maize and sorghum, as proposed by the applicants. Full details of the representative uses can be found in Appendix A to this report.

Two data gaps were identified in the section identity.

Data gaps were identified in the mammalian toxicology section to address the relevance of the impurities present in the technical specification for both the Syngenta and Oxon sources. As the batches used in the toxicological studies do not support the technical specification from either the Syngenta or the Oxon source, a critical area of concern was identified. An assessment of the equivalence of the formulation used to perform the acute toxicity studies and the representative formulation ‘Gardo® Gold®’ was not presented. As classification with R40 (carcinogen category 3) is proposed for terbuthylazine, the groundwater metabolites (MT1, MT13, MT14, LM1, LM2, LM3, LM4, LM5, LM6) are considered toxicologically relevant.

Based on the metabolism study conducted on maize and on rotational crops, the plant residue definition was defined as terbuthylazine for monitoring, and as the sum of terbuthylazine and metabolites MT1 and MT14 for risk assessment. No data gaps were identified in the residue section.

Concerning the environmental fate and behaviour of terbuthylazine, the groundwater exposure assessment is not finalised for the toxicologically relevant metabolites LM1, LM2, LM3, LM4, LM5 and LM6. However, based on the results from lysimeter studies and groundwater monitoring data, metabolites LM3, LM5 and LM6 may be expected to occur above the parametric drinking water limit of 0.1 μg/L over a wide range of geo-climatic conditions. The potential for groundwater exposure by the relevant herbicidally active metabolite desethyl-terbuthylazine, the toxicologically relevant metabolites desethyl-hydroxy-terbuthylazine and hydroxy-terbuthylazine above the parametric drinking water limit of 0.1 μg/L is predicted to be high over a wide range of the geo-climatic conditions represented by the FOCUS groundwater scenarios. The number of FOCUS scenarios exceeding the parametric drinking water limit of 0.1 μg/L was 6 for desethyl-terbuthylazine, 8 for desethyl-hydroxy-terbuthylazine and 8 for hydroxy-terbuthylazine. Additional information on the groundwater leaching potential of these metabolites was available in lysimeter and groundwater monitoring studies and experts agreed that this further information should also be taken into account when considering the overall leaching behaviour of these metabolites. Considering all the available data critical areas of concern are identified with respect to the potential for groundwater contamination by desethyl-terbuthylazine, desethyl-hydroxy-terbuthylazine and hydroxy-terbuthylazine.

A high long-term risk and a high risk from secondary poisoning of mammals were identified in the risk assessment. A high long-term risk to birds was indicated for the higher application rate (1 x 0.844 kg a.s./ha). A high risk was also indicted to aquatic organisms and non-target plants. Risk mitigation comparable to a no-spray buffer zone of 10 m plus 90% run-off reduction would be needed to achieve TERs above the trigger in the majority of FOCUS scenarios. A high long-term risk was indicated for earthworms from the representative use of GARDO® GOLD® (Syngenta). Risk mitigation comparable to in-field no-spray buffer zones of 5 and 20 m are needed to protect non-target plants in the off-field area.

KEY WORDS

terbuthylazine, 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 applicants 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

Terbuthylazine 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 the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR provided by the designated rapporteur Member State, the United Kingdom, which was received by the EFSA on 21 August 2007 (United Kingdom, 2007).

The peer review was initiated on 8 October 2007 by dispatching the DAR to Member States and the applicants Syngenta Crop Protection AG and Oxon Italia SpA for consultation and comments.

The peer review process was subsequently terminated following the applicants decision, in accordance with Article 11e, to withdraw support for the inclusion of terbuthylazine in Annex I to Council Directive 91/414/EEC.

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

Following the Commission Decision of 5 December 2008 (2008/934/EC)[10] concerning the non-inclusion of terbuthylazine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicants Syngenta Crop Protection AG and Oxon Italia SpA made a resubmission application for the inclusion of terbuthylazine 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 DAR.

In accordance with Article 18, the United Kingdom, 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 3 February 2010 (United Kingdom, 2010a).

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicants for comments on 4 February 2010. In addition, the EFSA conducted a public consultation on the Additional Report and the DAR. The EFSA collated and forwarded all comments received to

[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 333, 11.12.2008, p.11

the Commission on 22 March 2010. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The applicants were invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicants' 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 23 April 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on terbuthylazine 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 applicants 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 applicants in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 28 April 2010; the applicants were also invited to give their view on the need for additional information. On the basis of the comments received, the applicants' responses 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, environmental fate and behaviour, and ecotoxicology and that further information should be requested from the applicants in these areas.

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 applicants, were compiled by the EFSA in the format of an Evaluation Table.

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

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in October 2010.

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 in maize and sorghum, as proposed by the applicants. 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 (EFSA, 2010), 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 comprises the following documents:

- the comments received,
- the Reporting Table (revision 1-1; 29 April 2010),
- the Evaluation Table (15 November 2010),
- the report(s) 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 October 2010 containing all individually submitted addenda) (United Kingdom, 2010b) 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

Terbuthylazine is the ISO common name for N^2-*tert*-butyl-6-chloro-N^4-ethyl-1,3,5-triazine-2,4-diamine (IUPAC).

The representative formulated products for the evaluation were 'Gardo® Gold®' (A9476C), a suspo-emulsion (SE) containing 187.5 g/l terbuthylazine and 312.5 g/l S-metolachlor, and 'Terbuthylazine 500 g/l SC', a suspension concentrate (SC) containing 500 g/l terbuthylazine, both registered under different trade names in Europe.

The representative uses evaluated comprise foliar spraying on maize and sorghum against annual and perennial monocotyledonous and dicotyledonous weeds. 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 minimum purity of terbuthylazine technical material is 960 g/kg for Syngenta and 980 g/kg for Oxon. The minimum purity of terbuthylazine technical material in the FAO specification AGP:CP/304 (1993) is 930 g/kg (234/TC/S (1991)).

Propazine and simazine are relevant impurities in terbuthylazine technical material of Syngenta origin with maximum limits of 10 g/kg and 30 g/kg respectively, while atrazine and simazine are relevant impurities in technical material of Oxon origin with maximum limits of 1 g/kg and 5 g/kg respectively. The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of terbuthylazine or the representative formulations. However, data gaps were identified for the level of ethoxylation of formulants and validation data for the method of determination of the additive in the technical material (relevant for Syngenta). The main data regarding the identity of terbuthylazine and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of terbuthylazine and the relevant impurities in the technical materials and for the determination of the active substance in the representative formulations. Terbuthylazine residues in food of plant origin can be monitored with the multi method DFG-S19 by GC-NPD. Monitoring methods in food of animal origin are not required since no MRLs have been proposed. Adequate analytical methods are available for monitoring the compounds in the residue definitions for soil and air. HPLC-MS/MS methods are available for monitoring terbuthylazine and metabolites MT1, MT13, MT14, LM3, LM5 and LM6 in water. It should be noted that the residue definition for monitoring includes, besides the previously mentioned metabolites also metabolites LM1, LM2 and LM4, for which no analytical methods were submitted, however the marker compound concept might be used for monitoring. It should still be decided which compounds could be considered and which factors may be used to calculate the total residue amount. As a consequence a data gap was identified for an analytical method for the compounds in the residue definition for water. Analytical methods for the determination of residues in body fluids and tissues are not required as terbuthylazine is not classified as toxic or highly toxic.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 – rev. 10-final (European Commission, 2003), SANCO/222/2000 rev. 7 (European Commission, 2004), SANCO/10597/2003 – rev. 8.1, May 2009 (European Commission, 2009).

Terbuthylazine was discussed at the PRAPeR Experts' Meeting on mammalian toxicology (PRAPeR 81) in September 2010. The batches used in the toxicological studies do not support the technical specification from either the Syngenta or the Oxon source, and this was listed as a critical area of concern. The relevance of the impurities was not addressed, except for the known relevant impurities, propazine, simazine and atrazine and data gaps are identified to address the relevance of the impurities present in the technical specification from both sources. An assessment of the equivalence between the formulation used in the acute toxicity studies and the representative formulation ‘Gardo® Gold®’ is missing and a data gap was identified.

Low to moderate acute toxicity is observed when terbuthylazine is administered by the oral, dermal or inhalation routes. Slight eye irritation, minimal skin irritation and skin sensitisation were observed. Classification as “harmful if swallowed”, R22, is proposed regarding acute toxicity. Main effects observed upon short-term exposure to terbuthylazine consist of body weight and food consumption decreases in rat, mouse, dog and rabbit; upon long-term exposure, additional effects on organ weights in rats and mice and red blood cells parameters in rats were observed. The relevant short-term and long-term NOAELs are set at 0.4 mg/kg bw/day derived from the 1-year study in dogs (NOAEL 0.4 mg/kg bw/day) and 2-year study in rats (NOAEL 0.35 mg/kg bw/day). No genotoxic potential is attributed to terbuthylazine. As an increased incidence of mammary adenocarcinomas was observed in rats at the dose level of 7.6 mg/kg bw/day, classification with R40 “limited evidence of carcinogenic effect” is proposed. Although reduced fertility in females secondary to reduced or absent *corpora lutea* and uterine endometrial hyperplasia were inconsistently seen and associated with parental toxicity, it was judged that there was insufficient evidence to trigger a classification proposal regarding reproduction. In rats, an increased incidence of small interventricular septal defects was observed in pups together with maternal toxicity and in rabbits no foetotoxicity was observed when clear signs of maternal toxicity were seen. No evidence of neurotoxicity was found up to 7 mg/kg bw/day.

Toxicity studies were submitted on several plant and soil metabolites. The reference values of terbuthylazine are applicable to the metabolites desethyl-terbuthylazine (MT1), hydroxy-terbuthylazine (MT13) and desethyl-hydroxy-terbuthylazine (MT14). No genotoxic potential is attributed to the metabolite LM6, but insufficient information is available on the other metabolites (LM1, LM2, LM3, LM4, LM5) to conclude on their genotoxic potential or if the reference values of the parent are applicable to these metabolites as well. Taking into account the proposal for classification of the parent compound as a carcinogen category 3 (R40), the metabolites are relevant in groundwater according to the guidance document on the relevance of groundwater metabolites (European Commission, 2003).

The acceptable daily intake (ADI) of terbuthylazine is 0.004 mg/kg bw/day, based on the NOAEL of the 1-year dog and 2-year rat studies, 100 safety factor (SF) applied. The acceptable operator exposure level (AOEL) is 0.0032 mg/kg bw/day, based on the same NOAEL and SF but corrected by 79 % to account for the limited oral absorption. The acute reference dose (ARfD) is 0.008 mg/kg bw based on the maternal NOAEL of 0.8 mg/kg bw/day from the developmental toxicity study in rabbits, 100 SF applied.

Estimated operator exposure level is below the AOEL for ‘Terbuthylazine 500 SC’ and the terbuthylazine component of ‘Gardo® Gold®’ formulation according to the German model when personal protective equipment (PPE) is used (gloves during mixing and loading; gloves, coverall and sturdy footwear during application). Worker exposure to ‘Gardo® Gold®’ is calculated to be below the AOEL without the use of PPE, while worker exposure to ‘Terbuthylazine 500 SC’ is below the AOEL when PPE (gloves, long sleeved shirt and long trousers) is considered. Bystander exposure is estimated to be below the AOEL.

3. Residues

Separate metabolism studies on primary crop (maize) and on rotational crops were provided by both applicants, all performed with a ^{14}C-label on the triazine moiety and experimental designs according to the representative uses. Both datasets provide similar and consistent information.

Terbuthylazine is rapidly and extensively metabolised in maize, representing less than 5% of the TRR in all plant parts, and being not detected in mature grains at harvest. The metabolism in primary crop proceeds by desalkylation to the desethyl metabolite (MT1) and by dechlorination resulting in the 2-hydroxy-terbuthylazine (MT13), which are further metabolised to the desethyl-hydroxy-terbuthylazine (MT14). A similar profile is observed in the rotational crops where the TRRs are mainly composed of these three metabolites: MT1 (up to 41% TRR in spinach leaves), MT13 (up to 37% TRR in cereal grain) and MT14 (up to 70% TRR in radish roots). The toxicological profile of these 3 metabolites was discussed during the PRAPeR 81 meeting and the experts concluded that they are considered to be of similar toxicity to the parent, the toxicological reference values set for terbuthylazine being applicable. Based on these data, the RMS proposed to limit the residue definition for monitoring to the parent compound only and to define the residue for risk assessment as the sum of terbuthylazine and desethyl-terbuthylazine (MT1). EFSA is however of the opinion that the metabolite MT14 should not be ignored in the risk assessment since it was observed at a level of 0.03 mg/kg in maize forage and 0.05 mg/kg in rapeseed grain in one rotational crops study and considering that the PRAPeR meeting on toxicology concluded it has to be regarded of similar toxicity to the parent.

Supervised residue trials were provided by both applicants. Samples were analysed for terbuthylazine but also for the metabolites MT1 and MT14 in a significant number of experiments. No residues were observed above the LOQ, except for the metabolite MT14 detected at the level of 0.03 mg/kg in maize forage in two locations. In addition, cold rotational crop trials were submitted where cereals, oilseed and tuber/root crops were rotated with maize treated as a primary crop at a dose rate of 844 to 937 g/ha. Parent residues were always below or at the LOQ of 0.02 mg/kg, MT1 was observed at the level of 0.02 to 0.06 mg/kg in cereal straw, sugar beet tops and sunflower seeds and metabolite MT14 was only detected in a single location in rapeseed grain (0.05 mg/kg). These trials confirm that parent residues are not expected to be present in rotational crops above the LOQ of 0.02 mg/kg. The residue data are supported by the storage stability studies, showing the residues of the parent, MT1 and MT14 to be stable up to 2 years when stored frozen at -18°C. Processing studies were not submitted and are not required because of the low residue levels.

A cow metabolism study was provided where animals were dosed with ^{14}C-terbuthylazine over 10 days at a dose rate calculated to represent a 18N and 15N dose rate for dairy and beef cattle respectively. This study has however to be considered as not appropriate to propose a residue definition as no characterisation was performed in animal tissues, except in milk where MT1 and MT20 were identified as major metabolites (*c.a.* 50% and 12% TRR). Considering that TRRs are expected to be <0.01 mg/k in milk, muscle and fat and <0.05 mg/kg in liver and kidney when expressed on a 1N dose basis, it was concluded that no significant residues of any metabolite are expected to be present in animal matrices. The setting of a residue definition and proposals for MRLs for animal products were therefore considered not necessary with regard to the representative uses.

As a worst case, the consumer risk assessment was conducted considering the total residue levels (MT0+MT1+MT14) observed in maize and sorghum grains (primary crop) and in oilseed and root crops (rotational crops). No concern was identified, the IEDI being 10% of the ADI (WHO cluster B) and the IESTI 63% of the ARfD (carrots).

Finally, and even if it is not an appropriate approach to consider levels of relevant metabolites in drinking water above 0.1 µg/L, it must be highlighted that the predicted levels of the metabolites MT1, MT13 and MT14 in groundwater (see section 4), may represent an additional exposure of 10%, 29% and 44% of the ADI for adult, child and infant respectively, when calculated using the water consumption figures proposed by the WHO guideline. These calculations exceed the 20% threshold percentage recommended by WHO for drinking water quality.

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, terbuthylazine exhibits medium to high persistence forming the major (>10% applied radioactivity (AR)) metabolites desethyl-terbuthylazine (MT1, max. 25.1% AR) and hydroxy-terbuthylazine (MT13, max. 34.5% AR). The persistence of these two metabolites ranged from moderate to high for desethyl-terbuthylazine and high to very high for hydroxy-terbuthylazine. Mineralisation of the triazine ring radiolabel to carbon dioxide accounted for 0.4 – 10.4% AR after 112-120 days. The formation of unextractable residues (not extracted using acetonitrile:water) for this radiolabel accounted for 17-31% AR after 112-120 days. In anaerobic soil incubations terbuthylazine was essentially stable. In the available field dissipation studies (spray application to the soil surface on bare soil plots in late spring) the persistence of terbuthylazine was moderate to high (23 European sites) while that of desethyl-terbuthylazine was low to high (10 European sites). Terbuthylazine and hydroxy-terbuthylazine exhibited medium mobility in soils, while the mobility of desethyl-terbuthylazine and desethyl-hydroxy-terbuthylazine was high to very high and low to very high respectively. There was no evidence that the adsorption of these metabolites was pH dependent. Leaching assessments (modelling) for terbuthylazine were completed assuming a pH dependence for adsorption as it is apparent that adsorption may be lower under alkaline soil conditions.

Terbuthylazine, desethyl-terbuthylazine (MT1) and hydroxy-terbuthylazine (MT13) did not leach in average concentrations exceeding 0.1 µg/l in any of the available lysimeter studies (n=8 for terbuthylazine and desethyl-terbuthylazine, n=6 for hydroxy-terbuthylazine), whereas the metabolite desethyl-hydroxy-terbuthylazine (MT14) leached in average annual concentration exceeding 0.1 µg/l in one of the three lysimeters analysing this metabolite. Moreover five lysimeter studies identified a high leaching risk of 6 additional metabolites, which were not triggered as metabolites requiring further consideration via the standard laboratory route of degradation studies. Annual average leaching exceeding 0.1 µg/l was observed for LM3, LM4, LM5, LM6 (5 out of 5 lysimeters) and LM2 and LM1 (3 out of 5 lysimeters). In these five lysimeters the application rate was 5-15% higher than the representative use. Nevertheless measured concentration suggested that, had the application rate been similar to the representative use of 850 g/ha average, the leaching concentration of all metabolites would still exceed the 0.1 µg/l.

In laboratory incubations in dark aerobic natural sediment water systems, terbuthylazine exhibited moderate to very high persistence, forming the metabolites desethyl-terbuthylazine (max. ca. 8 % AR in water and 3% in sediment, exhibiting high persistence), hydroxy-terbuthylazine (max. ca. 6% AR in water and 15% in sediment, exhibiting high persistence), and terbutryn (MT26, max. 7% AR in sediment but only max 0.3% AR in water, exhibiting high persistence). The unextractable sediment fraction (not extracted using acetonitrile: water) was the major sink for the triazine ring ^{14}C radiolabel, accounting for 31-76 % AR at study end (110- 219 days). Mineralisation of this radiolabel accounted for only 0.2-0.3 % AR at the end of the study. The rate of declination of terbuthylazine in a laboratory sterile aqueous photolysis experiment was relatively fast compared to that which occurred in the aerobic sediment water incubations forming hydroxy-terbuthylazine (39% AR after 30 days) and desethyl-terbuthylazine (11% after 30 days).

The necessary surface water and sediment exposure assessments were carried out for terbuthylazine as well as for the metabolites desethyl-terbuthylazine, hydroxy-terbuthylazine and terbutryn (MT26) using the FOCUS (FOCUS, 2001)[11] Steps 1 to 3 approach. For desethyl-hydroxy-terbuthylazine only Steps 1 and 2 were needed. For terbuthylazine the Step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones of up to 10 m being implemented for the drainage scenarios (representing a 75-90 % spray drift reduction), and combined no-spray buffer zones with vegetative buffer strips of up to 20 m (reducing solute flux in runoff by 90 %) being implemented for the run-off scenarios. Risk managers and others may wish to note that whilst run-off mitigation is included in the step 4 calculations available, the FOCUS (FOCUS, 2007) report acknowledges that for substances with K_{Foc} < 2000 mL/g (such as terbuthylazine), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than is the case for more strongly adsorbed compounds.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2000) scenarios and the models PEARL 3.3.3 and PELMO 3.3.2[12] for the active substance

[11] Step 3 and 4 simulations utilised a Q10 of 2.2 and Walker equation coefficient of 0.7
[12] Simulations complied with EFSA, 2004 and utilised a Q10 of 2.2 and Walker equation coefficient of 0.7

terbuthylazine and the metabolites desethyl-terbuthylazine, hydroxy-terbuthylazine and desethyl-hydroxy-terbuthylazine. While the most conservative modelling results were used to assess the groundwater exposure (see section 6.2) all available modelling results are detailed in Appendix A.

For terbuthylazine the potential for groundwater exposure from the representative uses above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all 8 FOCUS groundwater scenarios. The potential for groundwater exposure by the metabolites desethyl-terbuthylazine (MT1), hydroxy-terbuthylazine (MT13) and desethyl-hydroxy-terbuthylazine (MT14) was however concluded to be high over a wide range of geoclimatic conditions represented by the FOCUS groundwater scenarios (see table in section 6.2).

It should be noted that for desethyl-terbuthylazine and hydroxy-terbuthylazine the high leaching risk calculated with the FOCUS scenario modelling tools was not consistent with the result from the individual lysimeter studies, which all suggested a low leaching risk of these two metabolites (see table in section 6.2). However, because terbuthylazine has an extensive metabolic pathway, a limited number of applications was made (perennial use not investigated), and the observation that leachate concentrations of some of the metabolites were increasing in the second year, the pattern of leaching observed in these lysimeter studies does not provide a definitive picture of leaching that would enable the first tier FOCUSgw exposure estimates to be overruled.

A large number of groundwater monitoring data were presented in the dossier, and the experts' meeting (PRAPeR 84) discussed to what extent these monitoring data should be taken into account in the groundwater risk assessment. The experts considered that FOCUS scenario modelling results should not normally be overruled by using monitoring data unless there is a very strong justification. In the case of terbuthylazine, information on the extent of uses (both the proportion of the monitored area and the application rate) and the average travel time to the monitoring screen was generally not provided in many of the monitoring exercises presented in the dossier. Without this information it becomes very difficult to justify that the monitoring data actually reflect a realistic use condition that will continue should terbuthylazine be included in Annex I, and so it is difficult to use in a regulatory context. However, among the available studies, the experts considered that two monitoring exercises provided data of sufficient quality and quantity and should be viewed alongside the FOCUS modelling results in order to establish the most representative picture possible of the overall leaching potential. The two monitoring studies comprised a targeted monitoring study in Germany (samples taken from shallow wells mostly situated less than 5 m below ground surface) and field leaching studies comprising 8 field sites in Northern Italy (samples taken from the saturated zone via piezometers, with an average depth to groundwater ranging from 1.1 to 6.2 m). As had been agreed previously in the context of the use of residue levels in samples taken from the saturated zone (EFSA, 2008), it was considered appropriate to compare regulatory triggers with concentrations measured in individual samples and not with the annual averages that are relevant when assessing concentrations in leachate recharge leaving the upper layers of the soil column[13]. A summary of the monitoring and modelling results are presented in the following bullets and in Table 4.1.

- *Terbuthylazine:* Both monitoring data and modelling results suggested that the potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L is expected to be low in geoclimatic and use situations represented by the monitoring study in Northern Italy and Germany and 8 FOCUS groundwater scenarios (Table 4.1.)

- *Desethyl-terbuthylazine:* The potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L is expected to be
  - High in geoclimatic and use situations represented by 6 FOCUS groundwater scenarios.

[13] Leaching assessments that consider the leachate recharge leaving the upper layers of the soil column include lysimeter studies, field leaching studies utilising suction cup samplers placed in the unsaturated zone and FOCUS groundwater modelling)

- Low in geoclimatic and use situations represented by 2 FOCUS groundwater scenarios, the monitoring study in Northern Italy and Germany.

While desethyl-terbuthylazine was rarely detected in a German monitoring study (and never above 0.1 µg/L), the potential for leaching of desethyl-terbuthylazine in Italian field sites seems to be higher than that of terbuthylazine (Table 4.1). The latter finding is consistent with the FOCUS scenarios suggesting that desethyl-terbuthylazine would leach to a higher degree than terbuthylazine. At 2 of the 8 Italian field sites, frequency of exceedence of 0.1 µg/L reached 12% and 14% indicating that leaching below the root zone in concentrations above 0.1 µg/L is likely to occur in some areas. However, when averaging all sites the frequency of exeedence of 0.1 µg/L was only 5% so the experts concluded that the overall potential for groundwater exposure from the representative uses above the parametric drinking water limit of 0.1 µg/L is expected to be low under conditions represented by the two monitoring exercises and the Porto and Sevilla FOCUS scenarios.

- *Desethyl-hydroxy-terbuthylazine:* The potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L is expected to be
  - High in geoclimatic and use situations represented by the monitoring study in Northern Italy and 8 FOCUS groundwater scenarios.
  - Low in geoclimatic and use situations represented targeted monitoring in Germany

Consistent with the FOCUS modelling result, the monitoring data suggest that the potential for leaching of desethyl-hydroxy-terbuthylazine is higher than for desethyl-terbuthylazine and terbuthylazine. However, it should be noted that groundwater concentrations exceeding 0.1 µg/L were not observed in the German monitoring study.

- *Hydroxy-terbuthylazine:* The potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L is expected to be
  - High in geoclimatic and use situations represented by the 8 FOCUS groundwater scenarios
  - Low in geoclimatic and use situations represented by the monitoring study in Northern Italy and Germany

The FOCUS scenarios suggest that leaching of hydroxy-terbuthylazine is approximately five times higher than that of desethyl-hydroxy-terbuthylazine. This is noted to be a relative tendency which (unlike the information for the other metabolites) is not reflected in the available monitoring data.

Table 4.1 Results from the FOCUS modelling as well as the field leaching study in Northern Italy and targeted monitoring data from Germany.

	Terbu thylazine	Desethyl-terbuthylazine	Hydroxy-terbuthylazine MT13	Desethyl-Hydroxy-terbuthylazine MT14
FOCUS modelling results				
Number of scenarios > 0.1 µg/L	0	6	8	8
Number of scenarios < 0.1 µg/L	8	2	0	0
Monitoring data				
Northern Italy (8 field leaching study[1)], 395 samples)				
-Detection (% of analysed samples)	16%	32%	1%[3)]	40%[3)]
- Detection >0.1 µg/L (% of analysed samples)	3%	5%	0%[3)]	29%[3)]
Germany [2)] (targeted monitoring, 25 wells, 29 samples)				
-Detection (% of analysed samples)	7%	7%	3%	14%
- Detection >0.1 µg/L (% of analysed samples)	0%	0%	0%	0%

[1)] The two sites receiving "basin irrigation" are not included

[2)] Monitored area being treated with terbuthylazine ranges between 8 – 80% (average 25%),

[3)] Only 144 samples were analysed for hydroxy-terbuthylazine and desethyl-hydroxy-terbuthylazine.

Based on the above information, the experts considered that, when viewing the FOCUS modelling and acceptable monitoring data sets side by side, a number of scenarios with both high and low potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L could be identified for the desethyl, hydroxy and desethyl-hydroxy terbuthylazine metabolites. Overall the experts considered that Member States would have to consider very carefully the potential for groundwater contamination posed by these metabolites based on this information.

- For the metabolites *LM1, LM2, LM3, LM4, LM5* and *LM6* the groundwater exposure assessment cannot be finalised as valid data describing the sorption and degradation are not available. Therefore a data gap has been identified to address the groundwater leaching potential of these metabolites. However, in two monitoring studies considered by experts to provide reliable information on leaching potential, LM3, LM5 and LM6 were frequently detected in groundwater in concentrations exceeding 0.1 µg/l. Frequency of exceedance of 0.1 µg/l reached 29%, 38% and 34% for LM3, LM5 and LM6 respectively. Similar monitoring data on the other metabolites LM1, LM2 and LM4 were not available.

5. Ecotoxicology

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

The acute and short-term risk to birds was assessed as low but the first-tier long-term TERs were below the Annex VI trigger of 5. The long-term risk assessment was refined using residue decline data, PD refinement and skylark (Alauda arvensis) as the focal species. Clarification was needed on the growth stages at which the residues were measured and on two residues studies which were originally not included in the calculation of the refined residue values. The RMS explained that according to national registration procedures herbivorous birds grazing on maize would be considered up to growth stage BBCH 30 and hence all residue trials could be included in the calculation of mean initial RUD values. The refined risk assessment resulted in a TER of 4.6 for the application rate of 1 x 0.844 kg a.s./ha. The RMS considered that the TER of 4.6 would be close enough to the trigger of 5 to conclude on a low long-term risk to birds. EFSA suggests using only the residue trials with maize where the growth stage of the treated maize plants was clearly indicated and where it is clear that the growth stage was in accordance with the proposed GAP. In these residue trials, higher initial residues were measured on average. Consequently the initial mean RUD value would be higher and the resulting TERs would be lower than the ones currently calculated. Furthermore, uncertainty remains with regard to the exposure to metabolite MT1.

It is the opinion of EFSA that on the basis of the available data a high long-term risk to birds cannot be excluded for the application rate of 1 x 0.844 kg a.s./ha. The risk assessment for the lower application of 1 x 0.75 kg a.s./ha would lead to a TER above the trigger. However, it should be noted that for the lower application rate a dual product including S-metolachlor as a second active substance is the lead formulation. EFSA suggests using only the residue trials with maize where the growth stage of the treated maize plants was clearly indicated. This would lead to higher initial residue values and hence the TERs would be lower than the current ones. It is noted by EFSA that a potential high risk to medium herbivorous birds from the use in early growth stages of maize could not be excluded in the peer-review for another active substance. It may be that the risk to medium herbivorous birds is not covered by the risk assessment for skylark (small omnivorous bird) if the risk assessment is refined further (e.g. by PT refinement) and a risk assessment for herbivorous birds may be needed.

The risk from secondary poisoning of fish-eating birds was assessed as low at Tier I. The risk to earthworm-eating birds was assessed as low in a refined risk assessment on the basis of an earthworm bioaccumulation study.

The acute risk to mammals was assessed as low but the long-term TERs were significantly below the Annex VI trigger of 5. The TERs were still below the trigger in the refined risk assessment indicating a high long-term risk to mammals from both representative uses. The risk to fish-eating mammals was assessed as low in the first-tier risk assessment. A high risk to earthworm-eating mammals was indicated in a first-tier risk assessment. Also the refined risk assessment for earthworm-eating mammals resulted in TERs below the trigger. The RMS considered that the risk could be adequately addressed using the omnivorous wood mouse as the focal species. As a high long-term risk to woodmice cannot be excluded, the risks to earthworm-eating mammals also require further assessment to demonstrate low risk. Overall it is concluded that the available risk assessment indicates a high long-term risk to mammals and a critical area of concern was identified.

Terbuthylazine is very toxic to aquatic organisms. The lowest endpoints driving the aquatic risk assessment were observed for algae (EbC50 = 12 µg a.s./L) and aquatic plants (12.8 µg a.s./L). No full FOCUS Step 3 scenario resulted in TERs above the trigger indicating a high risk to the aquatic environment. Risk mitigation comparable to a no-spray buffer zone of 10 m plus 90% run-off mitigation would be needed to achieve TERs above the trigger in the majority of the scenarios. Only the scenarios R1 (stream) and R4 (stream) still result in TERs below the trigger. A mesocosm study was submitted and discussed in the meeting of experts (PRAPeR 80 in August 2010). It was not possible on the basis of the available information to derive a clear NOEC and further information would be needed to aid the interpretation of the mesocosm study and a data gap was identified. The metabolites desethyl-terbuthylazine and terbutryn are very toxic and the metabolite hydroxy-terbuthylazine is toxic to aquatic organisms. The TERs exceeded the Annex VI trigger for all FOCUS step 3 scenarios. Therefore the risk to aquatic organisms from these metabolites was considered to be low. No ecotoxicological data and no risk assessment were available for the metabolite desethyl-hydroxy-terbuthylazine and a data gap was identified by EFSA.

The acute risk to earthworms was assessed as low in a first-tier risk assessment but a potential high risk was indicated on the long-term time scale. No significant effects were observed one year after application of the single active substance formulation (Oxon) indicating a low risk. However statistically significant adverse effects were observed in a field study with the product containing also S-metolachlor (Syngenta). A high long-term risk to earthworms from the representative use of the product containing also S-metolachlor (Syngenta) was indicated. The acute and long-term risks of the metabolites desethyl-terbuthylazine (MT1), and hydroxy-terbuthylazine (MT13) were assessed as low.

A high risk was identified for non-target plants in the off-field area. Risk mitigation comparable to an in-field no-spray buffer zone of 5 m (Syngenta formulation) and 20 m (Oxon formulation) are needed to protect non-target plants in the off-field area.

The risk to bees, soil-micro organisms, soil macro-organisms and biological methods of sewage treatment was assessed as low.

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

6.1. Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
Terbuthylazine	Medium to high persistence Single first order DT_{50} 65 - 167 days; 20˚ C, soil moisture 13-36 % w/w). (Field dissipation studies: single first order DT_{50} 10 - 148 days; 20˚ C, pF 2 soil moisture).	The acute risk to earthworms was assessed as low. The long-term risk needed refinement and was demonstrated to be low in field studies for the single active formulation (Oxon) but not for the dual product (Syngenta). The lowest endpoint driving the risk assessment for earthworms is 56d reproduction NOEC < 0.5 mg/kg dw soil (regulatory concentration including a safety factor of 5 = 0.1 mg/kg dw soil). The risk to soil micro-organisms and other soil macro-organisms was assessed as low.
Desethyl terbuthylazine	Moderate to high persistence Single first order DT_{50} 27 - 113 days (20˚ C, soil moisture 11-29% w/w) (Field dissipation studies: single first order DT_{50} 2 - 223 days; 20˚ C, pF 2 soil moisture).	The risk to earthworms, soil micro-organisms and other soil macro-organisms was assessed as low.
Hydroxy terbuthylazine	High to very high persistence Single first order DT_{50} 207 - >1000 days (20˚ C, soil moisture 11-29% w/w)	The risk to earthworms, soil micro-organisms and other soil macro-organisms was assessed as low.

6.2. Groundwater

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Terbuthylazine	Medium mobility 191 - 318 mL/g	FOCUS: No Lysimeter: No The trigger value of 0.1 µg/L was not exceeded in the 8 lysimeters available.	Yes	Yes	A high risk to the aquatic environment was indicated in the risk assessment for surface water.
Desethyl-terbuthylazine MT1	High to very high mobility 44 - 122 mL/g	FOCUS: Yes The number of FOCUS scenarios exceeding the trigger values of 0.1, 0.75 and 10 µg/L was 6, 1 and 0 respectively. Lysimeter: No The trigger value of 0.1 µg/L was not exceeded in the 8 lysimeters available.	Yes	Yes, based on the proposed classification of the parent as carcinogen category 3 (R40). From the consumer exposure assessment point of view, the reference values of the parent are applicable to this metabolite.	The risk to aquatic organisms in surface water was assessed as low.

Hydroxy-terbuthylazine MT13	Medium mobility 104 - 280 mL/g	FOCUS: Yes The number of FOCUS scenarios exceeding the trigger values of 0.1, 0.75 and 10 µg/L was 8, 7 and 5 respectively. Lysimeter: No The trigger value of 0.1 µg/L was not exceeded in the 6 lysimeters available.	No	Yes, based on the proposed classification of the parent as carcinogen category 3 (R40). From the consumer exposure assessment point of view, the reference values of the parent are applicable to this metabolite.	The risk to aquatic organisms in surface water was assessed as low.
Desethyl-hydroxy-terbuthylazine MT14	Low - very high mobility 22 - 1010 mL/g	FOCUS: Yes The number of FOCUS scenarios exceeding the trigger values of 0.1, 0.75 and 10 µg/L was 8, 8 and 5, respectively. Lysimeter: Yes The trigger value of 0.1 µg/L was exceeded in 1 of the 3 lysimeters.	No	Yes, based on the proposed classification of the parent as carcinogen category 3 (R40). From the consumer exposure assessment point of view, the reference values of the parent are applicable to this metabolite.	The risk to aquatic organisms in surface water was assessed as low.
LM1	Not available	FOCUS: Not available Lysimeter: Yes The trigger value of 0.1 µg/L was exceeded in 3 of 5 lysimeters.	No, based on the argumentation that it is a breakdown product of LM5 that did not exhibit pesticidal activity.	Yes, based on the proposed classification of the parent as carcinogen category 3 (R40). The toxicity/genotoxicity assessment is open from the consumer exposure risk assessment point of view.	An assessment was provided. However no reliable PECgw were available and a data gap was identified.

LM2	Not available	FOCUS: Not available Lysimeter: Yes The trigger value of 0.1 µg/L was exceeded in all 5 lysimeters.	No	Yes, based on the proposed classification of the parent as carcinogen category 3 (R40). The toxicity/genotoxicity assessment is open from the consumer exposure risk assessment point of view.	An assessment was provided. However no reliable PECgw were available and a data gap was identified.
LM3	Not available	FOCUS: Not available Lysimeter: Yes The trigger value of 0.1 µg/L was exceeded in all 5 lysimeters.	No	Yes, based on the proposed classification of the parent as carcinogen category 3 (R40). The toxicity/genotoxicity assessment is open from the consumer exposure risk assessment point of view.	An assessment was provided. However no reliable PECgw were available and a data gap was identified.
LM4	Not available	FOCUS: Not available Lysimeter: Yes The trigger value of 0.1 µg/L was exceeded in all 5 lysimeters.	No	Yes, based on the proposed classification of the parent as carcinogen category 3 (R40). The toxicity/genotoxicity assessment is open from the consumer exposure risk assessment point of view.	An assessment was provided. However no reliable PECgw were available and a data gap was identified.

LM5	Not available	FOCUS: Not available Lysimeter: Yes The trigger value of 0.1 µg/L was exceeded in all 5 lysimeters.	No	Yes, based on the proposed classification of the parent as carcinogen category 3 (R40). The toxicity/genotoxicity assessment is open from the consumer exposure risk assessment point of view.	An assessment was provided. However no reliable PECgw were available and a data gap was identified.
LM6	Not available	FOCUS: Not available Lysimeter: Yes The trigger value of 0.1 µg/L was exceeded in all 5 lysimeters.	No	Yes, based on the proposed classification of the parent as carcinogen category 3 (R40). No genotoxic potential is attributed to this metabolite, but the toxicity assessment is open from the consumer exposure risk assessment point of view.	An assessment was provided. However no reliable PECgw were available and a data gap was identified.

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Terbuthylazine	Very toxic to aquatic organisms, endpoint driving the aquatic risk assessment: algae EbC50 = 12 µg a.s./L (regulatory concentration including a safety factor of 10 = 1.2 µg a.s./L). A high risk to the aquatic environment was identified and risk mitigation comparable to 10 m no-spray buffer zone and 90% run-off mitigation are needed to achieve TERs above the trigger in the majority of FOCUS scenarios.

Desethyl-terbuthylazine	Very toxic to aquatic organisms, lowest endpoint driving the aquatic risk assessment for this metabolite: algae EbC50 = 140 µg/L (regulatory concentration including a safety factor of 10 = 14 µg a.s./L). The risk to aquatic organisms was assessed as low with FOCUS step3 PECsw.
Hydroxy-terbuthylazine	Toxic to aquatic organisms, lowest endpoint driving the aquatic risk assessment for this metabolite: fish acute LC50 > 2.5 mg/L (regulatory concentration including a safety factor of 100 = 25 µg a.s./L). The risk to aquatic organisms was assessed as low with FOCUS step3 PECsw.
Desethyl-hydroxy-terbuthylazine	No data available. Data gap.
Terbutryn	Very toxic to aquatic organisms, endpoint driving the aquatic risk assessment for this metabolite: algae EbC50 = 1.7 µg a.s./L (regulatory concentration including a safety factor of 10 = 0.17 µg a.s./L). The risk to aquatic organisms was assessed as low with FOCUS step3 PECsw.

6.4. Air

Compound (name and/or code)	**Toxicology**
Terbuthylazine	Rat LC_{50} inhalation > 5.3 mg/L air/4 h, nose-only exposure, no classification proposed

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

- Level of ethoxylation of formulants (relevant for ‘Gardo® Gold®’; submission date proposed by the applicant: information provided, however could not be taken into account in the peer review in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the resubmission to the RMS, as laid down in Commission Regulation (EC) No. 33/2008; see section 1)

- Validation data for the method of determination of the additive in the technical material (relevant for Syngenta; submission date proposed by the applicant: unknown; see section 1)

- Analytical method for the compounds LM1, LM2 and LM4 in the residue definition for water (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1 and 4)

- Toxicological information to address the relevance of the impurities present in the technical specification (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2)

- Genotoxicity studies on the metabolites LM1, LM2, LM3, LM4 and LM5 have been submitted to the RMS but not evaluated or considered during the peer review in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the resubmission to the RMS, as laid down in Commission Regulation (EC) No. 33/2008 (relevant for all representative uses evaluated; see section 2).

- Assessment of the toxicological equivalence between the formulation used in the acute toxicity studies and the representative formulation ‘Gardo® Gold®’ (relevant for all representative uses evaluated with the ‘Gardo® Gold®’ formulation; submission date proposed by the applicant: unknown; see section 2)

- Groundwater exposure assessment for the metabolites LM1, LM2, LM3, LM4, LM5 and LM6 is needed including an assessment of ecotoxicological activity (relevant for all representative uses evaluated; submission date proposed by the applicant unknown; see section 4 and 5)

- The long-term risk to birds needs further refinement for the higher application rate (Oxon); (submission date proposed by the applicants: unknown; see section 5)

- The long-term risk assessment for mammals needs further refinement (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5)

- Further information would be needed to aid the interpretation of the mesocosm study (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5)

- The long-term risk to earthworms needs further refinement (relevant for the representative uses of the formulation ‘Gardo® Gold®’ (Syngenta); submission date proposed by the applicant: unknown; see section 5)

- The risk to aquatic organisms needs to be addressed for the metabolite desethyl-hydroxy-terbuthylazine (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

- Estimated operator exposure is below the AOEL for both representative formulations ‘Terbuthylazine 500 SC’ and ‘Gardo® Gold®’ when PPE (gloves during mixing and loading; gloves, coverall and sturdy footwear during application) is considered – according to the German model (see section 2).

- Estimated worker exposure is below the AOEL for the representative formulation ‘Terbuthylazine 500 SC’ when PPE (gloves, long sleeved shirt and long trousers) is worn (see section 2).

- Risk mitigation comparable to an in-field no-spray buffer zone of 5 m (Northern European uses, ‘Gardo® Gold®’) and 20 m (Southern European uses, ‘Terbuthylazine 500 SC’) are needed to protect non-target plants in the off-field area (see section 5).

- Risk mitigation comparable to a no-spray buffer zone of 10 m plus 90% run-off mitigation would be needed to achieve TERs above the trigger in the majority of scenarios (see section 5).

ISSUES THAT COULD NOT BE FINALISED

- The relevance of the impurities present in the technical specification from both sources Syngenta and Oxon could not be concluded (except for the known relevant impurities propazine, simazine and atrazine).

- The toxicological equivalence between the representative formulation ‘Gardo® Gold®’ and the formulation used in the acute toxicity studies was not assessed.

- For the metabolites LM1, LM2, LM3, LM4 LM5 and LM6 the groundwater exposure assessment cannot be finalised, and consequently the risk to aquatic organisms in the situation when groundwater becomes surface water body could not be finalised either[14].

- A high long-term risk to birds was indicated for the higher application rate of 1 x 0.844 kg a.s./ha.

- A high long-term risk to earthworms was indicated in the risk assessment for the representative uses of the formulation ‘Gardo® Gold®’ (Syngenta).

CRITICAL AREAS OF CONCERN

- The batches used in the toxicological studies do not support the technical specification from either the Syngenta or the Oxon source.

- The potential for groundwater exposure by the toxicologically relevant, herbicidally active metabolite desethyl-terbuthylazine above the parametric drinking water limit of 0.10 µg/L is predicted to be high over a wide range of geo-climatic conditions. For the representative uses assessed; 6 out of the 8 FOCUS groundwater scenarios exceeded the 0.1 µg/L limit. In 20 out of 395 (or 5%) groundwater samples taken at 8 sites in Northern Italy where terbuthylazine had been applied at a rate of 856 g/ha (1.01N), desethyl-terbuthylazine concentrations exceeded 0.1µg/L.

- The potential for groundwater exposure by the toxicologically relevant metabolites desethyl-hydroxy-terbuthylazine and hydroxy-terbuthylazine above the parametric drinking water limit of 0.10 µg/L is predicted to be high over a wide range of geo-climatic conditions. For the representative uses assessed, all 8 FOCUS groundwater scenarios exceeded the 0.1 µg/l limit for both metabolites. In 42 out of 144 (or 29%) groundwater samples taken at 8 sites in Northern Italy

[14] Note the EFSA conclusion is that using the available peer reviewed mammalian toxicology information, these metabolites are relevant groundwater metabolites when following the criteria of the European Commission (2003) guidance

where terbuthylazine had been applied at a rate of 856 g/ha (1.01N), desethyl-hydroxy-terbuthylazine concentrations exceeded 0.1 µg/L.

- A high long-term risk and a high risk from secondary poisoning were indicated for mammals even after refinement of the risk assessment.

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APPENDICES

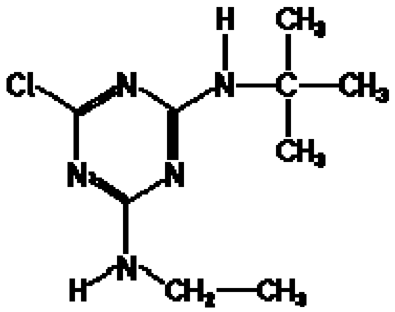
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	Terbuthylazine (ISO 1750)
Function (*e.g.* fungicide)	Herbicide

Rapporteur Member State	United Kingdom (UK)

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	N^2-*tert*-butyl-6-chloro-N^4-ethyl-1,3,5-triazine-2,4-diamine
Chemical name (CA) ‡	6-chloro-*N*-(1,1-dimethylethyl)-*N*'-ethyl-1,3,5-triazine-2,4-diamine
CIPAC No ‡	234
CAS No ‡	5915-41-3
EC No (EINECS or ELINCS) ‡	227-637-9
FAO Specification (including year of publication) ‡	Yes (1993) terbuthylazine content not less than 930 g/kg. (234/TC/S (1991))
Minimum purity of the active substance as manufactured ‡	Syngenta 960 g/kg Oxon 980 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Propazine (SYN) 10 g/kg Atrazine (Oxon) 1 g/kg Simazine (SYN) 30 g/kg Simazine (Oxon) 5 g/kg Open for others
Molecular formula ‡	$C_9H_{16}ClN_5$
Molecular mass ‡	229.7 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Syngenta: 175.5°C (99.4%) Oxon: 175.7°C (99.6%)
Boiling point (state purity) ‡	Syngenta: decomposition observed at 224°C (99.4%) Oxon: decomposition after melting (99.6%)
Temperature of decomposition (state purity)	Syngenta: 224°C (99.4%) Oxon: 230°C (99.6%)
Appearance (state purity) ‡	Syngenta: White crystalline powder (99.4%) Oxon: White powder (99.6%)
Vapour pressure (state temperature, state purity) ‡	Syngenta: 9.0 x 10^{-5} Pa at 25 °C (99.4%) Oxon: 1.52 X 10^{-4} Pa at 22 °C (>99%.)
Henry's law constant ‡	Syngenta: 2.3 X 10^{-3} Pa m^3 mol^{-1} Oxon: 4.18 X 10^{-3} Pa m^3 mol^{-1}
Solubility in water (state temperature, state purity and pH) ‡	Syngenta:9.0 mg/L at 25 °C (pH 7.4) (99.4%) Oxon: 6.6 mg/L at 20 °C (pH 4-10) (>99%)
Solubility in organic solvents ‡ (state temperature, state purity)	Syngenta: at 25°C in g/L (96.8%) hexane 0.41 toluene 9.8 dichloromethane 51 methanol 18 octanol 12 acetone 41 ethyl acetate 35 Oxon: at 20°C in g/L (99.5%) hexane 0.275 toluene 7.17 dichloromethane 62.7 methanol 14.9 acetone 32.8 ethyl acetate 30.5
Surface tension ‡ (state concentration and temperature, state purity)	Syngenta: 71.8 mN/m at 20 °C (90 % saturated solution)(96.5%) Oxon: 70.9 mN/m at 20 °C (90 % saturated solution)(96.8%)
Partition co-efficient ‡ (state temperature, pH and purity)	Syngenta: log $P_{O/W}$ = 3.4 at 25 °C (not pH dependant (99.4%) Oxon: log $P_{O/W}$ = 3.41 at 20 °C (not pH dependant (99.5%)

Dissociation constant (state purity) ‡	Syngenta: pKa_1 = 1.95 (99.4%) Oxon: pKa_1 = 1.84 (99.5%)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Syngenta: solution: Solution λ (nm) ε (l/mol cm) neutral 222 38538 263 3444 acidic 223 30103 263 4468 basic 223 37426 263 3395 No absorption maximum observed between 290 and 750 nm in neutral and basic solution and between 310 nm and 750 nm in acidic solution. Oxon: solution: Solution λ (nm) ε (l/mol cm) neutral 222 38696 262 3291 acidic 222 29424 basic 222 38191 262 3241
Flammability ‡ (state purity)	Syngenta: Not highly flammable (96.8%) Oxon: Not highly flammable (96.5%) Not classified.
Explosive properties ‡ (state purity)	Syngenta: Not explosive (96.8%) Oxon: Not explosive (96.5%)
Oxidising properties ‡ (state purity)	Syngenta: Not oxidising (96.8%) Oxon: Not oxidising (96.5%)

Summary of representative uses evaluated

a) Syngenta - Tradename: [GARDO® GOLD®] Active Ingredients: [Terbuthylazine and S-metolachlor]

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation: Type (d-f)	Formulation: Conc. of as (i)	Application: method kind (f-h)	Application: growth stage & season (j)	Application: number min-max (k)	Application: interval between applications (min)	Application rate per treatment: kg as/hL min-max	Application rate per treatment: water L/ha min-max	Application rate per treatment: kg as/ha min-- max	PHI (days) (l)	Remarks: (m)
Maize	N.EU.	GARDO® GOLD®	F	Dicot and monocot weeds	SE	187.5 g/L Terbuthylazine 312.5 g/L S-metolachlor	Tractor - mounted sprayer	pre-emergence - 8 leaf	1	Not applicable	0.15-0.375 Terbuthylazine 0.25-0.614 S-metolachlor	200 500	Max. 0.75 Terbuthylazine Max. 1.228 S-metolachlor	Not appli-cable	[1] [2] [3] [4] [5] [6]
Maize	S.EU.	GARDO® GOLD®	F	Dicot and monocot weeds	SE	187.5 g/L Terbuthylazine 312.5 g/L S-metolachlor	Tractor - mounted sprayer	pre-emergence - 8 leaf	1	Not applicable	0.168-0.422 Terbuthylazine 0.28-0.71 S-metolachlor	200 500	Max. 0.844 Terbuthylazine Max. 1.415 S-metolachlor	Not appli-cable	[1] [2] [3] [4] [5] [6]

b) Oxon - Tradename: [Terbuthylazine 500 g/L SC] Active Ingredients: [Terbuthylazine]

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					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 (l)	Water L/ha min-max	kg as/ha min-max (l)		
Maize	France (N) Germany (N) The Netherlands (N) France(S) Italy (S) Spain S)	Terbuthyl-azine 500 g/l SC	F	Annual and perennial broad leaved weeds	SC	500 g/l	Spray	Pre-emergence Early post emergence (12-16)	1	-	0.15-0.5	200-500	0.75-0.844	n.r	[1] [3] [4] [6]
Sorghum	Italy (S) Spain (S)	Terbuthyl-azine 500 g/l SC	F	Annual and perennial broad leaved weeds	SC	500 g/l	Spray	Pre-emergence Early post emergence (14)	1	-	0.2-0.5	200-500	0.844	n.r.	[1] [3] [4] [6]

[1] A critical area of concern is identified because a high long-term risk and a high risk from secondary poisoning were indicated for mammals in section 5.
[2] A high long-term risk to earthworms was indicated in the risk assessment for the representative uses of the formulation ‘Gardo® Gold®’.
[3] A critical area of concern is identified for groundwater contamination of toxicologically relevant metabolites and a herbicidally relevant metabolite over a wide range of geoclimatic conditions.
[4] For the metabolites LM1, LM2, LM3, LM4, LM5 and LM6 the groundwater exposure assessment cannot be finalised.
[5] A high long-term risk to birds was indicated.
[6] The batches used in the toxicological studies do not support the technical specification from either the Syngenta or the Oxon source.

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L.
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval
n.r.= not relevant, the pre-harvest interval is covered by the growing period remaining between the envisaged application and harvest

Methods of Analysis

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

Technical as (analytical technique)	Syngenta: Method AW52/3. GC-FID and internal calibration with prometryn Oxon: HPLC-UV at 220nm and external calibration
Impurities in technical as (analytical technique)	Syngenta: Relevant impurities: GC-FID and internal calibration with prometryn Oxon: GC-FID and internal calibration with 0.02% solution dibutylphthalate in acetone
Plant protection product (analytical technique)	Syngenta: Method AF-1301/3. Reverse phase HPLC-UV at 210nm and external calibration Oxon: Method MAN/024/01. Reverse phase HPLC-UV at 254nm and external calibration

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Terbuthylazine (MT0)
Food of animal origin		Not necessary for the representative uses.
Soil		Terbuthylazine (MT0) plus desethyl-terbuthylazine (MT1) plus hydroxyl-terbuthylazine (MT13)
Water	surface	Terbuthylazine (MT0) plus desethyl-terbuthylazine (MT1) plus hydroxyl-terbuthylazine (MT13)
	drinking/ground	Terbuthylazine (MT0) plus desethyl-terbuthylazine (MT1) plus hydroxy-terbuthylazine (MT13) plus desethyl-hydroxy-terbuthylazine (MT14) plus LM1, LM2, LM3, LM4, LM5 and LM6
Air		Terbuthylazine

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Syngenta: DFG S19. GC-NPD with LOQ of 0.02 mg/kg in grain (acceptable ILV). Terbuthylazine only Oxon: Published method. GC-NPD with LOQ of 0.02 mg/kg in grain. Terbuthylazine only
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required

Soil (analytical technique and LOQ)	Syngenta: REM 148.05 GC-MS confirmation with target *m/z* of 214 and 3 qualifier ions (*m/z* 216, 229 and 173). LOQ was 0.02 mg/kg. REM 148.11. HPLC-MS/MS parent ion *m/z* = 230 and daughter ion *m/z* was 174. MT1 m/z was 202 and daughter m/z 146. MT13 *m/z* was 212 and daughter *m/z* was 156. MT14 *m/z* was 184 and daughter *m/z* was 128. LOQ was 0.01 mg/kg for each. Oxon: HPLC-MS/MS parent ion *m/z* = 230 and daughter ion *m/z* was 174. MT1 m/z was 202 and daughter m/z 146. MT13 *m/z* was 212 and daughter *m/z* was 156. LOQ was 0.01 mg/kg for each
Water (analytical technique and LOQ)	Syngenta: RAM 426/01 (validated in river, ground and drinking water). Reverse phase HPLC-MS/MS. Parent ion *m/z* = 230 and daughter ion *m/z* was 174. MT1 m/z was 202 and daughter m/z 146. MT13 *m/z* was 212 and daughter *m/z* was 156. MT14 *m/z* was 184 and daughter *m/z* was 128. LOQ was 0.1 µg/l for each. HPLC-MS/MS (surface, ground and drinking water); LM5 *m/z* was 183 and daughter m/z 97, LM6 m/z was 197 and daughter *m/z* 97; LOQ was 0.05 µg/l for each HPLC-MS/MS (ground water); LM3 *m/z* was 199 and daughter *m/z* 129, LOQ was 0.05 µg/l Oxon: Reverse phase HPLC-MS/MS (validated in surface and drinking water). . Parent ion *m/z* = 230 and daughter ion *m/z* was 174. MT1 m/z was 202 and daughter m/z 146. MT13 *m/z* was 212 and daughter *m/z* was 156. LOQ was 0.05 µg/l for each. LM1, LM2, LM4: no methods submitted
Air (analytical technique and LOQ)	Syngenta: GC-NPD with confirmation by GC-MS with target *m/z* 214 and qualifier ions *m/z* 216, 229 and 173. LOQ was 1µg/m^3. Oxon: GC-NPD with LOQ of 1µg/m^3.
Body fluids and tissues (analytical technique and LOQ)	Syngenta: No data submitted or required. Oxon: No data submitted or required.

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

	RMS/peer review proposal
Active substance	None

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	79 % following low dose administration in females based on urinary and biliary excretion, cagewash and carcass residues 48h after administration.
Distribution ‡	Widely distributed; initial distribution into fat. Significant and persistent binding to blood cells.
Potential for accumulation ‡	No evidence for bioaccumulation.
Rate and extent of excretion ‡	Rapid excretion: 60-65 % in urine and 30-40 % in faeces within 96 h (most of it during the first 48 h). Biliary excretion within 48 h: 40-64 % (in females and males respectively).
Metabolism in animals ‡	Extensive metabolism in the rat; only trace level of unchanged terbuthylazine detected.
Toxicologically relevant compounds ‡ (animals and plants)	Terbuthylazine
Toxicologically relevant compounds ‡ (environment)	Terbuthylazine and metabolites (MT1, MT13, MT14, LM1, LM2, LM3, LM4, LM5, LM6)

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	1000-1590 mg/kg bw	**R22**
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 5.3 mg/L air/4 h (dust aerosol, nose-only exposure)	
Skin irritation ‡	minimal irritant	
Eye irritation ‡	slight irritant	
Skin sensitisation ‡	Weak sensitiser (M&K test), no classification required	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Bodyweight and food consumption effects in rats, mice dogs and rabbits	
Relevant oral NOAEL ‡	1-year, dog: 0.4 mg/kg bw/day 90-day, rat: 2.1 mg/kg bw/day 28-day, mouse: LOAEL 43.2 mg/kg bw/day 28-day, rabbit: LOAEL 5 mg/kg bw/day	
Relevant dermal NOAEL ‡	28-day, rabbit: 0.5 mg/kg bw/day 28-day, rat: 10 mg/kg bw/day	
Relevant inhalation NOAEL ‡	No data - not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

	Weight of evidence indicates no genotoxic potential	

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

Target/critical effect ‡	Decreased bodyweight and food consumption, changes in organ weights (rat and mouse) red blood cells parameters and correlated histopathology, uterine endometrial hyperplasia (rat)	
Relevant NOAEL ‡	0.35 mg/kg bw/day, 2-year rat 2.97 mg/kg bw/day, 2-year mouse	
Carcinogenicity ‡	Rat: increased incidence of mammary adenocarcinoma at 7.6 mg/kg bw/day. (NOAEL for carcinogenic effects 1.7 mg/kg bw/day)	**R40**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Reproductive toxicity: Reduced fertility of females secondary to reduced or absent corpora lutea Parental toxicity: reduced bodyweight Offpring's toxicity: reduced survival	
Relevant parental NOAEL ‡	0.4 mg/kg bw/day	
Relevant reproductive NOAEL ‡	4.5 mg/kg bw/day	
Relevant offspring NOAEL ‡	3.5 mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect ‡	**Rat** Maternal: clinical signs, reduced bodyweight and food consumption Offspring: interventricular septal defect **Rabbit** Maternal: clinical signs, reduced bodyweight and food consumption Offspring: no effects at top dose tested	
Relevant maternal NOAEL ‡	Rat: 5 mg/kg bw/day Rabbit: 0.8 mg/kg bw/day	
Relevant developmental NOAEL ‡	Rat: 5 mg/kg bw/day Rabbit: 7 mg/kg bw/day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data submitted- not required	
Repeated neurotoxicity ‡	No evidence of neurotoxicity up to 7.0 mg/kg bw/day dose level (highest dose tested) (90-day	

	neurotoxicity study in rat)	
Delayed neurotoxicity ‡	No data submitted - not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	None submitted
Studies performed on metabolites or impurities ‡	
MT14	Acute oral LD_{50} (rats) : > 2000 mg/kg bw. 90-day dietary rats: NOAEL and LOAEL of 10.3 and 45.7 mg/kg bw/day, based on increased mortality and water consumption, changes in haematology, clinical chemistry and urinalysis parameters and increased kidney weight, renal (histo)pathology secondary to chronic renal failure. Mutagenicity in bacterial cells: negative. Clastogenicity in CHO (Chinese Hamster Ovary) cells: negative. Mouse Lymphoma assay: negative
MT13	Acute oral LD_{50} (rats) : > 2000 mg/kg bw. 90-day dietary rats: NOAEL and LOAEL of 3.4 and 10.3 mg/kg bw/day based on changes in haematology and clinical chemistry parameters. Mutagenicity in bacterial cells: negative Mouse lymphoma assay in L5178Y cells: negative Clastogenicity in cultured human lymphocytes: negative
MT20	Acute oral LD_{50} (rats) : > 5500 mg/kg bw 90-day dietary rats: M: NOAEL and LOAEL of 16.7 and 34.1 mg/kg bw/day, based on decreased bodyweight, changes in clinical chemistry and urinalysis parameters and organ weight effects F: NOAEL and LOAEL of 0.7 and 7.6 mg/kg bw/day, based on altered oestrus cycle length and prolonged oestrus and/or dioestrus Mutagenicity in bacterial cells: negative Mouse micronucleus assay: negative

MT1	Acute oral LD_{50} (rats) : 236 mg/kg bw Acute oral LD_{50} (rats) : 300-500 mg/kg bw Mutagenicity in bacterial cells: negative Second Mutagenicity in bacterial cells: negative *In Vitro* Cytogenetic Assay in Human Lymphocytes: negative Gene Mutation Assay: weakly positive Mouse micronucleus assay: negative *in vivo* unscheduled DNA synthesis: negative 90-day rat study Reduced bodyweight gain Total WBC (white blood cells) reduced no NOAEL
LM3	Mutagenicity in bacterial cells: negative *In Vitro* Chromosome Aberration: negative
LM5	Mutagenicity in bacterial cells: negative
LM6	Mutagenicity in bacterial cells: negative Gene Mutation Assay: weakly positive *In Vitro* Chromosome Aberration: negative Mouse micronucleus assay: negative

Medical data ‡ (Annex IIA, point 5.9)

	No evidence of adverse effects in production workers or operators

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.004 mg/kg bw/day	dog, 1-year & rat, 2-year	100
AOEL ‡	0.0032 mg/kg bw/day	dog, 1-year	Overall 126* (100 + 79 %*)
ARfD ‡	0.008 mg/kg bw	rabbit developmental study	100

*correction for oral absorption (79 %)

Dermal absorption ‡ (Annex IIIA, point 7.3)

Gardo® Gold® (AC9476C, 187.5 g terbuthylazine/L and 312.5 g S-metolachlor/L SE formulation)	Concentrate: 0.04 % Spray dilution: 1.4 % *in vitro* human data
Terbuthylazine 500 g/L SC	Concentrate: 0.1 % Spray dilution: 2.5 % *in vitro* human data

Exposure scenarios (Annex IIIA, point 7.2)

Operator	<u>Tractor mounted equipment</u> **Terbuthylazine 500 SC** (application rate 850 g terbuthylazine/ha <> 1.7 L product/ha) <u>UK POEM</u> % of AOEL Without PPE 2475 % With PPE (gloves during M/L) 2434 % With PPE (gloves during M/L & application) 491 % <u>German model</u> Without PPE 419 % With PPE (gloves during M/L) 400 % With PPE (gloves for M/L, gloves, coverall & sturdy footwear during application) 41 % **Gardo® Gold®** (application rate of 0.844 kg terbuthylazine/ha <> 4.5 L product/ha) <u>UK POEM</u> % of AOEL Without PPE 1434 % With PPE (gloves during M/L) 1413 % With PPE (gloves during M/L & application) 331 % <u>German model</u> Without PPE 234 % With PPE (gloves during M/L) 228 % With PPE (gloves for M/L, gloves, coverall & sturdy footwear during application) 28 % Operator exposure study with the product BOXER 800 EC; coverall, gloves during mixing/loading, maintenance work and application; 66 % (Gardo® Gold®) and 97 % (Terbuthylazine 500 g/L SC) of the AOEL.
Workers	EUROPOEM II re-entry model: **Terbuthylazine 500g/l SC** 156 % of the AOEL without PPE, ~16 % with gloves. **Gardo® Gold®** 94 % of the AOEL without PPE.
Bystanders	Based on a simulated bystander exposure study for field crop sprayers : **Terbuthylazine 500g/l SC**: 19 % of the AOEL **Gardo® Gold®:** 16 % of the AOEL Worst case estimates of bystander exposure to terbuthylazine vapour following the application of the formulated products, based on published surrogate data: 19 % of the AOEL Estimates based on published spray drift deposition values and published EPA residential exposure values for children in areas contaminated by spray drift fallout: **Terbuthylazine 500g/L SC**: 7 % of the AOEL **Gardo® Gold®:** 6 % of the AOEL

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

	RMS/peer review proposal
Terbuthylazine	**Xn** “Harmful” **R22** “Harmful if swallowed” **R40** “Limited evidence of a carcinogenic effect”

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

Plant groups covered	Cereals (maize) - foliar treatment (OXON: 3-4 leaf stage) and - soil treatment (SYN: pre-emergence)
Rotational crops	Lettuce, radish, wheat (SYN only) and spinach, radish, summer/winter wheat (SYN & OXON)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes (terbuthylazine and metabolites MT1, MT13 and MT14 main components in rotational crops)
Processed commodities	Not provided and not required
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No statement can be made as no processing studies were submitted/evaluated
Plant residue definition for monitoring	Terbuthylazine (MT0)
Plant residue definition for risk assessment	Sum terbuthylazine (MT0), desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14)
Conversion factor (monitoring to risk assessment)	Not necessary for maize grains (all residue data <LOQ)

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

Animals covered	Lactating cow (but considered not acceptable since identification of metabolites performed in milk only)
Time needed to reach a plateau concentration in milk and eggs	Within 24 hours
Animal residue definition for monitoring	No data, not necessary for the representative uses
Animal residue definition for risk assessment	No data, not necessary for the representative uses
Conversion factor (monitoring to risk assessment)	n/a
Metabolism in rat and ruminant similar (yes/no)	n/a
Fat soluble residue: (yes/no)	n/a

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

	Residues in following crops are expected to be low. However residues of MT1 and MT14 above the LOQ occur in sunflower seed, rape seed, sugar beet tops and cereal straw.

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

	Residues of terbuthylazine, MT1 and MT14 stable for up to 24 months in cereal commodities when stored frozen at -18°C. The stability data are sufficient to support the residues trials

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

	Ruminant:	**Poultry:**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes 0.35 mg/kg DM[1] dairy/beef cattle	No 0.06 mg/kg DM	Yes 0.17 mg/kg DM
Potential for accumulation (yes/no):	n/a	n/a	n/a
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	n/a	n/a	n/a
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	No data not required	No data not required	No data not required
Liver	No data not required	No data not required	No data not required
Kidney	No data not required	No data not required	No data not required
Fat	No data not required	No data not required	No data not required
Milk	No data not required		
Eggs			

[1]: This calculation is however a gross overestimate relying on a total residue level in maize silage of 0.07 mg/kg resulting from the summing of the LOQs of terbuthylazine and MT1 and the HR of 0.03 mg/kg for MT14 (whereas it was shown that parent is extensively metabolised and almost not present in plant). A more realistic approach based on the residue levels of the compounds effectively detected in animal feed, gives intakes of 0.02 mg/kg DM for poultry, 0.08 mg/kg DM for pig and 0.15 mg/kg DM for dairy and beef cattle. Based on these estimates and the TRRs measured in the metabolism study conducted with terbuthylazine on cow over 10 days, TRRs are expected to be <0.01 mg/kg in fat, muscle and milk and <0.05 mg/kg in kidney and liver. Therefore, it is concluded that no individual compounds are expected to be present in ruminant matrices in significant levels and the setting of a residue definition and MRLs for ruminant products is not necessary.

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

Crop	Northern or Southern Region, field or glasshouse	**Trial results relevant to the representative uses** (a)	**Recommendation/comments**	**MRL** estimated from trials according to representative uses	**HR** (mg/kg) (c)	**STMR** (mg/kg) (b)
Maize	North 1x 0.75 kg a.s./ha	**<u>Grain</u>** **MT0:** 8x <0.02 **MT1:** 8x <0.02 **MT14:** 8x <0.02 **Total residues**: 8x <0.06 **<u>Forage</u>** **MT0:** 8x <0.02 **MT1:** 8x <0.02 **MT14:** 7x <0.02, 0.03 **Total residues:** 7x <0.06, 0.07	**MT0:** terbuthylazine (GS 13529) **MT1:** desethyl-terbuthylazine (GS 26379) **MT14:** desethyl-2- hydroxy-terbuthylazine (GS 28620) **Total residues**: Sum MT0+MT1+MT14 4 additional trials on grain and forage available in Northern EU, with MT0 and MT1 <0.02 mg/kg, but not analysed for MT14 3 additional trials on grain and forage available in Southern EU, with MT0 and MT1 <0.02 mg/kg, but not analysed for MT14 Numerous additional trials available in Northern and Southern EU where samples were analysed for terbuthylazine only. All values below the LOQ (0.02 to 0.08 mg/kg) in grain and forage.	0.02*	**<u>Grain</u>** <0.02 (MT0) <0.06 (Total) **<u>Forage</u>** <0.02 (MT0) 0.07 (Total)	**<u>Grain</u>** <0.02 (MT0) <0.06 (Total) **<u>Forage</u>** <0.02 (MT0) <0.06 (Total)
	South 1x 0.844 kg a.s./ha	**<u>Grain</u>** **MT0:** 4x <0.02 **MT1:** 4x <0.02 **MT14:** 4x <0.02 **Total residues:** 4x <0.06 **<u>Forage</u>** **MT0:** 8x <0.02 **MT1:** 8x <0.02 **MT14:** 7x <0.02, 0.03 **Total residues:** 7x <0.06, 0.07				

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

ADI	0.004 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	
IEDI (% ADI) according to EFSA PRIMo rev2 model	Highest IEDI: 10% ADI (WHO cluster B) considering as a worst case, the STMRs of 0.06 mg/kg (total residues) in maize, sorghum and in oilseed and root crops (rotational crops).
NEDI (% ADI) according to national diets (to be specified)	
Factors included in IEDI and NEDI	
ARfD	0.008 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo rev2 model	Highest IESTI: 63% ARfD (Carrot as rotational crop, HR 0.08 mg/kg)
NESTI (% ARfD) according to national (to be specified)	
Factors included in IESTI and NESTI	

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Not provided and not required	-	-	-	-

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

Maize	0.02* mg/kg
Sorghum	0.02* mg/kg (by extrapolation from maize)

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

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1) – SYN and OXON

Mineralization after 100 days ‡	0.4 – 10.35 % after 112 - 120 d at 20 °C, [^{14}C-triazine ring]-label (n[15]= 17) 0.29 % after 118 d at 10 °C, [^{14}C-triazine ring]-label (n= 1; SYN only)
Non-extractable residues after 100 days ‡	17.3 – 30.8 % after 112 - 120 d at 20 °C, [^{14}C-triazine ring]-label (n= 17) 9.31 % after 118 d at 10 °C, , [^{14}C-triazine ring]-label (n= 1; SYN only)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Max values from studies: desethyl-terbuthylazine (MT1) – 3.0 – 25.1 % at 56 - 210 d at 20 °C (n= 17) 14.6 % at 118 d at 10 °C (n=1; SYN only) hydroxy-terbuthylazine (MT13) – 4.2 – 34.5 % at 90 - 311 d at 20 °C (n= 17) 1.4 % at 98 d at 10 °C (n= 1; SYN only) [^{14}C-triazine ring]-label

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2) – SYN and OXON

Anaerobic degradation ‡	
Mineralization after 100 days	≤ 0.1 % after 100 - 118 d, [^{14}C-triazine ring]-label (n= 2)
Non-extractable residues after 100 days	30.1 – 39.43 % after 100 - 118 d, [^{14}C-triazine ring]-label (n= 2)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Max values from studies: desethyl-terbuthylazine (MT1) – 0.3 – 4.5 % at 30 - 56 d (n= 2) hydroxy-terbuthylazine (MT13) – 1.0 – 8.16 % at 91 - 100 d (n= 2) [^{14}C-triazine ring]-label
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	DT50 in light exposed samples = 52 d; DT50 in dark control = 117 d (DT50 via photolysis only = 93.6 d; SYN) DT50 in light exposed samples = 28.2 d; DT50 in dark control = 126.6 d (DT50 via photolysis only = 36.3 d; OXON) Max values from studies (irradiated value minus non-irradiated value): Desethyl-terbuthylazine (MT1) – 3.6 % at 31 d exposure 12 hours irradiated at 550 W.m^{2}/ 12 hours dark (n= 1;

[15] n corresponds to the number of soils.

	SYN) 12.59 % at 15 d – exposure 700 W.m^2 continuous (n= 1; OXON). Hydroxy-terbuthylazine (MT13) – 5.49 % at 15 d – exposure 700 W.m^2 continuous (n= 1; OXON)

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1) – SYN and OXON

Laboratory studies ‡

Terbuthylazine	Aerobic conditions							
Soil name and classification	% OM	pH (KCl or $CaCl_2$)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	$DT_{50, actual}$ (d)	$DT_{50, ref}$ 20 °C pF2 (d)	Min chi² error (%)	Method of calc.
Gartenacker Sandy Loam	3.79	7.25	20 °C / 26.73 %	48.92	78.7	51.6	1.7	SFO
Pappelacker Loamy Sand	1.9	7.6	20 °C / 15.8 %	29.3	93.1	60.4	2.9	SFO
Weide Sandy Loam	2.24	7.5	20 °C / 18.96 %	36.6	65.0	41.0	2.5	SFO
Speyer 2.2 Loamy Sand	3.91	6.1	20 °C / 19.2 %	12.1	167	167	2.1	SFO
Borstel Loamy Sand	2.59	5.8	20 °C / 10.88 %	14[b]	143	120	1.0	SFO
Lorsch Sandy Clay Loam	3.1	5.3	20 °C / 19.92 %	22[b]	110	103	1.4	SFO
Gartenacker Silt Loam 1.57 kg/ha	3.59	7.32	20 °C / 29.17 %	48.61	77.0	53.9	4.4	SFO
Gartenacker Silt Loam 0.15 kg/ha	3.59	7.32	20 °C / 29.17 %	48.61	59.7	41.8	4.9	SFO
Collombey Sand	2.29	7.7	20 °C / 16.8 %	25.31	80.0	60.0	5.9	SFO
Les Evouettes Silt Loam	2.41	6.1	20 °C / 22.12 %	40.21	58.4	38.2	7.7	SFO
Speyer 2.2 Loamy Sand	4.4	6.0	20 °C / 16.16 %	21.21	122	101	2.2	SFO
Speyer 2.3 Sandy Loam	1.28	6.6	20 °C / 12.56 %	18.61	112	85.2	2.4	SFO
Les Evouettes Loam	6.4	6.8	20 °C / 35.85 %	47.8	69.7	57.0	4.3	SFO
Speyer 2.2 Loamy Sand	3.95	6.18	20 °C / 17.72 %	14[b]	136	138	5.6	SFO
Sisseln Sandy Loam	2.71	7.16	20 °C / 20.96 %	19[b]	83.7	83.7	4.1	SFO
Collombey Loamy Sand	2.02	7.45	20 °C / 16.12 %	14[b]	73.6	73.6	4.2	SFO
Diegten Clay Loam	2.74	6.9	20 °C / 20.76 %	28[b]	117	94.9	1.9	SFO
Geometric mean[a]					**91.1**	**72.0**	-	-
Median					**88.4**	**75.1**	-	-

(a) Geometric mean for replicate soil values calculated first (excluding the two Les Evouettes soils that were considered to be substantially different from each other due to contrasting organic matter contents e.g. 2.41 and 6.4% organic matter)

(b) FOCUS default moisture content based on soil texture

Note that the t-test result was >99% for every soil

Desethyl-terbuthylazine	Aerobic conditions (where metabolite applied as starting material)							
Soil name and classification	% OM	pH (KCl or $CaCl_2$)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	$DT_{50, actual}$ (d)	$DT_{50, ref}$ 20 °C pF2 (d)	Min chi² error (%)	Method of calc.
Borstel – Loamy Sand	2.63	5.79	20 °C / 10.9 %	14[a]	83.9	70.3	1.9	SFO

Desethyl-terbuthylazine	Aerobic conditions (where metabolite applied as starting material)							
Soil name and classification	% OM	pH (KCl or $CaCl_2$)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	$DT_{50, actual}$ (d)	$DT_{50, ref}$ 20 °C pF2 (d)	Min chi^2 error (%)	Method of calc.
Gartenacker* - Loam	3.20	7.28	20 °C / 26.7 %	25 [a]	61.8	61.8	3.1	SFO
Lorsch – Sandy Clay Loam	3.16	5.25	20 °C / 19.9 %	22 [a]	40.7	38.0	3.3	SFO
Speyer 2.3 – Sandy Loam	2.1	6.4	20 °C / 15.6 %	19 [a]	61.8	53.8	6.7	SFO
Speyer 2.1 – Sand	1.07	5.9	20 °C / 12.4 %	12 [a]	45.2	45.2	4.9	SFO
Speyer 2.2 – Loamy Sand	4.00	5.6	20 °C / 19.2 %	14 [a]	50.7	50.7	4.1	SFO
Westmaas – Silt Loam	2.41	7.4	20 °C / 15.6 %	26 [a]	93.8	65.6	6.0	SFO
Geometric mean					**60.0**	**54.0**	-	-
Median					**61.8**	**53.8**	-	-

* NB. Significant volatiles observed for Gartenacker soil

[a] FOCUS default moisture content based on soil texture

[b] t-test result was >99% for every soil

Desethyl-terbuthylazine	Aerobic conditions (where metabolite formed from parent terbuthylazine during the study)								
Soil name and classification	% OM	pH (KCl or $CaCl_2$)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	$DT_{50, actual}$ (d)	Form. frac. (ffm)	$DT_{50, ref}$ 20 °C pF2 (d)	Min chi^2 error (%)	Method of calc.
Gartenacker Sandy Loam	3.79	7.25	20 °C / 26.73 %	48.92	66.0	0.606	43.2	5.8	SFO
Pappelacker Loamy Sand	1.9	7.6	20 °C / 15.8 %	29.3	105.7	0.591	68.6	6.2	SFO
Weide Sandy Loam	2.24	7.5	20 °C / 18.96 %	36.6	87.4	0.536	55.2	4.6	SFO
Borstel Loamy Sand	2.59	5.8	20 °C / 10.88 %	14[b]	53.8	0.357	45.1	2.3	SFO
Gartenacker Silt Loam 1.57 kg/ha	3.59	7.32	20 °C / 29.17 %	48.61	112.8	0.430	78.9	11.3	SFO
Gartenacker Silt Loam 0.15 kg/ha	3.59	7.32	20 °C / 29.17 %	48.61	42.9	0.575	30.0	9.3	SFO
Collombey Sand	2.29	7.7	20 °C / 16.8 %	25.31	26.9	0.498	20.2	18.1	SFO
Les Evouettes Silt Loam	2.41	6.1	20 °C / 22.12 %	40.21	21.7	0.594	14.3	13.7	SFO
Speyer 2.3 Sandy Loam	1.28	6.6	20 °C / 12.56 %	18.61	91.6	0.346	69.6	11.7	SFO
Sisseln Sandy Loam	2.71	7.16	20 °C / 20.96 %	19[b]	76.6	0.536	76.6	6.0	SFO
Collombey Loamy Sand	2.02	7.45	20 °C / 16.12 %	14[b]	60.4	0.580	60.4	3.5	SFO
Diegten Clay Loam	2.74	6.9	20 °C / 20.76 %	28[b]	63.5	0.323	51.5	7.7	SFO
Arithmetic mean[a]					-	**0.484**	-	-	-
Geometric mean[a]					**61.8**	-	**46.9**	-	-
Median[a]					**68.4**	**0.536**	**51.5**	-	-

(a) Average formation fraction and geometric mean DT_{50} for replicate soil values calculated first
(b) FOCUS default moisture content based on soil texture
Note that the t-test result was >99% for all soils except Collombey (>95%), Les Evouettes (>98%) and Speyer 2.3 (>92%)

Hydroxy-terbuthylazine	Aerobic conditions (where metabolite applied as starting material)							
Soil type	% OM	pH (K Cl)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	$DT_{50,\ actual}$ (d)	$DT_{50,\ ref}$ 20 °C pF2 (d)	Min chi^2 error (%)	Method of calc.
Borstel – Loamy Sand	2.6	5.8	20 °C / 10.88 %	14[a]	207	173	4.7	SFO
Gartenacker – Loam	2.8	7.6	20 °C / 25.08 %	25[a]	298	298	2.2	SFO
Vetroz – Silt Loam	3.1	7.7	20 °C / 23.56 %	26[a]	281	278	2.9	SFO
Cranfield 115 – Clay Loam	2.9	7.4	20 °C / 22.1 %	28[a]	>1000	>1000	3.3	SFO
Cranfield 164 – Silt Loam	5.2	6.5	20 °C / 29.12 %	26[a]	>1000	>1000	3.7	SFO
Cranfield 243 – Sandy Loam	1.9	4.3	20 °C / 20.44 %	22.7[a]	645	600	1.7	SFO
Geometric mean					**473[b]**	**453[b]**	-	-

[a] FOCUS default moisture content based on soil texture

[b] the geomean was calculated assuming a default DT_{50} of 1000 d for Cranfield 115 and Cranfield 164 soils (the results for the Cranfield 115 and Cranfield 164 soils were excluded from the geometric mean calculated by the Applicants on the basis of unacceptable parameter significance based on results of the t-test (Applicants geomean DT_{50}, actual = 325 d, DT_{50}, ref = 305d))

Hydroxy-terbuthylazine	Aerobic conditions (where metabolite formed from parent terbuthylazine during the study)					
Soil type	% OM	pH (KCl or $CaCl_2$)	Visual inspection	Form. frac. (ffm	Min chi^2 error (%)	Method of calc.
Gartenacker Sandy Loam	3.79	7.25	Acceptable	0.080	12.1	SFO using a fixed DT_{50} of 325 d
Pappelacker Loamy Sand	1.9	7.6	Acceptable	0.065	28.0	SFO using a fixed DT_{50} of 325 d
Weide Sandy Loam	2.24	7.5	Acceptable	0.059	28.6	SFO using a fixed DT_{50} of 325 d
Speyer 2.2 Loamy Sand	3.91	6.1	Acceptable	0.313	26.4	SFO using a fixed DT_{50} of 325 d
Borstel Loamy Sand	2.59	5.8	Very good	0.219	3.0	SFO using a fixed DT_{50} of 325 d
Lorsch Sandy Clay Loam	3.1	5.3	Very good	0.379	7.0	SFO using a fixed DT_{50} of 325 d
Gartenacker Silt Loam 2.6 kg/ha	3.59	7.32	Acceptable	0.064	18.1	SFO using a fixed DT_{50} of 325 d
Gartenacker Silt Loam 0.25 kg/ha	3.59	7.32	Acceptable	0.073	21.8	SFO using a fixed DT_{50} of 325 d
Collombey Sand	2.29	7.7	Acceptable	0.301	18.2	SFO using a fixed DT_{50} of 325 d
Les Evouettes Silt Loam	2.41	6.1	Good	0.381	9.6	SFO using a fixed DT_{50} of 325 d
Speyer 2.2 Loamy Sand	4.4	6.0	Good	0.379	12.0	SFO using a fixed DT_{50} of 325 d
Speyer 2.3 Sandy Loam	1.28	6.6	Acceptable	0.250	27.1	SFO using a fixed DT_{50} of 325 d
Speyer 2.2 Loamy Sand	3.95	6.18	Reasonable	0.515	23.1	SFO using a fixed DT_{50} of 325 d
Sisseln Sandy Loam	2.71	7.16	Acceptable	0.149	15.0	SFO using a fixed DT_{50} of 325 d
Collombey Loamy Sand	2.02	7.45	Good	0.112	15.4	SFO using a fixed DT_{50} of 325 d
Diegten Clay Loam	2.74	6.9	Very good	0.203	3.8	SFO using a fixed DT_{50} of 325 d
Arithmetic mean[a]				**0.217**	-	-
Median[a]				**0.207**	-	-

(a) Average formation fraction for replicate soil values calculated first prior to derivation of overall mean or median

All studies performed at 20°C

Desethyl hydroxy-terbuthylazine	Aerobic conditions (where metabolite applied as starting material)							
Soil type	% OM	pH (K Cl)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	$DT_{50, actual}$ (d)	$DT_{50, ref}$ 20 °C pF2 (d)	Min chi^2 error (%)[b]	Method of calc.
Borstel – Loamy Sand	2.6	5.8	20 °C / 10.88 %	14[a]	135	113	7.7	SFO
Gartenacker – Loam	2.8	7.6	20 °C / 25.08 %	25[a]	50.1	50.1	5.3	SFO
Lorsch – sandy clay loam	3.1	5.3	20 °C / 19.92 %	22[a]	377	351	5.1	SFO
Vetroz – Silt Loam	3.1	7.7	20 °C / 23.56 %	26[a]	69.7	65.1	4.0	SFO
Geometric mean					**115**	**107**	-	-

[a] FOCUS default moisture content based on soil texture

[b] t-test result was >99% for every soil except Lorsch where it was >97%

Desethyl hydroxy-terbuthylazine	Aerobic conditions (where metabolite formed from parent desethyl-terbuthylazine during the study)					
Soil type	% OM	pH (K Cl)	Visual inspection	Form. frac. (ffm	Min chi^2 error (%)	Method of calc.
Borstel – Loamy Sand	2.6	5.8	Very good	0.203	2.7	SFO using a fixed DT_{50} of 135 d
Gartenacker – Loam	2.8	7.6	Very good	0.179	9.1	SFO using a fixed DT_{50} of 50.1 d
Lorsch – sandy clay loam	3.1	5.3	Very good	0.458	3.5	SFO using a fixed DT_{50} of 377 d
Arithmetic mean				**0.280**	-	-

All studies performed at 20°C

LM5	Aerobic conditions (where metabolite was formed from parent desethyl-hydroxy terbuthyalzine)								
Soil type	% OM	pH (KCl)	temp. °C / soil moisture for study (% w/w)	Soil moisture at pF 2 (% w/w)	$DT_{50, actual}$ (d)	$DT_{50, ref}$ 20 °C pF2 (d)	Formation fraction	Min chi² error (%)[b]	Method of calc.
Gartenacker – Loam	2.8	7.6	20 °C / 25.08 %	25[a]	119	119	0.491	4.72 (p = 0.0812)	SFO
Vetroz – Silt Loam	3.1	7.7	20 °C / 23.56 %	26[a]	146	136	0.440	3.00 (p = 0.1570)	SFO
Geometric mean					**132**	**128**	0.466 (arithmetic mean)	-	-

[a] FOCUS default moisture content based on soil texture

Field studies ‡

Terbuthylazine	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	% OM	pH	Depth (cm)	$DT_{50, ref}$ 20 °C pF2 (d)	$DT_{90, ref}$ 20 °C pF2 (d)	Min chi² error (%)	t-test (%)	Method of calc.[a]
Loam – Bare soil	St Aubin, Switzerland	3.1	7.2	0 – 10	18.0	59.8	5.4	> 99%	SFO
Silt loam – Bare soil	Eschwege, Germany	4.0	6.2	0 – 20	17.3	57.5	16.8	> 99%	SFO
Silt loam – Bare soil	Goch, Germany	6.4	6.25	0 – 20	30.1	99.8	8.1	> 99%	SFO
Silty clay loam – Bare soil	Keeken, Germany	7.6	6.1	0 – 20	26.1	86.9	17.4	> 99%	SFO
Silt loam – Bare soil	Pleidsheim, Germany	2.1	6	0 – 20	17.4	57.7	19.0	> 99%	SFO
Loamy sand – Bare soil	Lorsch Helming, Germany	1.4	5.25	0 – 20	6.83	22.7	21.0	> 99%	SFO
Loamy sand – Bare soil	Weeze Wemb, Germany	3.8	6.2	0 – 20	12.3	40.7	17.3	> 99%	SFO
Clay loam – Bare soil	Grisolles, Southern France	1.62	7.3	0 – 30	53.1	176	12.7	> 99%	SFO
Silt loam – Bare soil	Molinella, Italy[d]	1.31	7.6	0 - 30	148	491	12.8	> 99%	SFO
Silt loam – Bare soil	St Firmin, France (North) (1.0)	1.6	8.4	0 – 10	24.7	82.2	8.9	> 99%	SFO
Silt loam – Bare soil	St Firmin, France (North) (1.5)	1.6	8.4	0 – 10	21.0	69.8	9.9	> 99%	SFO
Sand – Bare soil	Nevoy, France (North) (1.0)	1.0	8.6	0 – 10	12.1	40.2	9.1	> 99%	SFO
Sand – Bare soil	Nevoy, France (North) (1.5)	1.0	8.6	0 – 10	18.9	62.7	7.3	> 99%	SFO

Field studies ‡

Terbuthylazine	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	% OM	pH	Depth (cm)	$DT_{50, ref}$ 20 °C pF2 (d)	$DT_{90, ref}$ 20 °C pF2 (d)	Min chi^2 error (%)	t-test (%)	Method of calc.[a]
Silt loam – Bare soil	Charny, France (North) (1.0)	1.0	5.9	0 – 10	16.8	55.9	10.1	> 99%	SFO
Silt loam – Bare soil	Charny, France (North) (1.0)	1.0	5.9	0 – 10	22.6	75.1	8.3	> 99%	SFO
Silty sand – Bare soil	Ports sur Vienne, France (North) (1.0)	1.9	6.6	0 – 10	13.6	45.0	5.0	> 99%	SFO
Silty sand – Bare soil	Ports sur Vienne, France (North) (1.5)	1.9	6.6	0 – 10	27.3	90.6	14.0	> 99%	SFO
Sandy silt loam – Bare soil	Eraclea, Italy (1.0)[b]	3.4	7.6	0 – 10	77.9	259	40.0	> 82%	SFO
Sandy silt loam – Bare soil	Eraclea, Italy (1.0)[b]	3.4	7.6	0 – 10	10.0	33.3	20.9	> 97%	SFO
Clay – Bare soil	Emilia, Italy	3.3	7.5	0 – 10	31.3	104	7.9	> 99%	SFO
Clay – Bare soil	Emilia Italy	3.3	7.5	0 – 10	30.6	102	6.0	> 99%	SFO
Soft clayey sand – Bare soil	Hilgermissen, Germany[e]	1.5	5.9	0 – 10	35.8	119	12.5	> 99%	SFO
Clayey sand – Bare soil	Leutzke, Germany	2.9	5.5	0 – 10	10.1	33.5	25.6	> 99%	SFO
Geometric mean[c]					**22.4**	**74.4**	-	-	-
Median[c]					**19.4**	**64.3**	-	-	-

NK – not known

[a] soils were normalised for temperature assuming a Q10 of 2.2 using a time step normalisation procedure. Soil moisture content was assumed to be at pF2 and not corrected for.

[b] Excluded from statistical evaluations due to poor fits

[c] Geometric mean of replicate trials calculated first; median based on n = 16

[d] The un-normalised SFO DT50 at the Molinella field site (SEU) was 149.9 d (chi2 error level = 12.8%, acceptable visual fit)

[d] The un-normalised SFO DT50 at the Hilgermissen field site (NEU) was 46.6 d (chi2 error level = 17.2%, acceptable visual fit up to approximate DT90)

Field studies

Desethyl terbuthylazine	Aerobic conditions (where metabolite formed from parent terbuthylazine during the study)								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	% OM	pH	$DT_{50, ref}$ 20 °C pF2 (d)	$DT_{90, ref}$ 20 °C pF2 (d)	Form. frac. (ffm	Min chi^2 error (%)	t-test (%)	Method of calc.[d]
Loam – Bare soil	St Aubin, Switzerland	3.1	7.2	16.5	54.9	0.298	17.1	>99%	SFO
Silt loam – Bare soil	Pleidsheim, Germany	2.1	6	30.9	103	0.117	13.7	>77%	SFO
Loamy sand – Bare soil	Lorsch Helming, Germany	1.4	5.25	1.72	5.72	0.320	21.6	>64%	SFO
Clay loam – Bare soil	Grisolles, Southern France	1.62	7.3	46.8	155	0.829	14.9	>99%	SFO
Silt loam – Bare soil	Molinella, Italy	1.31	7.6	223	740	0.497	7.1	>75%	SFO
Silt loam – Bare soil	St Firmin, France (North) (1.0)	1.6	8.4	15.9	52.7	0.818	18.2	>92%	SFO
Silt loam – Bare soil	St Firmin, France (North) (1.5)	1.6	8.4	19.5	64.8	0.438	5.4	>95%	SFO
Silt loam – Bare soil	Charny, France (North) (1.0)	1.0	5.9	52.7	175	0.289	6.2	>97%	SFO
Silt loam – Bare soil	Charny, France (North) (1.0)	1.0	5.9	77.8	258	0.249	11.4	>96%	SFO
Soft clayey sand – Bare soil	Hilgermissen, Germany	1.5	5.9	26.2	87.1	0.678	9.3	>99%	SFO
Arithmetic mean[a,b]				-	-	**0.45**	-	-	-
Geometric mean[a,c]				**26.9**	**89.2**	-	-	-	-
Median[a,c]				**28.6**	**95.1**	-			

[a] only valid datasets considered
[b] arithmetic mean of replicate soils calculated first
[c] geometric mean of replicate soils calculated first
[d] soils were normalised for temperature assuming a Q10 of 2.2 using a time step normalisation procedure. Soil moisture content was assumed to be at pF2 and not corrected for.
NB the applicant proposed a geometric mean of 29.6 d based on a marginally different set of soils considered acceptable

Field studies

Hydroxy-terbuthylazine	Aerobic conditions (where metabolite formed from parent terbuthylazine during the study)						
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	% OM	pH	Visual inspection	Form. frac. (ffm	Min chi^2 error (%)	Method of calc.
Loam – Bare soil	St Aubin, Switzerland	3.1	7.2	Reasonable	0.079	22.7	SFO using a fixed DT_{50} of 305 d
Sand – Bare soil	Nevoy, France (North) (1.0)	1.0	8.6	Acceptable	0.174	22.3	SFO using a fixed DT_{50} of 305 d
Sand – Bare soil	Nevoy, France (North) (1.5)	1.0	8.6	Good	0.466	13.6	SFO using a fixed DT_{50} of 305 d
Silty sand – Bare soil	Ports sur Vienne, France (North) (1.5)	1.9	6.6	Reasonable	0.213	21.4	SFO using a fixed DT_{50} of 305 d
Soft clayey sand – Bare soil	Hilgermissen, Germany	1.5	5.9	Acceptable	0.169	32.3	SFO using a fixed DT_{50} of 305 d
Arithmetic mean[a]					**0.195**	-	-
Median[a]					**0.191**	-	-

[a]arithmetic mean of replicate soils calculated first

pH dependence ‡ (yes / no) (if yes type of dependence)	Possible weak negative correlation between degradation of terbuthylazine and soil pH based on laboratory studies (r^2 = 0.3485). No correlation observed based on field dissipation studies.
Soil accumulation and plateau concentration ‡	No evidence of accumulation of terbuthylazine, desethyl-terbuthylazine, hydroxy-terbuthylazine or desethyl-hydroxy-terbuthylazine after repeated applications at 7 locations in Northern Italy.

Laboratory studies ‡

Terbuthylazine	Anaerobic conditions						
Soil type	OM %	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Gartenacker – Sandy loam - SYN	3.79	7.25	20 oC / flooded soil	108.3 / 359.9	N/A	0.981	SFO
Speyer 2.3 – Sandy Loam - SYN	2.07	6.3	20 oC / flooded soil	131 / 436	N/A	0.966	SFO
Geometric mean				**119.1**			

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Terbuthylazine ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2 Loamy Sand – OXON	2.29	6.0	N/A	N/A	5.34	233	0.98
Les Evouettes Sandy Loam – OXON	1.20	5.9	N/A	N/A	2.95	246	0.90
Sisseln Sandy Loam – OXON	1.57	7.1	N/A	N/A	2.37	151	0.93
Vetroz Silt Loam - OXON	4.1	7.3	N/A	N/A	8.18	200	0.90
Pappelacker Loamy Sand – SYN	1.1	7.6	N/A	N/A	2.10	191	0.92
Lorsch Sandy Clay Loam – SYN	1.8	5.3	N/A	N/A	5.86	318	0.94
Gartenacker Loam – SYN	2.0	7.1	N/A	N/A	3.74	187	0.88
Vetroz Silt Loam - SYN	4.7	7.2	N/A	N/A	10.49	223	0.97
Borstel Loamy Sand – SYN*	1.48	6.1	N/A	N/A	4.93	333	0.91
Arithmetic mean					**5.1**	**231**	**0.93**
pH dependence, Yes or No			Possible weak negative correlation between sorption and soil pH (r^2 = 0.5456)				

NR = not recorded

Desethyl-terbuthylazine (MT1) ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Collombey Loamy Sand - SYN	0.80	7.3	N/A	N/A	0.594	74.0	0.85
Les Evouettes Silt Loam – SYN	2.40	7.2	N/A	N/A	1.43	59.0	0.86
Vetroz Silt Loam - SYN	4.70	7.2	N/A	N/A	3.29	70.0	0.91
Speyer 2.1 Sand – OXON	0.6	5.9	N/A	N/A	0.43	67.2	0.95
Speyer 2.2 Loamy Sand – OXON	2.3	5.6	N/A	N/A	1.9	81.7	0.91
Beek Silt Loam – OXON	0.6	6.6	N/A	N/A	0.28	43.8	0.94
Marknesse Silt Loam - OXON	1.3	7.5	N/A	N/A	1.24	96.9	0.92
Lorsch Sandy Clay Loam - SYN	1.84	5.25	N/A	N/A	1.56	85.0	0.94
Borstel Loamy Sand – SYN*	1.48	6.1	N/A	N/A	1.80	122	0.77
Arithmetic mean					**1.34**	**72.2**	**0.91**
pH dependence (yes or no)			No				

* Data from this soil not included in arithmetic mean as the study was submitted after risk exposure modelling was completed. A re-calculated Kfoc would = 77.7 mL/ g.

Hydroxy-terbuthylazine (MT13) ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Cranfield 115 Clay Loam – OXON	1.7	7.9	N/A	N/A	3.51	208.6	0.82
Cranfield 164 Silt Loam – OXON	3.0	7.1	N/A	N/A	5.94	196.9	0.8
Cranfield 243 Sandy Loam - OXON	1.1	5.4	N/A	N/A	2.14	193.1	0.85
Borstel Sandy Loam - SYN	1.3	5.0	N/A	N/A	3.64	279.7	0.87
Collombey Loamy Sand - SYN	0.80	7.3	N/A	N/A	1.19	149	0.91
Les Evouettes Silt Loam - SYN	2.40	7.2	N/A	N/A	2.49	104	0.79
Vetroz Silt Loam - SYN	4.70	7.2	N/A	N/A	8.36	178	1.31
Arithmetic mean					**3.90**	**187**	**0.91**
pH dependence (yes or no)			No				

Desethyl-hydroxy-terbuthylazine (MT14) ‡							
Soil Type	OC %	Soil pH ($CaCl_2$)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Borstel Loamy Sand	1.3	5.0	1.8	136	1.44	111	0.93
Lorsch Sandy Clay Loam	1.8	5.3	3.8	211	3.39	188	0.97
Gartenacker Loam/Silt Loam	2.0	7.1	1.2	59	1.10	55	0.98
Vetroz Silt Loam	4.7	7.2	2.8	60	2.67	57	0.98

Wisborough- Silty Clay Loam	3.44	5.02	4.40	375	3.36	98	0.8892
18 Acres - Sandy Clay Loam	1.95	5.27	4.79	242	3.34	171	0.9166
Kochi - Loam	1.17	5.65	8.26	213	2.98	254	0.8991
Bosket - Loam[a]	0.58	5.68	3.97	158	5.83	1010	0.9572
Ushiku - Sandy Clay Loam	1.98	5.99	6.98	1208	2.83	143	0.8674
Tsukuba - Loam	3.87	6.49	5.23	152	5.07	131	0.8881
Pappelacker - Sandy Loam	2.76	7.06	0.78	28	0.61	22	0.9220
Champaign - Silty Clay	2.52	7.34	4.62	236	2.50	99	0.8787
Median (all data, n=12)					**2.91**	**121**	**0.92**
pH dependence (yes or no)					No		

Terbutryn (MT26) ‡							
Soil Type	OC %	Soil pH (KCl)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Pappelacker - Sandy Loam	1.1	7.6	N/A	N/A	4.3	392	1.01
Speyer 2.1 - sand	0.6	7.4	N/A	N/A	3.7	605	1.06
Gartenacker Loam/Silt Loam	2.1	7.3	N/A	N/A	10.5	504	1.39
Vetroz Silt Loam	4.7	7.2	N/A	N/A	25.1	533	1.01
Illarsaz – silt loam	19.8	6.7	N/A	N/A	109.9	555	1.02
Arithmetic mean					**13**	**518**	**1.04**
pH dependence (yes or no)			No evidence from narrow pH range studied				

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2) – SYN and OXON

Column leaching ‡ (SYN)	Eluation (mm): 200 mm Time period (d): 2 d
	Leachate: < 0.01 - 0.04 % total residues/radioactivity in leachate 82.45 - 90.14 % active substance and 0.46 - 1.49 % extractable metabolites in soil. 45.48 – 87.37 % total residues/radioactivity retained in top 2 cm

Lysimeter/ field leaching studies ‡ (SYN) Summary of metabolite codes:- MT1 = GS26379 MT13 = GS23158 MT14 = GS28620 MT19 = GS17792 MT20 = GS28273 MT22 = G28279 LM1 = MT24 = G35713 LM2 = MT28 = CSAA036479 LM3 = SM9 = CSCD692760 LM4 = CSAA404949 LM5 = MT23 = SM12 = GS16984 LM6 = SM6 = CSCD648241	Location: Schmallenberg/Grafschaft, Germany Study type (e.g.lysimeter, field): lysimeter (x2) Soil properties (0 – 30 cm): Borstel Sandy Loam, pH = 5.7, OC= 1.5 % , MWHC = not stated (FC = 20 – 34 % by volume) Dates of application : 28/05/1990 Crop : maize followed by the rotational crops winter wheat and winter barley. Number of applications: 1 application to maize in first year only Duration: 2 years, Application rate: 700 - 790 g/ha Average annual rainfall (mm): 863 mm Average annual leachate volume (mm): 418.3 mm % radioactivity in leachate (maximum/year): 1.45 – 1.48 % AR Annual average maximum concentrations (e.g. 1st or 2nd yr, Lysimeter 38 or 44): < 0.02 µg/L terbuthylazine, < 0.02 µg/L desethyl-terbuthylazine, 0.03 µg/L hydroxy-terbuthylazine. 0.03 µg/L G 28273 (MT20) 0.05 µg/L GS 17792 (MT19) < 0.02 µg/L G 28279 (MT22), G 28260 (MT14) 1.96 µg/L Unidentified radioactivity Bi-annual average concentrations (e.g. 1st and 2nd yr, Lysimeter 38 and 44): < 0.02 µg/L terbuthylazine, < 0.02 µg/L desethyl-terbuthylazine, 0.02 µg/L hydroxy-terbuthylazine. 0.02 µg/L G 28273 (MT20) 0.03 µg/L GS 17792 (MT19) < 0.02 µg/L G 28279 (MT22), G 28260 (MT14) 1.21 µg/L Unidentified radioactivity Amount of radioactivity in the soils at the end of the study = 65.6 – 75.2 % AR; consisting of: 5.9 – 6.4 % AR as terbuthylazine, 1.2 – 1.5 % AR as desethyl-terbuthylazine,

	0.2 – 0.5 % AR as hydroxy-terbuthylazine, < LOD – 0.2 % AR as G 28279 (MT22), 0.1 – 0.2 % AR as GS 28260 (MT14)
Lysimeter/ field leaching studies ‡ (SYN)	Location: Itingen, Switzerland Study type (e.g.lysimeter, field): lysimeter Soil properties (0 – 30 cm): Neustadt Sand, pH = 6.1, OC= 1.05, MWHC = 34.5 % Dates of application : May 1992 Crop : maize followed by two rotations of winter wheat Interception estimated: 25 % (based on standard crop interception values and growth stage of maize at time of application) Number of applications: 1 application to maize in first year only Duration: Application rate: 891 g/ha Average annual rainfall (mm): 1090 mm Average annual leachate volume (mm): 413.2 mm % radioactivity in leachate (maximum/year): 2.34 % AR Structural assignments for the parent and metabolites in the leachate were determined based on analysis during the original study coupled with additional information from further more recent accurate mass structural elucidation work. Parent and desethyl terbuthylazine were identified in the original study. Two further metabolites were plausibly assigned to LM3 and LM6 based on the additional mass spectral elucidation work. Assignation of other peaks was less certain based on matching relative retention times since matching HPLC conditions between this study and later definitive studies were not available. Quantitative concentrations are also uncertain due to the presence of multiple components in single peaks. Annual average concentrations (μg/l parent equivalents) Lysimeter 27: < 0.05 μg/L terbuthylazine (1st year); < 0.05 μg/L terbuthylazine (2nd year); < 0.05 μg/L terbuthylazine (mean of 1st and 2nd year) < 0.05 μg/L desethylterbuthylazine (1st year); < 0.05 μg/L desethylterbuthylazine (2nd year); < 0.05 μg/L desethylterbuthylazine (mean of 1st and 2nd year) 0.12 μg/L LM1* (1st year); 0.33 μg/L LM1* (2nd year); 0.25 μg/L LM1* (mean of 1st and 2nd year) 0.17 μg/L LM2* (1st year); 0.17 μg/L LM2* (2nd year); 0.17 μg/L LM2* (mean of 1st and 2nd year) 0.43 μg/L LM3 (1st year); 1.09 μg/L LM3 (2nd year); 0.84 μg/L LM3 (mean of 1st and 2nd year) 0.36 μg/L LM5* (1st year); 0.70 μg/L LM5* (2nd year); 0.57 μg/L LM5* (mean of 1st and 2nd year) 0.07 μg/L MT14 and LM4* (1st year); 0.11 μg/L MT14 and LM4* (2nd year); 0.09 μg/L MT14 and LM4* (mean of 1st and 2nd year)

	0.05 µg/L LM6 (1st year); 0.50 µg/L LM6 (2nd year); 0.33 µg/L LM6 (mean of 1st and 2nd year) 0.25 µg/L LM7* (1st year); 0.05 µg/L LM7* (2nd year); 0.12 µg/L LM7* (mean of 1st and 2nd year) *= structures tentatively assigned to peaks Additional unidentified radioactivity (sum of smaller peaks) 0.11 µg/L (1st year); 0.29µg/l (2nd year); 0.22µg/l (mean of 1st and 2nd year) Amount of radioactivity in the soils at the end of the study = 67.7 % AR; consisting of (0 – 18 cm depth only) 0.92 % AR as parent 0.92 % AR as desethyl-terbuthylazine, 11.97 % AR as hydroxy-terbuthylazine, 1.52 % as desethyl-hydroxy-terbuthylazine, 6.29 % unidentified
Lysimeter/ field leaching studies ‡ (OXON)	Location: Itingen, Switzerland Study type (e.g.lysimeter, field): lysimeter (x2) Soil properties (0 – 30 cm): Neustadt Sand, pH = 6.1, OC= 1.05, MWHC = 34.5 % Dates of application : 18/05/93 Crop : maize, followed by two rotations of winter wheat Number of applications: 1 application to maize in first year only. Duration: 2 years Application rate: 905 g/ha/lysimeter 7; 929 g/ha/lysimeter 9 (application in first year only) Average annual rainfall (mm): 1090 mm Average annual leachate volume (mm): 485.6 mm % radioactivity in leachate (maximum/year): 1.60 - 1.70 % AR Annual average concentrations (e.g. 1st and 2nd yr, Lysimeter 7 and 9): not detected – terbuthylazine, desethyl terbuthylazine, hydroxy terbuthyalzine 0.04/0.06µg/l LM1 (lysimeter 7/9, 1st year); 0.12/0.15µg/l LM1 (lysimeter 7/9, 2nd year) 0.04/0.03µg/l LM2 (lysimeter 7/9, 1st year); 0.10/0.10µg/l LM2 (lysimeter 7/9, 2nd year) 0.26/0.31µg/l LM3 (lysimeter 7/9, 1st year); 0.85/0.83µg/l LM3 (lysimeter 7/9, 2nd year) 0.38/0.40µg/l LM4 (lysimeter 7/9, 1st year); 0.14/0.18µg/l LM4 (lysimeter 7/9, 2nd year) 0.10/0.08µg/l LM5 (lysimeter 7/9, 1st year); 0.71/0.62µg/l LM5 (lysimeter 7/9, 2nd year) 0.03/0.01µg/l LM6 (lysimeter 7/9, 1st year); 0.53/0.40µg/l LM6 (lysimeter 7/9, 2nd year) 0.08/0.08µg/l LM7 (lysimeter 7/9, 1st year); 0.06/0.03µg/l LM7 (lysimeter 7/9, 2nd year)

	Amount of radioactivity in the soils at the end of the study = 76.20 - 80.62 %AR; consisting of (0 – 38 cm depth only – max values) 6.4 % AR as terbuthylazine 1.0 % AR as desethyl-terbuthylazine, 53.8 % AR as hydroxy-terbuthylazine, 30 - 52 % AR unextraced radioactivity
Lysimeter/ field leaching studies ‡ (OXON)	Location: Itingen, Switzerland Study type (e.g.lysimeter, field): lysimeter (x2) Soil properties (0 – 30 cm): Neustadt Sandy loam, pH = 6.18, OC= 1.43, MWHC = 45.35 % Dates of application : 10/05/05 Crop : bare soil followed by plot being split and one of the following crops being sown: radish, spinach, wheat Interception estimated: 0 % (based on application to bare soil) Annual rainfall during first year May 2005 to April 2006 (mm): 798.5 mm Number of applications: 1 application to bare soil Duration: 1 year Application rate: 972 g/ha (Lysimeter 4); 980 g/ha (Lysimeter 6) Average annual leachate volume (mm): 731 mm % radioactivity in leachate (maximum/year): 1.60 - 1.70 % AR Annual average concentrations (e.g. 1st yr, Lysimeter 4 or 6): not detected – terbuthylazine, desethyl terbuthylazine, hydroxy terbuthyalzine 0.03/0.02µg/l LM1 (lysimeter 4/6, 1st year); 0.07/0.08µg/l LM2 (lysimeter 4/6, 1st year); 0.24/0.23µg/l LM3 (lysimeter 4/6, 1st year); 0.11/0.21µg/l LM4 (lysimeter 4/6, 1st year); 0.68/0.78µg/l LM5 (lysimeter 4/6, 1st year); 0.18/0.19µg/l LM6 (lysimeter 4/6, 1st year); 0.08/0.08µg/l LM7 (lysimeter 4/6, 1st year); All concentrations are in µg metabolite/l. Amount of radioactivity in the soils at the end of the study = not reported
Lysimeter/ field leaching studies ‡ (SYN)	Location: Lorsch, Hessen, Germany Study type (e.g.lysimeter, field): Field leaching study Soil properties (0 – 30 cm): sandy loam, pH = 5.2 – 6.3, OC= 2.3 – 2.6, MWHC = not reported Dates of application : 1990, 1992, 1994 – 1997, 1999 - 2000 Crop : maize in application years. Interception estimated: 25 % (based on standard crop interception values and growth stage of maize at time of

	application) Number of applications: 8 applications, maximum of 1 per year Duration: 11 years Application rate: 735 g/ha in 1990; 750 g/ha in all other application years Average annual rainfall (mm): 587 mm (NB. data from 1993, 1995 and 1998 not reported) Average annual leachate volume (mm): Not applicable % radioactivity in leachate (maximum/year): Not applicable. Frequency of detections, detections above >0.1µg/l and maximum conc.: Terbuthylazine: 1 detection out of 418 samples; 0% (~0 samples) >0.1µg/l; maximum concentration = 0.09µg/l. Desethyl terbuthylazine: 0 detections out of 419 samples; Desethyl hydroxyterbuthylazine: 17 detections out of 51 samples; 24% (~12 samples) >0.1µg/l; maximum concentration = 0.41µg/l. 2-hydroxy terbuthylazine: 10 detections out of 51 samples, 0%(0 samples) >0.1µg/l; maximum concentration = 0.08µg/l. Individual annual maximum concentrations (e.g. 1st, 2nd, 3rd yr): < 0.05 µg/L terbuthylazine < 0.05 µg/L desethyl-terbuthylazine, 0.06 µg/L 2-hydroxy-terbuthylazine 0.25 µg/L desethylhydroxy-terbuthylazine Individual annual average concentrations (e.g. 1st, 2nd, 3rd yr): < 0.05 µg/L terbuthylazine < 0.05 µg/L desethyl-terbuthylazine, < 0.05 µg/L 2-hydroxy-terbuthylazine < 0.05 - 0.12 µg/L desethylhydroxy-terbuthylazine Amount of radioactivity in the soils at the end of the study = not reported Note that 2-hydroxy terbuthyalzine was only analysed for in 1999-2000 and 2000-2001. Desethylhydroxy terbuthylazine was only analysed for in 1997-1998, 1999-2000 and 2000-2001.
	Location: 10 sites in 5 regions (Emilia Romagna, Friuli Venezia – Giulia, Lombardia, Piemonte, Veneto) in Northern Italy Study type (e.g.lysimeter, field): field leaching study Soil properties: texture class – 5 sandy loams, 3 loams , 1 sandy clay and 1 clay loam; pH = 4.9 7.7; OC= 0.9 – 3.6%; MWHC = not reported

Groundwater depth: 0.12 to 7.1m below ground surface Dates of application : 2005 to 2007 Crop : maize Irrigation: sprinkler, basin , border or no irrigation Interception estimated: 0 % (applications made shortly after seeding maize) Number and rate of applications: between 2005 and 2007, 7 sites had 3 annual applications of 856 g terbuthylazine/ha. The remaining 3 sites had either 2 or 1 annual application. Duration: bi-monthly sampling for 3 years (17 sampling events) Average annual rainfall (mm): Reported to be below the overall average for the period 2000-2007 but supplemented by irrigation at 9 out of 10 sites. Frequency of detections, detection >0.1µg/l and maximum conc. (excluding basin irrigated sites, n=8): Terbuthylazine: 62 detections out of 395 samples; 3% (~13 samples) >0.1µg/l; maximum concentration = 3.20µg/l. Desethyl terbuthylazine: 125 detections out of 395 samples; 5% (~21 samples) >0.1µg/l; maximum concentration = 3.18µg/l. Desethyl hydroxyterbuthylazine: 57 detections out of 144 samples; 29% (~42 samples) >0.1µg/l; maximum concentration = 2.65µg/l. 2-hydroxy terbuthylazine: 2 detections out of 144 samples, 0%(0 samples) >0.1µg/l; maximum concentration = 0.05µg/l. LM5: 11 detections out of 21 samples; 29% (~6 samples) > 0.1µg/l; maximum concentration = 0.68µg/l. LM6: 9 detections out of 21 samples; 38% (~8 samples >0.1µg/l; maximum concentration = 1.58µg/l. Annual average concentrations: 0.03 – 0.58 µg/L terbuthylazine (basin irrigation) <0.01 – 0.07 µg/L terbuthylazine (sprinkler or border irrigation) 0.07 – 0.73 µg/L desethyl terbuthylazine (basin irrigation) <0.01 – 0.22 µg/L desethyl terbuthylazine (sprinkler or border irrigation) < 0.05 – 0.05 µg/L (single sample) 2-hydroxy terbuthylazine (analysed for 2007 only) 0.04 – 0.37 µg/L desethyl hydroxy-terbuthylazine (analysed for the 2007 season only) <0.05 – 0.48 µg/L GS16984 (LM5) (analysed for the

	2007 season only) <0.05 – 1.3 µg/L CSCD648241 (LM6) (analysed for the 2007 season only) Note that as high concentrations were also found in the upstream monitoring wells, parts of residues found in downstream monitoring wells are likely to derive from previous usage following several years of commercial application in the upstream areas.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 46.6 days in Northern Europe (Hilgermissen site, chi^2 = 17.2%) 149.9 days in Southern Europe (Molinella site, chi^2 = 12.8%) Kinetics: SFO Field or Lab: representative worst case un-normalised values from field studies.
Application data	Crop: maize Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: Worst-case is pre-emergence application therefore no crop interception Number of applications: 1 Application rate(s): 750 g as/ha in Northern Europe 844 g as/ha in Southern Europe

PEC_{soil} values for terbuthylazine following application to maize according to the proposed critical GAP in Northern Europe with an application rate of 0.75 kg as/ha (DT_{50} = 46.6 d)

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average
Initial		1.000	
Short term	24h	0.985	0.993
	2d	0.971	0.985
	4d	0.942	0.971
Long term	7d	0.901	0.950
	14d	0.812	0.903
	21d	0.732	0.859
	50d	0.475	0.705
	100d	0.226	0.520

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average
Plateau concentration	not required – no evidence of accumulation during a field soil accumulation trial	

PEC$_{soil}$ values for terbuthylazine following application to maize according to the proposed GAP in Southern Europe with an application rate of 0.844 kg as/ha (DT$_{50}$ = 149.9 d)

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average
Initial		1.125	
Short term	24h	1.120	1.123
	2d	1.115	1.120
	4d	1.105	1.115
Long term	7d	1.089	1.107
	14d	1.055	1.090
	21d	1.021	1.072
	50d	0.893	1.005
	100d	0.709	0.901
Plateau concentration		not required – no evidence of accumulation during a field soil accumulation trial	

Desethyl-terbuthylazine Method of calculation	Molecular weight relative to the parent: 201.7/229.7 = 0.878 Peak desethyl-terbuthylazine (MT1) PEC$_{soil}$s calculated based on peak terbuthylazine PEC$_{soil}$s with correction made for maximum formation of desethyl-terbuthylazine (MT1) from lab or field aerobic degradation studies (32.9 % - field) and molecular weight.
Application data	Based on a parent application rate of 750 g a.s./ha the maximum PECsoil for desethyl terbuthylazine = 0.289 mg/kg Based on a parent application rate of 844 g a.s./ha the maximum PECsoil for desethyl terbuthylazine = 0.325 mg/kg No evidence of accumulation during a field soil accumulation trial therefore accumulation not

	required

Hydroxy-terbuthylazine Method of calculation	Molecular weight relative to the parent: 211.3/229.7 = 0.920 Peak hydroxy-terbuthylazine (MT13) PEC_{soil}s calculated based on peak terbuthylazine PEC_{soil}s with correction made for maximum formation of hydroxy-terbuthylazine (MT13) from lab or field aerobic degradation studies (34.5 % - lab) and molecular weight.
Application data	Based on a parent application rate of 750 g a.s./ha the maximum PECsoil for hydroxy terbuthylazine = 0.317 mg/kg Based on a parent application rate of 844 g a.s./ha the maximum PECsoil for hydoxy terbuthylazine = 0.357 mg/kg No evidence of accumulation during a field soil accumulation trial

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

Hydrolytic degradation of terbuthylazine and metabolites > 10 % ‡	SYN - pH 5: 73 d at 25 °C (1st order) Hydroxy-terbuthylazine: 16 % AR (50 d) OXON - pH 4: > 1 year at 20 °C (1st order, extrapolated beyond study duration)
	pH 7: SYN - 205 d at 25 °C (1st order) OXON - No significant degradation at 50 °C after 5 days
	pH 9: SYN - 194 d at 25 °C (1st order) OXON - No significant degradation at 50 °C after 5 days
Photolytic degradation of terbuthylazine and metabolites above 10 % ‡	SYN - Xenon arc lamp (wavelengths filtered < 290 nm), 12 hours light/12 hours dark for 10 days. Light equivalent to 13.4 days of midsummer sunlight at 30/40° N. DT_{50} : No significant degradation OXON - Xenon arc lamp (wavelengths filtered < 290 nm) for 30 days. 1 day equivalent to 1.64 days of summer sunlight at 40° N. DT_{50} : 14.1 d under the test conditions; equivalent to 29.5 d in natural sunlight at 40° N in the summer. hydroxy-terbuthylazine: 38.9 % AR (30 d) desethyl-terbuthylazine: 11.4 % AR (30 d)
Quantum yield of direct phototransformation in water at Σ > 290 nm	3×10^{-6} mol · Einstein $^{-1}$
Readily biodegradable ‡ (yes/no) (OXON and SYN)	No

Hydrolytic degradation of desethyl-terbuthylazine (MT1) and metabolites > 10 % ‡ (SYN)	pH 4: 135.9 d at 25 °C (1st order) desethyl-2-hydroxy-terbuthylazine: 11.5 % AR (30 d) pH 5: No significant degradation at 50 ^{o}C after 5 days
	pH 7: No significant degradation at 50 ^{o}C after 5 days
	pH 9: No significant degradation at 50 ^{o}C after 5 days
Photolytic degradation of desethyl-terbuthylazine (MT1) and metabolites above 10 % ‡	SYN - Xenon arc lamp (wavelengths filtered < 290 nm) for 15 days. Light equivalent to 13, 15 and 23 days of summer sunlight at 30 and 50 ^{o}N on a 12 h light: 12 dark basis at pH 5, 7 and 9 respectively. DT_{50} : No significant degradation
Quantum yield of direct phototransformation in water at Σ > 290 nm	A valid molar absorption coefficient could not be calculated because of very little or no absorption occurring over the wavelength range 290 – 800 nm.
Readily biodegradable ‡ (yes/no)	No data submitted, substance considered to be not ready biodegradable.

Hydrolytic degradation of hydroxy-terbuthylazine (MT13) and metabolites > 10 % ‡ (SYN)	pH 4: No significant degradation at 50 ^{o}C after 5 days
	pH 7: No significant degradation at 50 ^{o}C after 5 days
	pH 9: No significant degradation at 50 ^{o}C after 5 days
Photolytic degradation of hydroxy-terbuthylazine (MT13) and metabolites above 10 % ‡	Not performed
Quantum yield of direct phototransformation in water at Σ > 290 nm	A valid molar absorption coefficient could not be calculated because of very little or no absorption occurring over the wavelength range 290 – 800 nm.
Readily biodegradable ‡ (yes/no)	Not readily biodegradable

Degradation in water / sediment - SYN and OXON

Terbuthylazine	Distribution – maximum concentrations terbuthylazine – 51.8 % sed (14 d) desethyl-terbuthylazine (MT1) - 8.8 % whole system (110 d), 2.8 % sed (110 d), 8.0 % water (365 d) hydroxy-terbuthylazine (MT13) – 20 % whole system (365 d), 14.5 % sed (272 d), 5.7 % water (365 d) terbutryn (MT26) – 7.4 % whole system (365 d), 7.4 % sed (272 d), 0.3 % water (118 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
River Rhine sandy loam - SYN	8.3	7.7	20	73 days / 242 days	0.9917	6 days / 131 days	0.9994	NC	-	SFO – whole system DFOP – water phase
Pond Ormalingen silt loam - SYN	8.1	7.5	20	33 days / 110 days	0.9994	6 days / 47 days	0.9991	NC	-	SFO – whole system DFOP – water phase
River Rhine Loamy sand – OXON	8.2	7.3	20	83.5 days / 277.5 days	0.9991	31.4 days / 104.4 days	0.850	NC	-	SFO
Pond Anwil clay loam - OXON	8.3	6.6	20	118.5 days / 393.8 days	0.967	32.1 days / 106.7 days	0.870	NC	-	SFO
Geometric mean			20	69.9 days / 232.2 days		NC – not all SFO		NC		SFO

NC = not calculated

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
River Rhine sandy loam - SYN	8.3	7.7	0.3 % (365 d)	55.2 % (365 d)	55.2 %
Pond Ormalingen silt loam - SYN	8.1	7.5	0.2 % (56 d)	75.9 % (219 d)	62.0 %
River Rhine Loamy sand - OXON	8.2	7.3	-	37.9 % (110 d)	37.9 %
Pond Anwil clay loam - OXON	8.3	6.6	-	31.4 % (110 d)	31.4 %

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

Terbuthylazine Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 229.7 Water solubility (mg/L): 8.5 at 20 °C K_{FOC} (L/kg): 151 DT_{50} soil (d): 19.4 days (median of field data; SFO) DT_{50} water/sediment system (d): 69.9 (geomean from sediment/ water studies) DT_{50} water (d): 1000 d (default value) DT_{50} sediment (d): 69.9 (geomean from whole system sediment/ water studies. Degradation only DT50 values for sediment phase could not be calculated) Crop interception (%): 0
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: FOCUS SWASH 1.1 FOCUS MACRO 4.4.2 FOCUS PRZM SW 3.21.b FOCUS TOXSWA 2.1.2 Vapour pressure: 0 – set to 0 because soil DT50 from field studies used which includes losses due to volatilisation. A Q10 of 2.2 was assumed. Kfoc: 151 L/kg 1/n: 0.93
Parameters used in FOCUSsw step 4 (if performed)	Step 4 spray drift mitigation was applied by the use of either 5 m or 10 m buffers. Varying levels of run-off mitigation were also applied at 50%, 75% or 90% with the fractional reduction equally applied to runoff volume, runoff flux, erosion mass and erosion flux.
Application rate	Crop: maize Crop interception: 0 % Number of applications: 1 Interval (d): N/A Application rate(s): 750 g as/ha Northern Europe 844 g as/ha Southern Europe Application window: March – May window at Step 2; application set by PAT at Step 3/4 with 30 d window set to start 2 weeks prior to emergence as shown below:-

Scenario	Window start date	Window end date	Actual application date selected
D3	21st April	21st May	20th April
D4	26th April	26th May	26th April
D5	26th April	26th May	26th April
D6	6th April	6th May	9th April
R1	19th April	19th May	26th April
R2	17th April	17th May	22nd April
R3	17th April	17th May	22nd April
R4	27th March	26th April	7th April

Step 1 and Step 2 Maximum PECsw and PECsed for terbuthylazine following applications to maize at 750 g a.s./ha

Compound	Step	Region	Maximum Calculated PEC			
			Water (μg/L)	On Day	Sediment (μg/kg)	On Day
Terbuthylazine	1	-	215	0	320	1
	2	North	42.1	4	62.5	5
		South	78.2	4	116.4	5

Step 1 and Step 2 Maximum PECsw and PECsed for terbuthylazine following applications to maize at 844 g a.s./ha.

Compound	Step	Region	Maximum Calculated PEC			
			Water (μg/L)	On Day	Sediment (μg/kg)	On Day
Terbuthylazine	1	-	242	0	360	1
	2	North	47.4	4	70.3	5
		South	88.0	4	131	5

Step 3 maximum PECsw and PECsed for terbuthylazine following applications to maize at 750 g a.s./ha

Scenario	Water Body	App. Rate (g a.s./ha)	PEC_{SW} (μg/ L)			Max PEC_{SED} (μg/kg)	Main route of entry to surface water
			Max	21d TWA	28d TWA		
D3	Ditch	750	3.93	0.195	0.146	0.967	Spray drift
D4	Pond	750	0.171	0.154	0.150	0.397	Spray drift
	Stream	750	3.32	0.048	0.040	0.179	Spray drift
D5	Pond	750	0.218	0.201	0.196	0.511	Spray drift
	Stream	750	3.37	0.034	0.032	0.181	Spray drift
D6	Ditch	750	3.99	0.267	0.217	1.20	Spray drift
R1	Pond	750	0.335	0.316	0.309	0.71	Run off
	Stream	750	11.3	0.373	0.290	2.15	Run off
R2	Stream	750	8.26	0.320	0.252	1.78	Run off
R3	Stream	750	3.85	0.094	0.111	0.58	Spray drift
R4	Stream	750	**26.3**	1.20	0.916	**6.80**	Run off

Step 3 maximum PECsw and PECsed for terbuthylazine following applications to maize at 844 g a.s./ha

Scenario	Water Body	App. Rate (g a.s./ha)	PEC_{SW} (µg/L)			Max PEC_{SED} (µg/kg)	Main route of entry to surface water
			Max	21d TWA	28d TWA		
D3	Ditch	844	4.42	0.219	0.164	1.08	Spray drift
D4	Pond	844	0.192	0.173	0.169	0.446	Spray drift
	Stream	844	3.74	0.054	0.045	0.201	Spray drift
D5	Pond	844	0.247	0.227	0.222	0.575	Spray drift
	Stream	844	3.79	0.039	0.037	0.205	Spray drift
D6	Ditch	844	4.50	0.302	0.245	1.35	Spray drift
R1	Pond	844	0.376	0.355	0.347	0.792	Run off
	Stream	844	12.7	0.419	0.326	2.42	Run off
R2	Stream	844	9.34	0.361	0.285	2.00	Run off
R3	Stream	844	4.33	0.104	0.124	0.651	Spray drift
R4	Stream	844	**29.7**	1.36	1.03	**7.65**	Run off

Step 4 refined PECsw values for terbuthylazine, using mitigation according to FOCUS modelling with a 5m and 10m spray drift buffer and 50, 75 or 90% runoff mitigation (750 g a.s./ha)

Scenario	Water Body	App. Rate (g a.s./ha)	5m buffer (all scenarios), 50% run-off mitigation (R scenarios only)		5m buffer(all scenarios), 75% run-off mitigation (R scenarios only)	
			Max PEC_{SW} (µg/L)	1 day TWA PEC_{SW} (µg/L)	Max PEC_{SW} (µg/L)	1day TWA PEC_{SW} (µg/L)
D3	Ditch	750	1.29	1.01	1.29	1.01
D4	Pond	750	0.154	0.152	0.154	0.152
	Stream	750	1.40	0.113	1.40	0.113
D5	Pond	750	0.202	0.200	0.202	0.200
	Stream	750	1.43	0.084	1.43	0.084
D6	Ditch	750	1.35	1.10	1.35	1.10
R1	Pond	750	0.217	0.215	0.164	0.163
	Stream	750	5.93	2.54	3.05	1.30
R2	Stream	750	4.54	2.19	2.39	1.15
R3	Stream	750	1.62	0.613	1.62	0.613
R4	Stream	750	14.6	11.0	7.75	5.85

Scenario	Water Body	App. Rate (g a.s./ha)	10m buffer (all scenarios), 75% run-off mitigation (R scenarios only)		10m buffer (all scenarios), 90% run-off mitigation (R scenarios only)	
			Max PEC_{SW} (µg/L)	1 day TWA PEC_{SW} (µg/L)	Max PEC_{SW} (µg/L)	1day TWA PEC_{SW} (µg/L)
D3	Ditch	750	0.683	0.533	0.683	0.533
D4	Pond	750	0.114	0.113	0.114	0.113
	Stream	750	0.745	0.076	0.745	0.076
D5	Pond	750	0.162	0.160	0.162	0.160
	Stream	750	0.767	0.054	0.767	0.054
D6	Ditch	750	0.747	0.614	0.747	0.614
R1	Pond	750	0.133	0.132	0.102	0.101
	Stream	750	3.05	1.30	1.24	0.528
R2	Stream	750	2.39	1.15	0.985	0.474
R3	Stream	750	0.859	0.325	0.859	0.325
R4	Stream	750	7.75	5.85	3.22	2.43

Step 4 refined PECsw values for terbuthylazine, using mitigation according to FOCUS modelling with a 5m and 10m spray drift buffer and 50, 75 or 90% runoff mitigation (844 g a.s./ha)

Scenario	Water Body	App. Rate (g a.s./ha)	5m buffer (all scenarios), 50% run-off mitigation (R scenarios only)			5m buffer (all scenarios), 75% run-off mitigation (R scenarios only)		
			Max PEC_{SW} (μg/L)	1 day TWA PEC_{SW} (μg/L)	Actual PEC_{SW} at 1 day (μg/L)	Max PEC_{SW} (μg/L)	1day TWA PEC_{SW} (μg/L)	Actual PEC_{SW} at 1 day (μg/L)
D3	Ditch	844	1.45	1.13	0.695	1.45	1.13	0.695
D4	Pond	844	0.173	0.171	0.170	0.173	0.171	0.170
	Stream	844	1.58	0.127	0.006	1.58	0.127	0.006
D5	Pond	844	0.228	0.226	0.224	0.228	0.226	0.224
	Stream	844	1.61	0.094	0.022	1.61	0.094	0.022
D6	Ditch	844	1.52	1.24	0.829	1.52	1.24	0.829
R1	Pond	844	0.243	0.242	0.240	0.184	0.183	0.182
	Stream	844	6.69	2.87	0.003	3.44	1.47	0.002
R2	Stream	844	5.13	2.48	0.006	2.70	1.30	0.003
R3	Stream	844	1.82	0.690	0.012	1.82	0.690	0.012
R4	Stream	844	16.5	12.5	0.131	8.74	6.60	0.070

Scenario	Water Body	App. Rate (g a.s./ha)	10m buffer (all scenarios), 75% run-off mitigation (R scenarios only)			10m buffer (all scenarios), 90% run-off mitigation (R scenarios only)		
			Max PEC_{SW} (μg/L)	1 day TWA PEC_{SW} (μg/L)	Actual PEC_{SW} at 1 day (μg/L)	Max PEC_{SW} (μg/L)	1day TWA PEC_{SW} (μg/L)	Actual PEC_{SW} at 1 day (μg/L)
D3	Ditch	844	0.769	0.600	0.369	0.769	0.600	0.369
D4	Pond	844	0.128	0.127	0.126	0.128	0.127	0.126
	Stream	844	0.839	0.085	0.006	0.839	0.085	0.006
D5	Pond	844	0.183	0.181	0.180	0.183	0.181	0.180
	Stream	844	0.863	0.060	0.022	0.863	0.060	0.022
D6	Ditch	844	0.843	0.692	0.474	0.843	0.692	0.474
R1	Pond	844	0.149	0.148	0.147	0.115	0.113	0.112
	Stream	844	3.44	1.47	0.002	1.404	0.596	< 0.001
R2	Stream	844	2.70	1.30	0.003	1.11	0.536	0.001
R3	Stream	844	0.966	0.366	0.006	0.966	0.366	0.006
R4	Stream	844	8.74	6.60	0.070	3.63	2.74	0.030

Desethyl-terbuthylazine Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: FOCUS STEPS 1-2 Vers. 1.1 Molecular weight: 201.7 Water solubility (mg/L): 327.1 Kfoc (L/kg): 78 DT_{50} soil (d): 29.6 days (geometric mean of field data; SFO. Note the actual geometric mean that should have been used is 26.9 d) DT_{50} water/sediment system (d): 1000 days (assumed worst-case value in the absence of sediment/ water studies) DT_{50} water (d): 1000 days (assumed worst-case value in the absence of sediment/ water studies) DT_{50} sediment (d): 1000 days (assumed worst-case value in the absence of sediment/ water studies) Maximum occurrence observed in soil: 54 % (note this is the formation fraction selected by the Applicants which was conservatively used to represent peak occurrence in the exposure assessment. Note the actual arithmetic mean formation fraction is 0.45) Maximum occurrence observed in sediment/ water studies: 7.3 %
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 0 Pa at 25 ^{o}C Kfoc (L/kg): 78 1/n: 0.895 Formation fraction in soil (k_{dp}/k_f): 0.54
Application rate	Crop: maize Number of applications: 1 Interval (d): N/A Application rate(s): 750 g as/ha Northern Europe 844 g as/ha Southern Europe Application window: March – May window at Step 2; application set by PAT at Step 3 with 30 d window set to start 2 weeks prior to emergence as shown for parent above
Main routes of entry	Drainage for this major soil metabolite

Hydroxy-terbuthylazine Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: FOCUS STEPS 1-2 Vers. 1.1 Molecular weight: 211.3 Water solubility (mg/L): 7.19 Kfoc (L/kg): 187.1 DT_{50} soil (d): 453 days (geometric mean of lab data; SFO) DT_{50} water/sediment system (d): 1000 days (assumed worst-case value in the absence of sediment/ water studies) DT_{50} water (d): 1000 days (assumed worst-case value in the absence of sediment/ water studies) DT_{50} sediment (d): 1000 days (assumed worst-case value in the absence of sediment/ water studies) Maximum occurrence observed in soil: 34.5 % Maximum occurrence observed in sediment/ water studies: 20.0 %
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 0 Pa at 25 ^{o}C Kfoc (L/kg): 187.1 1/n: 0.91 Formation fraction in soil (k_{dp}/k_f): 0.207
Application rate	Crop: maize Number of applications: 1 Interval (d): N/A Application rate(s): 750 g as/ha Northern Europe 844 g as/ha Southern Europe Application window: March – May window at Step 2
Main routes of entry	Drainflow/runoff at Step 1 and 2

Desethyl hydroxy-terbuthylazine Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: FOCUS STEPS 1-2 Vers. 1.1 Molecular weight: 183.2 Water solubility (mg/L): 18 (at 25C) Kfoc (L/kg): 121 DT_{50} soil (d): 107 days (geometric mean of lab data used as a conservative input parameter; SFO) DT_{50} water/sediment system (d): 1000 days (assumed worst-case value in the absence of sediment/ water studies) DT_{50} water (d): 1000 days (assumed worst-case value in the absence of sediment/ water studies) DT_{50} sediment (d): 1000 days (assumed worst-case value in the absence of sediment/ water studies) Maximum occurrence observed in soil: 28 % (NB: since the desethyl hydroxy metabolite was formed from the desethyl metabolite rather than direct from parent terbuthylazine, a revised application rate was calculated using the formation fraction of desethyl terbuthylazine corrected for molecular weight differences and the crop scenario at Step 1/2 was changed to give zero spray drift loading. For the terbuthyalzine rates of 750 and 844 g a.s./ha the amended application rates were 355.6 and 400.2 g/ha for the desethyl hydroxy 'parent' Step 1 and 2 calculations Maximum occurrence observed in sediment/ water studies: N/A (soil metabolite only)
Parameters used in FOCUSsw step 3 (if performed)	Not required
Application rate	Crop: maize Number of applications: 1 Interval (d): N/A Application rate(s): 750 g as/ha Northern Europe 844 g as/ha Southern Europe Application window: March – May window at Step 2
Main routes of entry	Drainflow/runoff at Step 1 and 2

Terbutryn (MT26) Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: FOCUS STEPS 1-2 Vers. 1.1 Molecular weight: 241.4 Water solubility (mg/L): 8.5 at 20 ^oC Kfoc (L/kg): 518 DT_{50} soil (d): 0.1 days (surrogate value for non-soil metabolite) DT_{50} water/sediment system (d): 190 days (geometric mean whole system values for two sediment/ water studies) DT_{50} water (d): 1000 days (assumed worst-case value in the absence of true water degradation rate) DT_{50} sediment (d): 190 days (geometric mean whole system values for two sediment/ water studies used as a surrogate for sediment degradation rate) Maximum occurrence observed in soil: 0.001 % (not observed in soil degradation studies a nominal low value input as a value > 0 % has to be input for the model to run. Maximum occurrence observed in sediment/ water studies: 7.4 %
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 0 Pa at 25 ^oC Kfoc (L/kg): 518 1/n: 1.0 Formation fraction in soil (k_{dp}/k_f): not a major soil metabolite. Concentrations of terbutryn arising from residues of terbuthylazine in surface water were estimated by factoring the drift of terbuthylazine at application by the percentage formation of terbutryn in water (7.4%) and by its molecular weight
Parameters used in FOCUSsw step 4 (if performed)	Not required
Application rate	Crop: maize Number of applications: 1 Interval (d): N/A Application rate(s): 750 g as/ha Northern Europe 844 g as/ha Southern Europe Application window: March – May window at Step 2; application set by PAT at Step 3 with 30 d window set to start 2 weeks prior to emergence as shown for parent above

Step 1 and Step 2 Maximum PECsw and PECsed for desethyl-terbuthylazine, hydroxy-terbuthylazine (MT13), desethyl-hydroxy-terbuthylazine (MT14) and terbutryn (MT26) following applications to maize at 750 g a.s./ha

Compound	Step	Region	Maximum Calculated PEC			
			Water (µg/L)	On Day	Sediment (µg/kg)	On Day
2-Hydroxy-terbuthylzine (GS23158)	1	-	64.8	0	120.6	1
	2	North	13.7	4	25.5	5
		South	26.3	4	49.1	5
Desethyl-terbuthylazine (GS26379)	1	-	108	0	84.0	1
	2	North	20.0	4	15.6	5
		South	39.5	4	30.8	5
Desethyl-hydroxy – terbuthylazine (GS28620)	1	-	26.0	0	31.4	0
	2	North	5.06	4	6.12	4
		South	10.1	4	12.2	4
Terbutryn (GS14260)	1	-	0.54	0	1.65	1
	2	North	0.54	0	1.63	5
		South	0.54	0	1.63	5

Step 1 and Step 2 Maximum PECsw and PECsed for desethyl-terbuthylazine, hydroxy-terbuthylazine (MT13), desethyl-hydroxy-terbuthylazine (MT14) and terbutryn (MT26) following applications to maize at 844 g a.s./ha

Compound	Step	Region	Maximum Calculated PEC			
			Water (µg/L)	On Day	Sediment (µg/kg)	On Day
2-Hydroxy-terbuthylzine (MT13; GS23158)	1	-	72.9	0	136	1
	2	North	15.4	4	28.7	5
		South	29.6	4	55.3	5
Desethyl-terbuthylazine (GS26379)	1	-	121	0	94.5	1
	2	North	22.5	4	17.5	5
		South	44.5	4	34.7	5
Desethyl-hydroxy – terbuthylazine (GS28620)	1	-	29.2	0	35.4	0
	2	North	5.69	4	6.89	4
		South	11.4	4	13.8	4
Terbutryn (GS14620)	1	-	0.61	0	1.85	1
	2	North	0.60	0	1.83	5
		South	0.60	0	1.83	5

Step 3 maximum PECsw and PECsed for desethyl-terbuthylazine following applications to maize at 750 g a.s./ha

Scenario	Water Body	App. Rate (g as/ha)	PEC_{SW} (µg/ L)			Max PEC_{SED} (µg/kg)
			Max	21d TWA	28d TWA	
D3	Ditch	750	0.004	0.004	0.004	0.031
D4	Pond	750	0.572	0.559	0.551	**1.73**
	Stream	750	0.618	0.361	0.313	0.584
D5	Pond	750	0.321	0.319	0.318	1.42
	Stream	750	0.186	0.145	0.145	0.409
D6	Ditch	750	0.229	0.113	0.101	0.396
R1	Pond	750	0.032	0.030	0.030	0.091
	Stream	750	1.13	0.045	0.035	0.193
R2	Stream	750	1.63	0.077	0.058	0.328
R3	Stream	750	0.551	0.023	0.017	0.085
R4	Stream	750	**2.31**	0.121	0.099	0.519

Step 3 maximum PECsw and PECsed for desethyl-terbuthylazine following applications to maize at 844 g a.s./ha

Scenario	Water Body	App. Rate (g as/ha)	PEC_{SW} (µg/ L)			Max PEC_{SED} (µg/kg)
			Max	21d TWA	28d TWA	
D3	Ditch	844	0.005	0.005	0.005	0.036
D4	Pond	844	0.651	0.636	0.627	**1.96**
	Stream	844	0.701	0.410	0.356	0.662
D5	Pond	844	0.365	0.363	0.362	1.60
	Stream	844	0.211	0.165	0.164	0.462
D6	Ditch	844	0.261	0.129	0.115	0.449
R1	Pond	844	0.035	0.033	0.033	0.101
	Stream	844	1.28	0.050	0.039	0.216
R2	Stream	844	1.85	0.087	0.066	0.367
R3	Stream	844	0.615	0.026	0.019	0.094
R4	Stream	844	**2.60**	0.137	0.112	0.582

Step 3 maximum PECsw and PECsed for hydroxyl-terbuthylazine following applications to maize at 750 g a.s./ha

Scenario	Water Body	App. Rate (g as/ha)	PEC_{SW} (µg/ L)			Max PEC_{SED} (µg/kg)
			Max	21d TWA	28d TWA	
D3	Ditch	750	0.707	0.701	0.699	5.278
D4	Pond	750	**3.589**	3.530	3.493	**16.839**
	Stream	750	2.674	2.076	1.958	6.006
D5	Pond	750	2.339	2.287	2.263	12.40
	Stream	750	1.352	0.833	0.745	3.118
D6	Ditch	750	1.718	0.950	0.873	5.298
R1	Pond	750	0.0224	0.0203	0.0200	0.077
	Stream	750	0.367	0.0209	0.0175	0.109
R2	Stream	750	0.408	0.0216	0.0219	0.183
R3	Stream	750	0.353	0.0210	0.0158	0.100
R4	Stream	750	0.757	0.0451	0.0403	0.255

Step 3 maximum PECsw and PECsed for hydroxy-terbuthylazine following applications to maize at 844 g a.s./ha

Scenario	Water Body	App. Rate (g as/ha)	PEC_{SW} (µg/ L)			Max PEC_{SED} (µg/kg)
			Max	21d TWA	28d TWA	
D3	Ditch	844	0.825	0.819	0.817	6.131
D4	Pond	844	**4.084**	7.017	3.976	**19.073**
	Stream	844	3.025	2.355	2.222	6.815
D5	Pond	844	2.660	2.602	2.574	14.039
	Stream	844	1.533	0.948	0.848	3.536
D6	Ditch	844	1.940	1.082	0.997	5.991
R1	Pond	844	0.0250	0.0227	0.0223	0.0853
	Stream	844	0.410	0.0235	0.0195	0.122
R2	Stream	844	0.463	0.0245	0.0247	0.205
R3	Stream	844	0.392	0.0233	0.0175	0.111
R4	Stream	844	0.856	0.0509	0.0453	0.286

Step 3 maximum PECsw and PECsed for terbutryn following applications to maize at 750 g a.s./ha

Scenario	Water Body	App. Rate (g as/ha)	PEC_{SW} (µg/L)			Max PEC_{SED} (µg/kg)
			Max	21d TWA	28d TWA	
D3	Ditch	750	0.015	0.001	0.001	**0.007**
D4	Pond	750	0.001	0.001	0.001	0.004
	Stream	750	0.011	< 0.001	< 0.001	<0.001
D5	Pond	750	0.002	0.002	0.002	**0.007**
	Stream	750	0.011	< 0.001	< 0.001	<0.001
D6	Ditch	750	0.013	0.001	0.001	0.007
R1	Pond	750	0.002	0.002	0.002	0.007
	Stream	750	0.015	< 0.001	< 0.001	0.001
R2	Stream	750	0.017	< 0.001	< 0.001	0.001
R3	Stream	750	0.006	< 0.001	< 0.001	0.001
R4	Stream	750	**0.033**	< 0.001	< 0.001	0.001

Step 3 maximum PECsw and PECsed for terbutryn following applications to maize at 844 g a.s./ha

Scenario	Water Body	App. Rate (g as/ha)	PEC_{SW} (µg/ L)			Max PEC_{SED} (µg/kg)
			Max	21d TWA	28d TWA	
D3	Ditch	844	0.017	0.001	0.001	**0.008**
D4	Pond	844	0.001	0.001	0.001	0.005
	Stream	844	0.012	< 0.001	< 0.001	0.001
D5	Pond	844	0.002	0.002	0.002	**0.008**
	Stream	844	0.012	< 0.001	< 0.001	0.000
D6	Ditch	844	0.014	0.001	0.001	0.008
R1	Pond	844	0.003	0.002	0.002	0.007
	Stream	844	0.017	< 0.001	< 0.001	0.001
R2	Stream	844	0.019	< 0.001	< 0.001	0.001
R3	Stream	844	0.007	< 0.001	< 0.001	0.001
R4	Stream	844	**0.037**	< 0.001	< 0.001	0.001

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)

For FOCUS gw modelling, values used –

Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.

Model(s) used: PEARL 3.3.3 and PELMO 3.3.2

Scenarios (list of names): Châteaudun (C), Hamburg (H), Kremsmünster (K), Okehampton (N), Piacenza (P), Porto (O), Sevilla (S), Thiva (T)

Q10 = 2.2

Crop: maize

Terbuthylazine:

DT_{50}: 19.4 d (normalised median of field studies).
K_{FOC}: worst case assessment using lowest Kfoc value of 151 L/kg and associated $^{1}/_{n}$ of 0.93 plus scenario specific Kfoc values to reflect possible pH dependence:-

Scenario	**Top soil pH (KCl)**	**Kfoc (l/kg)**	**Kom (l/kg)**	1/n
Chateaudun	7.3	184.9	107.3	0.93
Hamburg	5.7	277.7	161.1	
Kremsmunster	7.0	202.3	117.3	
Okehampton	5.1	312.5	181.3	
Piacenza	6.3	242.9	140.9	
Porto	4.2	364.7	211.5	
Sevilla	6.6	225.5	130.8	
Thiva	7.0	202.3	117.3	

(based on the linear regression equation y = -58.012x +608.37, r^2 = 0.5456 from a plot of Kfoc versus pH)

Metabolites:

Desethyl-terbuthylazine:
DT_{50}: 29.6 d (geomean of field studies).
K_{FOC}: 78.0 L/kg, $^{1}/_{n}$= 0.895 (mean values).

Formation fraction: 0.54 (note this is the formation fraction selected by the Applicants which was conservatively used to represent peak occurrence in the exposure assessment. Note the actual arithmetic mean formation fraction is 0.45)

Hydroxy-terbuthylazine:
DT_{50}: 305 d (Applicant) and 453 d (RMS) (geomean of lab studies)
K_{FOC}: 187.1 L/kg, $^{1}/_{n}$= 0.91 (mean values).
Formation fraction: 0.19 (Applicant) and 0.207 (RMS)

Desethylhydroxy-terbuthylazine:
DT_{50}: 107 d (geomean of lab studies).
K_{FOC}: 121 L/kg, $^{1}/_{n}$= 0.92 (median values, Applicant) or

	111 L/kg, $^1/_n$= 0.92 (median values excluding results from the Bosket loam soil, RMS) Formation fraction: 0.28 (from desethyl-terbuthylazine)
Application rate	Application rate: 750 g/ha Northern Europe 844 g/ha Southern Europe No. of applications: 1 Time of application (month or season): 1 day before crop emergence

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

FOCUS-PEARL PEC_{GW} values for Terbuthylazine and three metabolites, following application to Maize at 750 g/ha (Applicant simulations)

Scenario	PEC_{GW} at 1 m Soil Depth (µg/L)			
	Terbuthylazine	2-Hydroxy-terbuthylazine (GS23158)	Desethyl-terbuthylazine (GS26379)	Desethyl-hydroxy-terbuthylazine (GS28620)
Châteaudun	<0.001	5.58	0.176	1.88
Hamburg	<0.001	6.16	0.255	2.15
Kremsmünster	<0.001	4.86	0.222	1.72
Okehampton	<0.001	5.57	0.287	2.06
Piacenza	0.001	6.36	1.11	2.88
Porto	<0.001	0.589	<0.001	0.074
Sevilla	<0.001	2.44	0.013	0.504
Thiva	<0.001	5.04	0.164	1.65

FOCUS-PELMO PEC_{GW} values for Terbuthylazine and three metabolites following application to Maize at 750 g/ha (Applicant simulations)

Scenario	PEC_{GW} at 1 m Soil Depth (µg/L)			
	Terbuthylazine	2-Hydroxy-terbuthylazine (GS23158)	Desethyl-terbuthylazine (GS26379)	Desethyl-hydroxy-terbuthylazine (GS28620)
Châteaudun	<0.001	3.19	0.002	0.528
Hamburg	<0.001	5.27	0.063	1.40
Kremsmünster	<0.001	3.42	0.004	0.669
Okehampton	<0.001	3.99	0.014	0.90
Piacenza	<0.001	6.12	0.534	2.57
Porto	<0.001	0.086	<0.001	0.002
Sevilla	<0.001	<0.001	<0.001	<0.001
Thiva	<0.001	0.652	<0.001	0.031

FOCUS-PEARL PEC_{GW} values for Terbuthylazine and three metabolites following application to Maize at 844 g/ha (Applicant simulations)

Scenario	PEC_{GW} at 1 m Soil Depth (µg/L)			
	Terbuthylazine	**2-Hydroxy-terbuthylazine (GS23158)**	**Desethyl-terbuthylazine (GS26379)**	**Desethyl-hydroxy-terbuthylazine (GS28620)**
Châteaudun	<0.001	6.38	0.211	2.16
Hamburg	<0.001	7.01	0.298	2.48
Kremsmünster	<0.001	5.56	0.262	1.98
Okehampton	<0.001	6.36	0.341	2.36
Piacenza	0.001	7.21	1.27	3.28
Porto	<0.001	0.685	<0.001	0.089
Sevilla	<0.001	2.81	0.016	0.582
Thiva	<0.001	5.74	0.197	1.89

FOCUS-PELMO PEC_{GW} values for Terbuthylazine and three metabolites following application to Maize at 844 g/ha (Applicant simulations)

Scenario	PEC_{GW} at 1 m Soil Depth (µg/L)			
	Terbuthylazine	**2-Hydroxy-terbuthylazine (GS23158)**	**Desethyl-terbuthylazine (GS26379)**	**Desethyl-hydroxy-terbuthylazine (GS28620)**
Châteaudun	<0.001	3.67	0.002	0.619
Hamburg	<0.001	6.02	0.075	1.62
Kremsmünster	<0.001	3.94	0.005	0.775
Okehampton	<0.001	4.57	0.017	1.05
Piacenza	<0.001	6.98	0.622	2.93
Porto	<0.001	0.104	<0.001	0.003
Sevilla	<0.001	<0.001	<0.001	<0.001
Thiva	<0.001	0.785	<0.001	0.038

FOCUS-PEARL PEC_{GW} values for Terbuthylazine (using minimum measured Kfoc = 151 ml/g; Kfom = 87.6 ml/g) and three metabolites, following application to Maize at 750 g/ha (RMS simulations)

Scenario	PEC_{GW} at 1 m Soil Depth (µg/l)			
	Terbuthylazine	2-Hydroxy-terbuthylazine (GS23158)[1]	Desethyl-terbuthylazine (GS26379)	Desethyl-hydroxy-terbuthylazine (GS28620)[2]
Châteaudun	<0.001	9.915	0.200	2.203
Hamburg	0.002	11.27	0.308	2.617
Kremsmünster	0.001	8.834	0.252	2.041
Okehampton	0.002	9.567	0.384	2.459
Piacenza	0.030	10.055	1.237	3.174
Porto	<0.001	1.931	<0.001	0.110
Sevilla	<0.001	5.469	0.017	0.622
Thiva	<0.001	8.590	0.193	1.898

[1]: 2-hydroxy terbuthylazine DT_{50} = 453 d, formation fraction = 0.207
[2]: desethyl-hydroxy-terbuthylazine K_{foc} = 111 ml/g; K_{fom} = 64.4 ml/g (median of 11 values)

FOCUS-PEARL PEC_{GW} values for Terbuthylazine (using minimum measured Kfoc = 151 ml/g; Kfom = 87.6 ml/g) and three metabolites, following application to Maize at 844 g/ha (RMS simulations)

Scenario	PEC_{GW} at 1 m Soil Depth (µg/l)			
	Terbuthylazine	2-Hydroxy-terbuthylazine (GS23158)[1]	Desethyl-terbuthylazine (GS26379)	Desethyl-hydroxy-terbuthylazine (GS28620)[2]
Châteaudun	<0.001	11.27	0.239	2.530
Hamburg	0.002	12.83	0.367	3.009
Kremsmünster	0.001	10.06	0.297	2.345
Okehampton	0.002	10.87	0.456	2.810
Piacenza	0.035	11.40	1.429	3.627
Porto	<0.001	2.224	<0.001	0.129
Sevilla	<0.001	6.250	0.020	0.716
Thiva	<0.001	9.756	0.231	2.173

[1]: 2-hydroxy terbuthylazine DT_{50} = 453 d, formation fraction = 0.207
[2]: desethyl-hydroxy-terbuthylazine K_{foc} = 111 ml/g; Kfom = 64.4 ml/g (median of 11 values)

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	Not studied - no data requested
Photochemical oxidative degradation in air ‡	DT_{50} of 13.55 hours derived by the Atkinson model. OH (12 h) concentration assumed = 1.5 x 10^6 cm^{-3}.
Volatilisation ‡	from plant surfaces (BBA guideline): ≤ 10.2 % after 24 hours
	from soil surfaces (BBA guideline): ≤ 13.8 % after 24 hours
Metabolites	None

PEC (air)

Method of calculation	There is currently no guidance on determining the predicted environmental concentrations of pesticides in air.

$PEC_{(a)}$

Maximum concentration	N/A

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered.	Soil: terbuthylazine, desethyl-terbuthylazine, hydroxy-terbuthylazine Surface Water: terbuthylazine, desethyl-terbuthylazine, hydroxy-terbuthylazine (MT13), desethyl-hydroxy terbuthylazine and terbutryn (MT26) Sediment: terbuthylazine, desethyl-terbuthylazine, hydroxy-terbuthylazine (MT13), desethyl-hydroxy terbuthylazine and terbutryn (MT26) Groundwater: terbuthylazine, desethyl-terbuthylazine, hydroxy-terbuthylazine (MT13) and desethyl-hydroxy-terbuthylazine, LM1, LM2, LM3, LM4, LM5 and LM6 Air: terbuthylazine

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

Soil (indicate location and type of study)	
Surface water (indicate location and type of study)	a) Two sites in Germany susceptible to run-off and adjacent to streams in typical maize growing areas were

	selected. Upstream and downstream points of streams were monitored for terbuthylazine and desethyl-terbuthylazine (MT1) from May to August in 1999 and 2000 following terbuthylazine application to maize in adjacent field. Samples were taken every hour and combined into weekly samples. Samples also taken after heavy rainfall events. Neither analyte detected at 'Ramholz' site at concentrations > 0.05 µg/L (LOQ). Max weekly concentrations at the 'Kemading' site were 0.28 and 0.08 µg/L for terbuthylazine and desethyl-terbuthylazine (MT1) respectively. Max concentrations in event samples were 0.87 µg/L and 0.20 µg/L. Concentrations similar at upstream and downstream sample sites indicate residues arose from applications in upstream catchment. b) Two sites in Germany adjacent to brooks were selected each with 10 m vegetated filter strip. Formulations were applied to maize between growth stages BBCH 13 and 16 in 1999 and 2000, and brook surface water samples at the upstream and downstream field edges were taken from one week before application (early May) until early September. Streams were sampled hourly and combined into weekly samples. Samples were also taken after heavy rainfall events. At the 'Adenstadt' site neither terbuthylazine nor desethyl-terbuthylazine (MT1) were observed at concentrations > LOQ (0.05 µg/L). Only once, in the first week following application was terbuthylazine detected at the 'Süplingen' site at a max concentration of 0.07 µg/L in a weekly sample. Desethyl-terbuthylazine (MT1) was not detected above the LOQ.
Ground water (indicate location and type of study)	a) Full sample details not provided. 27103 sample data from Germany for the occurrence of terbuthylazine in groundwater. 328 detections of terbuthylazine were observed with 41 > (0.15% of the total analyses) displaying residues in excess of 0.1 µg/L. The Applicant states that none of these exceedences were due to the correct GAP for approved uses being applied. b) Full sample details not provided. Groundwater samples from more than 1000 intakes from 15 municipalities in counties around Denmark in 1990 – 2001 were analysed for residues of plant protection products and their degradation products. The mean depth to the top of the groundwater sample was 24 - 25 m with a mean intake length of 3.5 m. In addition to the groundwater survey, the report also contained information on the analyses of water samples taken from a group of "other borings" which are not used to extract groundwater for drinking purposes. 1016 intakes were analysed for terbuthylazine (the number of analyses was 4086). There were 17 (1.7 %) intakes with detections of terbuthylazine, however, none of them contained concentrations ≥ 0.1 µg/L. With regard to the group

	"other borings", 1156 and 311 borings were analysed for terbuthylazine and desethyl-terbuthylazine (MT1) respectively with 1492 and 527 individual analyses respectively. Terbuthylazine and desethyl-terbuthylazine (MT1) were found in 18 (1.6 %) and 14 (4.5 %) borings, with 3 (0.3 %) and 4 (1.3 %) of these findings being detected at concentrations ≥ 0.1 µg/L. c) Danish government monitoring programme selected two sites (Jyndevad and Silstrup) in Denmark to assess the leaching potential of pesticides including terbuthylazine. Applications were made to maize in May 2001 at Jyndevad and in May/June 2002 at Silstrup. Soil pore waters and groundwaters were analysed monthly for terbuthylazine and desethyl-terbuthylazine, additionally at Silstrup hydroxy-terbuthylazine, hydroxy-desethyl-terbuthylazine (MT1) and atrazine-desisopropyl-2-hydroxy (MT22) were also monitored for from February 2003. At Jyndevad, terbuthylazine was not detected in either the soil pore water or the groundwater at concentrations > 0.01 µg/L in the two year monitoring period. Desethyl-terbuthylazine (MT1) was detected in pore water at 1 m depth in all but three of the monthly samples between October 2001 (five months after application) and May 2003 at concentrations of 0.020 – 0.056 µg / L, however it was not detected in pore waters at 2 m and was only detected once in any of the downstream groundwater monitoring wells. At Silstrup terbuthylazine residues in well water at 1.5-2.5 m depth ranged from 0.013-0.124 µg/L over the year with one sample containing > 0.1 µg/L. Residues of desethyl-ranged from 0.046-0.143 µg/L over the year with two samples containing > 0.1 µg/L. Residues from deeper screens were always < 0.08 µg/L for both terbuthylazine and desethyl-terbuthylazine. Of the remaining metabolites hydroxy-terbuthylazine (MT13) was not detected in the well water. Hydroxy-desethyl-terbuthylazine (MT1) was only detected once in the well water at a depth of 1.5 – 2.5 m at a concentration of 0.016 µg/L. Atrazine-desisopropyl-2-hydroxy (MT22) was detected three times in the well at 1.5 – 2.5 m depth at concentrations around 0.01 µg/L. It was also detected once at a depth of 3.5 – 4.5 m at a concentration of 0.047 µg/L. d) Targeted groundwater monitoring studies were conducted in Germany in areas of documented use of terbuthylazine containing products. Typical maize regions were investigated i.e. Schleswig-Holstein, Mecklenburg-West Pomerania, Muenster-Emsland (stretching from the federal state North Rhine-Westfalia to Lower Saxony), Rottal (Bavaria) and the Upper Rhine

Valley (stretching from the federal state Baden-Wuerttemberg to Hesse). Groundwater was collected from monitoring screen typically situated 5 m below ground surface. Confirmed usage of terbuthylazine containing products in upstream areas (2.5 x 2.5km or 625 ha) was determined via farmer surveys and interviews over three years (2002 – 2004). Results for each site represent the sum over this period as follows:- Wanderup 277 ha, Alt-Bennebek 497ha, Breiholz-Ost 198 ha, Hagen-Suedost 61 ha, Luettow 57 ha, Torgelow 225 ha, Lelkendorf 72 ha, Warnow 60 ha, Pinnow 288ha, Tabeckendorf 114 ha, Postmuenster 92 ha, Hammersbach 102 ha, Kirchham-Pfaffenhof 336 ha, Simbach-Stoelln 137 ha, Biblis 82 ha, Lorsch 56 ha, Rheinhausen-Oberhausen 198 ha, Breisach-Weingenossenschaft 240 ha, Grezhausen 69 ha, Rehderfeld 154 ha, Flechum 114 ha, Dalumer Moor 174 ha, Bexten 139 ha, Große-Luettke 103 ha, and Veltrup 202 ha. The overall mean hectarage treated was reported to be 120 ha across all sites and only those sites that received at least 50 ha of treatment were included in the final 25 sites monitored. The groundwater table was mostly less than 5 meters below ground surface and a wide range of soil properties was covered by the selected regions. No residues of terbuthylazine and desethyl-terbuthylazine were detected in any of the ground water monitoring samples analysed. Small residues of GS 28620 (MT14) and GS 23158 (MT13) were found in water samples taken from ground water monitoring wells at two locations. The residues of GS 28620 (MT14) occurred in May-July 2003 and ranged from 0.05-0.06 µg/l. The residues of GS 23158 (MT13) were detectable but not quantifiable (i.e. < 0.05 but > 0.02 µg/l). In addition, the lysimeters metabolites LM3, LM5 and LM6 were detected at 19 of the 25 locations, confirming the linkage to terbuthylazine treated areas in the catchment. Residues of the metabolite CSCD648241 (LM6) in 29 samples from 25 individual sampling points were determined to be between < 0.05 µg/l and 0.66 µg/l. Residues of the metabolite GS16984 (MT23, LM5) in 29 samples from 25 individual sampling points, were determined to be between < 0.05 µg/l and 0.98 µg/l. The metabolite CSCD692760 (LM3) was detected at 19 (10 above the LOQ and 9 below the LOQ) of the 25 locations. Quantifiable residues ranged from 0.06-0.69 µg/l. e) In 1997, a monitoring study was carried out in four maize cultivated areas in the plain of the river Po in Italy to evaluate the degree of contamination of the groundwater table. No residues of terbuthylazine were detected above 0.1µg/l in the 1997 study. A follow-up study was conducted in 2006 in the same areas identified in the previous monitoring study. The majority of superficial wells sampled were over 20 m deep, with deep wells often greater than 50m. In these follow-up

	studies 8 out of approximately 100 wells were found to contain residues of terbuthylazine or its metabolites desethyl-terbuthylazine and hydroxy-terbuthylazine above 0.1 µg/l. However the average age of the wells was over 30 years and characterised by degraded materials, rust, holes or cracks etc and as a whole, the 90th percentile terbuthylazine and metabolite residues were all <0.05 µg/l on the basis of this monitoring f) A retrospective monitoring study was conducted in four regions of Portugal from 1999 to 2007. As a retrospective study, only limited details on the history of pesticide use in the upstream areas was available. However throughout the eight year duration of the study, 773 water samples were taken and analysed for terbuthylazine and desethyl-terbuthylazine from 68 different sampling sites, generating a total of 1546 data points. Sampling sites covered a relatively wide variety of sales history, cropping density, depth to groundwater and nitrate concentration (this last parameter used as general indicator for the vulnerability of an aquifer to agricultural practices). Although terbuthylazine has not been in widespread use in two of the monitored regions, it has been extensively used in vineyards in the Oeste and the Douro valley at a rate of 490 g/ha (1400 g/ha in row). Neither terbuthylazine nor desethyl-terbuthylazine residues exceeded 0.05 µg/l at the 90th percentile of the population. Overall the RMS considered that the additional data from the Portuguese monitoring programs did provide useful information. However it should be noted that the monitoring is only of partial relevance in the regions where prior use of terbuthylazine is known to be extensive, and also taking into account that the use covers applications to vineyards rather than the extensive use on maize as investigated in the German and Italian studies. Taking these caveats into account, the RMS considers that the data should be viewed as providing supporting information alongside the monitoring data from other regions, as well as taking into account the results of the standard first tier FOCUS groundwater exposure assessments. *g) Retrospective monitoring studies were conducted in 3 regions of Spain covering use of terbuthylazine on olive crops in Andalucia (2000 to 2003), use on maize and citrus crops in South Eastern Spain (2000 to 2001) and use on maize and vineyards in Northern Spain (2000-2001). As retrospective studies, only limited details on the history of pesticide use in the upstream areas was available. In addition in many cases, the relatively large distance between the discharge point and the upland aquifer made it difficult to relate monitored residues back to a specific product use pattern. However throughout each study sampling sites were selected using local knowledge of cropping density, regional product sales data, hydrogeological information and information*

	pertaining to the integrity of the respective sampling sites. In three regions the 90th percentile concentration was less than 0.1 µg/l for both terbuthylazine and metabolite desethyl-terbuthyalzine (the only metabolite monitored for). However it should be noted that methods of analysis were unvalidated and the LOQ was only reported to be 0.1µg/l in the studies conducted in South Eastern Spain. In Andalucia, following extensive use of terbuthylazine on olive crops, the 90th percentile concentration of terbuthylazine was 0.14 µg/l. However the majority of detections in this region came from springs discharging groundwater into lagoons, troughs or drainage canals that were not protected from direct contamination. Overall the RMS considered that the additional data from the Spanish monitoring programs did provide limited useful information. However it should be noted that the monitoring is only of partial relevance in the regions where prior use of terbuthylazine is known to be extensive, and also taking into account that the monitoring covers areas where terbuthylazine may be applied to olive crops, citrus and vineyards in addition to use on maize in two of the three regions investigated. In addition, the sampling of groundwater from springs discharging to surface water bodies meant that the influence of direct contamination (rather than conventional leaching) could not be excluded. Taking these caveats into account, the RMS considers that the data should be viewed as providing limited supporting information only alongside the monitoring data from other regions, as well as taking into account the results of the standard first tier FOCUS groundwater exposure assessments.
Air (indicate location and type of study)	None

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

Candidate for R53

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

Species	Test substance	Time scale	End point
Birds ‡			
Bobwhite quail	a.s.	Acute	LD_{50} = 1236 mg a.s./kg bw OXON
Bobwhite quail	Preparation - 'Terbuthylazine 500 g/L SC'	Acute	LD_{50} > 2000 mg form.n/kg bw (> 909 mg a.s./kg bw) OXON
Mallard duck	a.s.	Short-term	LC_{50} > 395 mg a.s./kg bw/d SYN
Japanese quail	a.s.	Long-term	NOEL = 13.85 mg a.s./kg bw/d SYN & OXON
Mammals ‡			
Rat	a.s.	Acute	LD_{50} = 1000 -1590 mg a.s./kg bw SYN
Rat	Preparation - 'Gardo Gold'	Acute	LD_{50} > 3000 mg form.n/kg bw (> 520 mg tba/kg bw) SYN
Rat	Preparation - 'Terbuthylazine 500 g/L SC'	Acute	LD_{50} > 2000 mg form.n/kg bw (> 909 mg tba/kg bw) OXON
Rat	Metabolite - MT14 (desethyl-hydroxy-terbuthylazine)	Acute	LD_{50} > 2000 mg/kg bw SYN
Rat	Metabolite - MT13 (hydroxy-terbuthylazine)	Acute	LD_{50} > 2000 mg/kg bw SYN
Rat	Metabolite - MT20 (diamino-chlorotriazine)	Acute	LD_{50} > 5500 mg/kg bw SYN
Rat	Metabolite - MT1 (desethyl-terbuthylazine)	Acute	LD_{50} = 236 mg/kg bw SYN
Rat	a.s.	Long-term	NOAEL = 3.3 mg/kg bw/d OXON

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

Indicator species/Category	Time scale	ETE (mg/kg bw/d)	TER	Annex VI Trigger
Tier 1 (Birds)				
1 x 0.75 kg terbuthylazine/ha on maize ('Leafy crops', early/late)				
Medium herbivorous bird	Acute	49.59	24.9	10
	Short-term	22.80	> 17.3	10
	Long-term	12.08	**1.15**	5
Insectivorous bird	Acute	40.56	30.5	10
	Short-term	22.62	> 17.5	10

Indicator species/Category	Time scale	ETE (mg/kg bw/d)	TER	Annex VI Trigger
	Long-term	22.62	**0.612**	5
1 x 0.844 kg terbuthylazine/ha on maize ('Leafy crops', early/late)				
Medium herbivorous bird	Acute	55.81	22.15	10
	Short-term	25.66	> 15.4	10
	Long-term	13.60	**1.02**	5
Insectivorous bird	Acute	45.64	27.1	10
	Short-term	25.46	> 15.5	10
	Long-term	25.46	**0.544**	5
Higher tier refinement (Birds)				
Skylark as indicator species to cover herbivorous and insectivorous birds. Refined PD, residues and dissipation rates. A high risk was indicated for the application rate of 0.844 kg a.s./ha. The TER in the refined risk assessment exceeded the Annex VI trigger for the lower application rate. However a high risk to birds from the representative use of "Gardo Gold" cannot be ruled out for the use with the lower application rate. Uncertainty remains with regard to residue refinement (EFSA suggests using only the data from residue trials in maize where the growth stages were clearly defined, this could result in lower TER values). The toxicity of the second active substance was not considered in the risk assessment. Hence the EU assessment does not cover the risk to birds from the representative use of the formulation "Gardo Gold".				
Tier 1 (Mammals)				
1 x 0.75 kg terbuthylazine/ha on maize ('Leafy crops', early/late)				
Medium herbivorous mammal	Acute	18.27	> 28.46	10
	Long-term	4.45	**0.74**	5
1 x 0.844 kg terbuthylazine/ha on maize ('Leafy crops', early/late)				
Medium herbivorous mammal	Acute	20.56	> 25.29	10
	Long-term	5.01	**0.66**	5
Higher tier refinement (Mammals)				
Medium herbivorous mammal – hare and wood mouse as indicator species, measured residues and dissipation rates and refined PDs No low risk identified – further refinements required				

Indicator species/Category	Time scale	DDD (mg/kg bw/d)	TER	Annex VI Trigger
Risk to earthworm-eating and fish-eating birds & mammals – Tier 1				
1 x 0.844 kg terbuthylazine/ha on maize				
Fish-eating bird	Long-term	0.0107*	1300*	5
Earthworm-eating bird (100 g bw)	Long-term	7.0	**1.98**	5
Fish-eating mammal	Long-term	0.006	549	5

Indicator species/Category	Time scale	DDD (mg/kg bw/d)	TER	Annex VI Trigger
Earthworm-eating mammals – omnivorous wood mouse used as the relevant focal species. No low risks demonstrated for 0.75 or 0.844 kg a.s./ha – further refinements required.				
Risk to earthworm-eating and fish-eating birds & mammals– higher tier				
1 x 0.844 kg terbuthylazine/ha on maize				
Earthworm-eating bird – measured BAF for earthworms	Long-term	1.01	13.7	5

***** the DDD and TER values were calculated for an application rate of 1 kg a.s./ha and hence cover the representative uses suggested in the GAP.

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	a.s.	96 hr (static)	Mortality, $_{nom}LC_{50}$	2.2 mg a.s./L (SYN)
Oncorhynchus mykiss	a.s.	90 d (flow-through)	Early life cycle $_{mm}NOEC$	0.09 mg a.s./L (SYN)
Oncorhynchus mykiss	Preparation: ‘Gardo Gold’ (A-9476 C)	96 hr (static)	Mortality, $_{mm}LC_{50}$	8.32 mg formulation/L (1.58 mg a.s./L) (SYN)
Oncorhynchus mykiss	Preparation: ‘Terbuthylazine 500 g/L SC’	96 hr (static)	Mortality, $_{mm}LC_{50}$	12 mg formulation/L (6.6 mg a.s./L) (OXON)
Oncorhynchus mykiss	Metabolite MT1 (GS 26379, desethyl-terbuthylazine)	96 hr (static)	Mortality, $_{nom}LC_{50}$	18 mg/L (SYN)
Oncorhynchus mykiss	Metabolite MT13 (GS 23158, 2-hyrdoxy-terbuthylazine)	96 hr (static)	Mortality, $_{mm}LC_{50}$	>2.5 mg/L (SYN)
Oncorhynchus mykiss	Metabolite MT26 (GS 14260, terbutryn)	96 hr (static)	Mortality, $_{mm}LC_{50}$	1.1 mg/L (SYN)
Aquatic invertebrate				
Daphnia magna	a.s.	48 h	Mortality, EC_{50}	No definitive endpoint available[2]
Daphnia magna	a.s.	21 d (semi-static)	Reproduction, $_{nom}NOEC$	0.019 mg a.s./L (SYN)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Daphnia magna	Preparation: 'Gardo Gold' (A-9476 C)	48 h (static)	Mortality, EC_{50}	No definitive endpoint available[3]
Daphnia magna	Preparation: 'Terbuthylazine 500 g/L SC'	48 h (static)	Mortality, EC_{50}	No definitive endpoint available[3]
Daphnia magna	Metabolite MT1 (GS 26379, desethyl-terbuthylazine)	48 h (static)	Mortality, $_{nom}EC_{50}$	42 mg/L (SYN)
Daphnia magna	Metabolite MT13 (GS 23158, 2-hyrdoxy-terbuthylazine)	48 h (static)	Mortality, $_{nom}EC_{50}$	>2.8 mg/L (SYN)
Sediment dwelling organisms				
Chironomus riparius	a.s.	27 d (static)	$_{nom}$NOEC (water phase)	0.5 mg a.s./L (SYN)
Chironomus riparius	Metabolite MT13 (GS 23158, 2-hydroxy-terbuthylazine)	28 d (static)	$_{nom}$NOEC (sediment phase)	400 mg/kg (sediment) (SYN)
Chironomus riparius	Metabolite MT26 (GS 14260, terbutryn)	28 d (static)	$_{nom}$NOEC (sediment phase)	16 mg/kg (sediment)
Algae				
Blue green algae (*Microcystis aeruginosa*)	a.s.	72 h (static)	Biomass: $_{mm}E_bC_{50}$	0.016 mg a.s./L (OXON)
			Growth rate: $_{mm}E_rC_{50}$	0.102 mg a.s./L (OXON)
Pseudokirchneriella subcapitata	a.s.	72 h (static)	Biomass: $_{mm}E_bC_{50}$	0.012 mg a.s./L (OXON)
			Growth rate: $_{mm}E_rC_{50}$	0.028 mg a.s./L (OXON)
Desmodesmus subspicatus	Preparation: 'Gardo Gold' (A-9476 C)	72 h (static)	Biomass: $_{nom}E_bC_{50}$	0.108 mg formulation/L (0.0205 mg a.s./L) (SYN)
			Growth rate: $_{nom}E_rC_{50}$	0.211 mg formulation/L (0.0401 mg a.s./L) (SYN)
Pseudokirchneriella subcapitata	Preparation: 'Terbuthylazine 500 g/L SC'	72 h (static)	Biomass: $_{mm}E_bC_{50}$	0.039 mg formulation/L (0.021 mg a.s./L) (OXON)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
			Growth rate: ${}_{mm}E_rC_{50}$	0.073 mg formulation/L (0.040 mg a.s./L) (OXON)
Selenastrum capricornutum	Metabolite MT1 (GS 26379, desethyl-terbuthylazine)	72 h (static)	Biomass: ${}_{mm}E_bC_{50}$	0.14 mg/L (SYN)
			Growth rate: ${}_{mm}E_rC_{50}$	0.38 mg/L (SYN)
Desmodesmus subspicatus	Metabolite MT13 (GS 23158) 2-hydroxy-terbuthylazine)	72 h (static)	Biomass: ${}_{nom}$ E_bC_{50}	>3.96 mg/L (OXON)
Selenastrum capricornutum			Growth rate: ${}_{mm}E_rC_{50}$	>3.8 mg/L (SYN)
Pseudokirchneriella subcapitata	Metabolite MT26(GS 14260) terbutryn)	72 h (static)	Biomass: ${}_{mm}E_bC_{50}$	0.0017 mg/L (SYN)
			Growth rate: ${}_{mm}E_rC_{50}$	${}_{mm}$ 0.0036 mg/L (SYN)
Higher aquatic plants				
Lemna gibba	a.s.	14 d (static)	Frond number: ${}_{nom}$ $E_{fn}C_{50}$	0.0128 mg a.s./L (OXON)
			Growth rate: ${}_{nom}$ E_rC_{50}	0.412 mg a.s./L (OXON)
			Biomass: ${}_{nom}$ E_bC_{50}	0.0133 mg a.s./L (OXON)
Lemna gibba	Metabolite MT26 (GS 14260, terbutryn)	14 d (static)	Frond density: ${}_{mm}$ EC_{50}	0.025
Myriophyllum aquaticum	Metabolite MT26 (GS 14260, terbutryn)	14 d (static)	Root fresh weight: ${}_{nom}$ EC_{50}	2.0 mg/kg (sediment)
Microcosm or mesocosm tests				
Higher tier data are available, but insufficient information is currently available to derive an endpoint.				

[1] nominal (${}_{nom}$) or mean measured concentrations (${}_{mm}$).
$E_{fn}C_{50}$: effect concentration on frond number
In the case of preparations indicate whether end points are presented as units of preparation or a.s.
[2] As discussed in Section B.9.2.4.3.1 of the DAR no definitive acute toxicity endpoint was derived from the submitted aquatic invertebrate studies as neither of the submitted studies used a suitable method to determine the amount of terbuthylazine in solution. However, the studies were considered to be of adequate quality to clearly demonstrate that terbuthylazine is of less toxicity to aquatic invertebrates than other aquatic species and therefore the risk assessment for fish is deemed to cover the aquatic invertebrate risk assessment.
[3] As discussed in Section B.9.2.4.5 of the DAR no definitive toxicity endpoint for aquatic invertebrates was determined for either of the submitted aquatic invertebrate studies. However, as for the a.s. both studies were considered suitable to clearly demonstrate the formulations are of less toxicity to aquatic invertebrates than other aquatic species and therefore the risk assessment for fish is deemed to cover the aquatic invertebrate risk assessment.

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

FOCUS Step1

Crop and rates: maize, 0.75 kg a.s./ha application in Northern Europe, 0.844 kg a.s./ha in Southern Europe.

FOCUS Step 1: Terbuthylazine

Organism	Toxicity (µg/L)	Time scale	PEC_i (µg/L)	TER	Annex VI Trigger
0.75 kg a.s./ha application (Northern Europe)					
Fish	2200	Acute	215	**10.23**	100
Fish	90	Chronic	215	**0.42**	10
Aquatic invertebrates[1]	n/a	Acute	215	n/a	100
Aquatic invertebrates	19	Chronic	215	**0.09**	10
Algae EbC50	12	Chronic	215	**0.06**	10
Algae ErC50	28	Chronic	215	**0.13**	10
Higher plants	12.8	Chronic	215	**0.06**	10
Sediment-dwellers[2]	500	Chronic	215	**2.33**	10
0.844 kg a.s./ha application (Southern Europe)					
Fish	2200	Acute	242	**9.09**	100
Fish	90	Chronic	242	**0.37**	10
Aquatic invertebrates[1]	n/a	Acute	242	n/a	100
Aquatic invertebrates	19	Chronic	242	**0.08**	10
Algae EbC50	12	Chronic	242	**0.05**	10
Algae ErC50	28	Chronic	242	**0.12**	10
Higher plants	12.8	Chronic	242	**0.05**	10
Sediment-dwellers[1]	500	Chronic	242	**2.07**	10

n/a definitive endpoint not available for aquatic invertebrates, see above for details.
TERs highlighted in **bold** are less than the respective Annex VI trigger value
[1] As discussed in Section B.9.2.4.3.1 of the DAR no definitive acute toxicity endpoint was derived from the submitted aquatic invertebrate studies as neither of the submitted studies used a suitable method to determine the amount of terbuthylazine in solution. However, the studies were considered to be of adequate quality to clearly demonstrate that terbuthylazine is of less toxicity to aquatic invertebrates than other aquatic species and therefore the risk assessment for fish is deemed to cover the aquatic invertebrate risk assessment.
[2] spiked water test so PEC_{sw} used

FOCUS Step 1: Metabolite MT1 (desethyl-terbuthylazine)

Organism	Toxicity (µg/L)	Time scale	PEC_i (µg/L)	TER	Annex VI Trigger
0.75 kg a.s./ha application (Northern Europe)					
Fish	18000	Acute	108	166.67	100
Aquatic invertebrates	42000	Acute	108	388.89	100
Algae EbC50	140	Chronic	108	**1.30**	10
Algae ErC50	380	Chronic	108	**3.52**	10
0.844 kg a.s./ha application (Southern Europe)					
Fish	18000	Acute	121	148.76	100
Aquatic invertebrates	42000	Acute	121	347.11	100

Algae EbC50	140	Chronic	121	**1.16**	10
Algae ErC50	380	Chronic	121	**3.14**	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value

FOCUS Step 1: Metabolite MT13 (2-hydroxy-terbuthylazine)

Organism	Toxicity (µg/L)	Time scale	PEC_i (µg/L)	TER	Annex VI Trigger
0.75 kg a.s./ha application (Northern Europe)					
Fish	2500	Acute	64.8	**38.58**	100
Aquatic invertebrates	2800	Acute	64.8	**43.21**	100
Sediment-dwellers	400[1]	Chronic	0.1206[1]	3316.75	10
Algae EbC50	3960	Chronic	64.8	61.11	10
Algae ErC50	3800	Chronic	64.8	58.64	10
0.844 kg a.s./ha application (Southern Europe)					
Fish	2500	Acute	72.9	**34.29**	100
Aquatic invertebrates	2800	Acute	72.9	**38.41**	100
Sediment-dwellers	400[1]	Chronic	0.136[1]	2941.18	10
Algae EbC50	3960	Chronic	72.9	54.32	10
Algae ErC50	3800	Chronic	72.9	52.13	10

[1]spiked sediment test so PEC_{sed} used (mg/kg)
TERs highlighted in **bold** are less than the respective Annex VI trigger value

FOCUS Step 1: Metabolite MT26 (terbutryn)

Organism	Toxicity (µg/L)	Time scale	PEC_i (µg/L)	TER	Annex VI Trigger
0.75 kg a.s./ha application (Northern Europe)					
Fish	1100	Acute	0.54	2037.04	100
Aquatic invertebrates	2660	Acute	0.54	4925.93	100
Sediment-dwellers	16[1]	Chronic	0.00165[1]	9696.97	10
Algae EbC50	1.7	Chronic	0.54	**3.15**	10
Algae ErC50	3.6	Chronic	0.54	**6.67**	10
Higher plants	25	Chronic	0.54	46.30	10
Higher plants	2[1]	Chronic	0.00165[1]	1212.12	10
0.844 kg a.s./ha application (Southern Europe)					
Fish	1100	Acute	0.61	1803.28	100
Aquatic invertebrates	2660	Acute	0.61	4360.66	100
Sediment-dwellers	16[1]	Chronic	0.00185[1]	8648.65	10
Algae EbC50	1.7	Chronic	0.61	**2.79**	10
Algae ErC50	3.6	Chronic	0.61	**5.90**	10
Higher plants	25	Chronic	0.61	40.98	10
Higher plants	2[1]	Chronic	0.00185[1]	1081.08	10

TERs highlighted in bold are less than the respective Annex VI trigger value
[1]spiked sediment test so PEC_{sed} used (mg/kg)

FOCUS Step 2

Crop and rates: pre-emergent application to maize, 0.75 kg a.s./ha application in Northern Europe, 0.844 kg a.s./ha in Southern Europe.

FOCUS Step 2: terbuthylazine

N/S	Organism	Toxicity (µg/L)	Time scale	PEC (µg/L)	TER	Annex VI Trigger
0.75 kg a.s./ha application (Northern Europe)						
S	Fish	2200	Acute	78.2	**28.13**	100
S	Fish	90	Chronic	78.2	**1.15**	10
S	Aquatic invertebrates	19	Chronic	78.2	**0.24**	10
S	Algae EbC50	12	Chronic	78.2	**0.15**	10
S	Algae ErC50	28	Chronic	78.2	**0.36**	10
S	Higher plants	12.8	Chronic	78.2	**0.16**	10
S	Sediment-dwellers[1]	500	Chronic	78.2	**6.39**	10
0.844 kg a.s./ha application (Southern Europe)						
S	Fish	2200	Acute	88	**25**	100
S	Fish	90	Chronic	88	**1.02**	10
S	Aquatic invertebrates	19	Chronic	88	**0.22**	10
S	Algae EbC50	12	Chronic	88	**0.14**	10
S	Algae ErC50	28	Chronic	88	**0.32**	10
S	Higher plants	12.8	Chronic	88	**0.15**	10
S	Sediment-dwellers[1]	500	Chronic	88	**5.68**	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value
[1]spiked water test so PEC_{sw} used

FOCUS Step 2: Metabolite MT1 (desethyl-terbuthylazine)

N/S	Organism	Toxicity (µg/L)	Time scale	PEC$_i$ (µg/L)	TER	Annex VI Trigger
0.75 kg a.s./ha application (Northern Europe)						
S	Algae EbC50	140	Chronic	39.5	**3.54**	10
S	Algae ErC50	380	Chronic	39.5	**9.62**	10
0.844 kg a.s./ha application (Southern Europe)						
S	Algae EbC50	140	Chronic	44.5	**3.15**	10
S	Algae ErC50	380	Chronic	44.5	**8.54**	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value

FOCUS Step 2: Metabolite MT13 (2-hyrdoxy-terbuthylazine)

N/S	Organism	Toxicity (µg/L)	Time scale	PEC$_i$ (µg/L)	TER	Annex VI Trigger
0.75 kg a.s./ha application (Northern Europe)						
S	Fish	2500	Acute	26.3	**95.06**	100
S	Aquatic invertebrates	2800	Acute	26.3	106.46	100
0.844 kg a.s./ha application (Southern Europe)						
S	Fish	2500	Acute	29.6	**84.46**	100
S	Aquatic invertebrates	2800	Acute	29.6	**94.59**	100

TERs highlighted in **bold** are less than the respective Annex VI trigger value

FOCUS Step 2: Metabolite MT26 (terbutryn)

N/S	Organism	Toxicity (µg/L)	Time scale	PEC$_i$ (µg/L)	TER	Annex VI Trigger
0.75 kg a.s./ha application (Northern Europe)						
S	Algae EbC50	1.7	Chronic	0.54	**3.15**	10
S	Algae ErC50	3.6	Chronic	0.54	**6.67**	10
0.844 kg a.s./ha application (Southern Europe)						
S	Algae EbC50	1.7	Chronic	0.6	**2.83**	10
S	Algae ErC50	3.6	Chronic	0.6	**6.00**	10

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Crop and rates: pre-emergent application to maize, 0.75 kg a.s./ha application in Northern Europe, 0.844 kg a.s./ha in Southern Europe.

Each group of organisms will be presented separately.

Terbuthylazine

FOCUS Step 3: Acute risk to fish (and aquatic invertebrates) (terbuthylazine)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application in Northern Member States								
terbuthylazine	D3	Ditch	fish	acute	2200	3.93	559.80	100
terbuthylazine	D4	Pond	fish	acute	2200	0.171	12865.50	100
terbuthylazine	D4	Stream	fish	acute	2200	3.32	662.65	100
terbuthylazine	D5	Pond	fish	acute	2200	0.218	10091.74	100
terbuthylazine	D5	Stream	fish	acute	2200	3.37	652.82	100
terbuthylazine	D6	Ditch	fish	acute	2200	3.99	551.38	100
terbuthylazine	R1	Pond	fish	acute	2200	0.335	6567.16	100
terbuthylazine	R1	Stream	fish	acute	2200	11.3	194.69	100
terbuthylazine	R2	Stream	fish	acute	2200	8.26	266.34	100
terbuthylazine	R3	Stream	fish	acute	2200	3.85	571.43	100
terbuthylazine	R4	Stream	fish	acute	2200	26.3	**83.65**	100
0.844 kg a.s./ha application in Southern Member States								
terbuthylazine	D3	Ditch	fish	acute	2200	4.42	497.74	100
terbuthylazine	D4	Pond	fish	acute	2200	0.192	11458.33	100
terbuthylazine	D4	Stream	fish	acute	2200	3.74	588.24	100
terbuthylazine	D5	Pond	fish	acute	2200	0.247	8906.88	100
terbuthylazine	D5	Stream	fish	acute	2200	3.79	580.47	100
terbuthylazine	D6	Ditch	fish	acute	2200	4.5	488.89	100
terbuthylazine	R1	Pond	fish	acute	2200	0.376	5851.06	100
terbuthylazine	R1	Stream	fish	acute	2200	12.7	173.23	100
terbuthylazine	R2	Stream	fish	acute	2200	9.34	235.55	100
terbuthylazine	R3	Stream	fish	acute	2200	4.33	508.08	100
terbuthylazine	R4	Stream	fish	acute	2200	29.7	**74.07**	100

TERs highlighted in **bold** are less than the respective Annex VI trigger value

FOCUS Step 3: Chronic risk to fish (terbuthylazine)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application in Northern Member States								
terbuthylazine	D3	Ditch	fish	chronic	90	3.93	22.90	10
terbuthylazine	D4	Pond	fish	chronic	90	0.171	526.32	10
terbuthylazine	D4	Stream	fish	chronic	90	3.32	27.11	10
terbuthylazine	D5	Pond	fish	chronic	90	0.218	412.84	10
terbuthylazine	D5	Stream	fish	chronic	90	3.37	26.71	10
terbuthylazine	D6	Ditch	fish	chronic	90	3.99	22.56	10
terbuthylazine	R1	Pond	fish	chronic	90	0.335	268.66	10
terbuthylazine	R1	Stream	fish	chronic	90	11.3	**7.96**	10
terbuthylazine	R2	Stream	fish	chronic	90	8.26	10.90	10
terbuthylazine	R3	Stream	fish	chronic	90	3.85	23.38	10
terbuthylazine	R4	Stream	fish	chronic	90	26.3	**3.42**	10
0.844 kg a.s./ha application in Southern Member States								
terbuthylazine	D3	Ditch	fish	chronic	90	4.42	20.36	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	PEC (µg/L)	TER	Annex VI trigger
terbuthylazine	D4	Pond	fish	chronic	90	0.192	468.75	10
terbuthylazine	D4	Stream	fish	chronic	90	3.74	24.06	10
terbuthylazine	D5	Pond	fish	chronic	90	0.247	364.37	10
terbuthylazine	D5	Stream	fish	chronic	90	3.79	23.75	10
terbuthylazine	D6	Ditch	fish	chronic	90	4.5	20.00	10
terbuthylazine	R1	Pond	fish	chronic	90	0.376	239.36	10
terbuthylazine	R1	Stream	fish	chronic	90	12.7	**7.09**	10
terbuthylazine	R2	Stream	fish	chronic	90	9.34	**9.64**	10
terbuthylazine	R3	Stream	fish	chronic	90	4.33	20.79	10
terbuthylazine	R4	Stream	fish	chronic	90	29.7	**3.03**	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value

FOCUS Step 3: Chronic risk to aquatic invertebrates (terbuthylazine)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application in Northern Member States								
terbuthylazine	D3	Ditch	aq invert	chronic	19	3.93	**4.83**	10
terbuthylazine	D4	Pond	aq invert	chronic	19	0.171	111.11	10
terbuthylazine	D4	Stream	aq invert	chronic	19	3.32	**5.72**	10
terbuthylazine	D5	Pond	aq invert	chronic	19	0.218	87.16	10
terbuthylazine	D5	Stream	aq invert	chronic	19	3.37	**5.64**	10
terbuthylazine	D6	Ditch	aq invert	chronic	19	3.99	**4.76**	10
terbuthylazine	R1	Pond	aq invert	chronic	19	0.335	56.72	10
terbuthylazine	R1	Stream	aq invert	chronic	19	11.3	**1.68**	10
terbuthylazine	R2	Stream	aq invert	chronic	19	8.26	**2.30**	10
terbuthylazine	R3	Stream	aq invert	chronic	19	3.85	**4.94**	10
terbuthylazine	R4	Stream	aq invert	chronic	19	26.3	**0.72**	10
0.844 kg a.s./ha application in Southern Member States								
terbuthylazine	D3	Ditch	aq invert	chronic	19	4.42	**4.30**	10
terbuthylazine	D4	Pond	aq invert	chronic	19	0.192	98.96	10
terbuthylazine	D4	Stream	aq invert	chronic	19	3.74	**5.08**	10
terbuthylazine	D5	Pond	aq invert	chronic	19	0.247	76.92	10
terbuthylazine	D5	Stream	aq invert	chronic	19	3.79	**5.01**	10
terbuthylazine	D6	Ditch	aq invert	chronic	19	4.5	**4.22**	10
terbuthylazine	R1	Pond	aq invert	chronic	19	0.376	50.53	10
terbuthylazine	R1	Stream	aq invert	chronic	19	12.7	**1.50**	10
terbuthylazine	R2	Stream	aq invert	chronic	19	9.34	**2.03**	10
terbuthylazine	R3	Stream	aq invert	chronic	19	4.33	**4.39**	10
terbuthylazine	R4	Stream	aq invert	chronic	19	29.7	**0.64**	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value

FOCUS Step 3: Risk to algae (terbuthylazine)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application in Northern Member States								
terbuthylazine	D3	Ditch	algae	chronic	12	3.93	**3.05**	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	PEC (µg/L)	TER	Annex VI trigger
terbuthylazine	D4	Pond	algae	chronic	12	0.171	70.18	10
terbuthylazine	D4	Stream	algae	chronic	12	3.32	**3.61**	10
terbuthylazine	D5	Pond	algae	chronic	12	0.218	55.05	10
terbuthylazine	D5	Stream	algae	chronic	12	3.37	**3.56**	10
terbuthylazine	D6	Ditch	algae	chronic	12	3.99	**3.01**	10
terbuthylazine	R1	Pond	algae	chronic	12	0.335	35.82	10
terbuthylazine	R1	Stream	algae	chronic	12	11.3	**1.06**	10
terbuthylazine	R2	Stream	algae	chronic	12	8.26	**1.45**	10
terbuthylazine	R3	Stream	algae	chronic	12	3.85	**3.12**	10
terbuthylazine	R4	Stream	algae	chronic	12	26.3	**0.46**	10
0.844 kg a.s./ha application in Southern Member States								
terbuthylazine	D3	Ditch	algae	chronic	12	4.42	**2.71**	10
terbuthylazine	D4	Pond	algae	chronic	12	0.192	62.50	10
terbuthylazine	D4	Stream	algae	chronic	12	3.74	**3.21**	10
terbuthylazine	D5	Pond	algae	chronic	12	0.247	48.58	10
terbuthylazine	D5	Stream	algae	chronic	12	3.79	**3.17**	10
terbuthylazine	D6	Ditch	algae	chronic	12	4.5	**2.67**	10
terbuthylazine	R1	Pond	algae	chronic	12	0.376	31.91	10
terbuthylazine	R1	Stream	algae	chronic	12	12.7	**0.94**	10
terbuthylazine	R2	Stream	algae	chronic	12	9.34	**1.28**	10
terbuthylazine	R3	Stream	algae	chronic	12	4.33	**2.77**	10
terbuthylazine	R4	Stream	algae	chronic	12	29.7	**0.40**	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value.

FOCUS Step 3: Risk to higher aquatic plants (terbuthylazine)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application in Northern Member States								
terbuthylazine	D3	Ditch	aq plants	chronic	12.8	3.93	**3.26**	10
terbuthylazine	D4	Pond	aq plants	chronic	12.8	0.171	74.85	10
terbuthylazine	D4	Stream	aq plants	chronic	12.8	3.32	**3.86**	10
terbuthylazine	D5	Pond	aq plants	chronic	12.8	0.218	58.72	10
terbuthylazine	D5	Stream	aq plants	chronic	12.8	3.37	**3.80**	10
terbuthylazine	D6	Ditch	aq plants	chronic	12.8	3.99	**3.21**	10
terbuthylazine	R1	Pond	aq plants	chronic	12.8	0.335	38.21	10
terbuthylazine	R1	Stream	aq plants	chronic	12.8	11.3	**1.13**	10
terbuthylazine	R2	Stream	aq plants	chronic	12.8	8.26	**1.55**	10
terbuthylazine	R3	Stream	aq plants	chronic	12.8	3.85	**3.32**	10
terbuthylazine	R4	Stream	aq plants	chronic	12.8	26.3	**0.49**	10
0.844 kg a.s./ha application in Southern Member States								
terbuthylazine	D3	Ditch	aq plants	chronic	12.8	4.42	**2.90**	10
terbuthylazine	D4	Pond	aq plants	chronic	12.8	0.192	66.67	10
terbuthylazine	D4	Stream	aq plants	chronic	12.8	3.74	**3.42**	10
terbuthylazine	D5	Pond	aq plants	chronic	12.8	0.247	51.82	10
terbuthylazine	D5	Stream	aq plants	chronic	12.8	3.79	**3.38**	10
terbuthylazine	D6	Ditch	aq plants	chronic	12.8	4.5	**2.84**	10
terbuthylazine	R1	Pond	aq plants	chronic	12.8	0.376	34.04	10
terbuthylazine	R1	Stream	aq plants	chronic	12.8	12.7	**1.01**	10
terbuthylazine	R2	Stream	aq plants	chronic	12.8	9.34	**1.37**	10
terbuthylazine	R3	Stream	aq plants	chronic	12.8	4.33	**2.96**	10
terbuthylazine	R4	Stream	aq plants	chronic	12.8	29.7	**0.43**	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value

FOCUS Step 3: Risk to sediment dwelling invertebrates (terbuthylazine)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application in Northern Member States								
terbuthylazine	D3	Ditch	sediment	chronic	500	3.93	127.23	10
terbuthylazine	D4	Pond	sediment	chronic	500	0.171	2923.98	10
terbuthylazine	D4	Stream	sediment	chronic	500	3.32	150.60	10
terbuthylazine	D5	Pond	sediment	chronic	500	0.218	2293.58	10
terbuthylazine	D5	Stream	sediment	chronic	500	3.37	148.37	10
terbuthylazine	D6	Ditch	sediment	chronic	500	3.99	125.31	10
terbuthylazine	R1	Pond	sediment	chronic	500	0.335	1492.54	10
terbuthylazine	R1	Stream	sediment	chronic	500	11.3	44.25	10
terbuthylazine	R2	Stream	sediment	chronic	500	8.26	60.53	10
terbuthylazine	R3	Stream	sediment	chronic	500	3.85	129.87	10
terbuthylazine	R4	Stream	sediment	chronic	500	26.3	19.01	10
0.844 kg a.s./ha application in Southern Member States								
terbuthylazine	D3	Ditch	sediment	chronic	500	4.42	113.12	10
terbuthylazine	D4	Pond	sediment	chronic	500	0.192	2604.17	10
terbuthylazine	D4	Stream	sediment	chronic	500	3.74	133.69	10
terbuthylazine	D5	Pond	sediment	chronic	500	0.247	2024.29	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	PEC (µg/L)	TER	Annex VI trigger
terbuthylazine	D5	Stream	sediment	chronic	500	3.79	131.93	10
terbuthylazine	D6	Ditch	sediment	chronic	500	4.5	111.11	10
terbuthylazine	R1	Pond	sediment	chronic	500	0.376	1329.79	10
terbuthylazine	R1	Stream	sediment	chronic	500	12.7	39.37	10
terbuthylazine	R2	Stream	sediment	chronic	500	9.34	53.53	10
terbuthylazine	R3	Stream	sediment	chronic	500	4.33	115.47	10
terbuthylazine	R4	Stream	sediment	chronic	500	29.7	16.84	10

Metabolite MT1 (desethyl-terbuthylazine)

Crop and rates: pre-emergent application to maize, 0.75 kg a.s./ha application in Northern Europe, 0.844 kg a.s./ha in Southern Europe.

FOCUS Step 3: Risk to algae (metabolite MT1 (desethyl-terbuthylazine))

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application (Northern Europe)								
MT1	D3	Ditch	algae	chronic	140	0.004	35000.00	10
MT1	D4	Pond	algae	chronic	140	0.572	244.76	10
MT1	D4	Stream	algae	chronic	140	0.618	226.54	10
MT1	D5	Pond	algae	chronic	140	0.321	436.14	10
MT1	D5	Stream	algae	chronic	140	0.186	752.69	10
MT1	D6	Ditch	algae	chronic	140	0.229	611.35	10
MT1	R1	Pond	algae	chronic	140	0.032	4375.00	10
MT1	R1	Stream	algae	chronic	140	1.13	123.89	10
MT1	R2	Stream	algae	chronic	140	1.63	85.89	10
MT1	R3	Stream	algae	chronic	140	0.551	254.08	10
MT1	R4	Stream	algae	chronic	140	2.31	60.61	10
0.844 kg a.s./ha application (Southern Europe)								
MT1	D3	Ditch	algae	chronic	140	0.005	28000.00	10
MT1	D4	Pond	algae	chronic	140	0.651	215.05	10
MT1	D4	Stream	algae	chronic	140	0.701	199.71	10
MT1	D5	Pond	algae	chronic	140	0.365	383.56	10
MT1	D5	Stream	algae	chronic	140	0.211	663.51	10
MT1	D6	Ditch	algae	chronic	140	0.261	536.40	10
MT1	R1	Pond	algae	chronic	140	0.035	4000.00	10
MT1	R1	Stream	algae	chronic	140	1.28	109.38	10
MT1	R2	Stream	algae	chronic	140	1.85	75.68	10
MT1	R3	Stream	algae	chronic	140	0.615	227.64	10
MT1	R4	Stream	algae	chronic	140	2.6	53.85	10

Metabolite MT13 (2-hydroxy-terbuthylazine)

Crop and rates: pre-emergent application to maize, 0.75 kg a.s./ha application in Northern Europe, 0.844 kg a.s./ha in Southern Europe.

FOCUS Step 3: Acute risk to fish (metabolite MT13 (2-hydroxy-terbuthylazine)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application (Northern Europe)								
MT13	D3	Ditch	Fish	Acute	2500	0.707	3536.07	100
MT13	D4	Pond	Fish	Acute	2500	3.589	696.57	100
MT13	D4	Stream	Fish	Acute	2500	2.674	934.93	100
MT13	D5	Pond	Fish	Acute	2500	2.339	1068.83	100
MT13	D5	Stream	Fish	Acute	2500	1.352	1849.11	100
MT13	D6	Ditch	Fish	Acute	2500	1.718	1455.18	100
MT13	R1	Pond	Fish	Acute	2500	0.0224	111607.14	100
MT13	R1	Stream	Fish	Acute	2500	0.367	6811.99	100
MT13	R2	Stream	Fish	Acute	2500	0.408	6127.45	100
MT13	R3	Stream	Fish	Acute	2500	0.353	7082.15	100
MT13	R4	Stream	Fish	Acute	2500	0.757	3302.51	100
0.844 kg a.s./ha application (Southern Europe)								
MT13	D3	Ditch	Fish	Acute	2500	0.825	3030.30	100
MT13	D4	Pond	Fish	Acute	2500	4.084	612.14	100
MT13	D4	Stream	Fish	Acute	2500	3.025	826.45	100
MT13	D5	Pond	Fish	Acute	2500	2.66	939.85	100
MT13	D5	Stream	Fish	Acute	2500	1.533	1630.79	100
MT13	D6	Ditch	Fish	Acute	2500	1.94	1288.66	100
MT13	R1	Pond	Fish	Acute	2500	0.025	100000.00	100
MT13	R1	Stream	Fish	Acute	2500	0.41	6097.56	100
MT13	R2	Stream	Fish	Acute	2500	0.463	5399.57	100
MT13	R3	Stream	Fish	Acute	2500	0.392	6377.55	100
MT13	R4	Stream	Fish	Acute	2500	0.856	2920.56	100

FOCUS Step 3: Acute risk to aquatic invertebrates (metabolite MT13 (2-hydroxy-terbuthylazine)

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	PEC (µg/L)	TER	Annex VI trigger
0.844 kg a.s./ha application (Southern Europe)								
MT13	D3	Ditch	aq invert	Acute	2800	0.825	3393.94	100
MT13	D4	Pond	aq invert	Acute	2800	4.084	685.60	100
MT13	D4	Stream	aq invert	Acute	2800	3.025	925.62	100
MT13	D5	Pond	aq invert	Acute	2800	2.66	1052.63	100
MT13	D5	Stream	aq invert	Acute	2800	1.533	1826.48	100
MT13	D6	Ditch	aq invert	Acute	2800	1.94	1443.30	100
MT13	R1	Pond	aq invert	Acute	2800	0.025	112000.00	100
MT13	R1	Stream	aq invert	Acute	2800	0.41	6829.27	100
MT13	R2	Stream	aq invert	Acute	2800	0.463	6047.52	100
MT13	R3	Stream	aq invert	Acute	2800	0.392	7142.86	100
MT13	R4	Stream	aq invert	Acute	2800	0.856	3271.03	100

Metabolite MT26 (terbutryn)

Crop and rates: pre-emergent application to maize, 0.75 kg a.s./ha application in Northern Europe, 0.844 kg a.s./ha in Southern Europe.

FOCUS Step 3: Risk to algae (MT26 (terbutryn))

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application (Northern Europe)								
MT26	D3	Ditch	algae	chronic	1.7	0.015	113.33	10
MT26	D4	Pond	algae	chronic	1.7	0.001	1700.00	10
MT26	D4	Stream	algae	chronic	1.7	0.011	154.55	10
MT26	D5	Pond	algae	chronic	1.7	0.002	850.00	10
MT26	D5	Stream	algae	chronic	1.7	0.011	154.55	10
MT26	D6	Ditch	algae	chronic	1.7	0.013	130.77	10
MT26	R1	Pond	algae	chronic	1.7	0.002	850.00	10
MT26	R1	Stream	algae	chronic	1.7	0.015	113.33	10
MT26	R2	Stream	algae	chronic	1.7	0.017	100.00	10
MT26	R3	Stream	algae	chronic	1.7	0.006	283.33	10
MT26	R4	Stream	algae	chronic	1.7	0.033	51.52	10
0.844 kg a.s./ha application (Southern Europe)								
MT26	D3	Ditch	algae	chronic	1.7	0.017	100.00	10
MT26	D4	Pond	algae	chronic	1.7	0.001	1700.00	10
MT26	D4	Stream	algae	chronic	1.7	0.012	141.67	10
MT26	D5	Pond	algae	chronic	1.7	0.002	850.00	10
MT26	D5	Stream	algae	chronic	1.7	0.012	141.67	10
MT26	D6	Ditch	algae	chronic	1.7	0.014	121.43	10
MT26	R1	Pond	algae	chronic	1.7	0.003	566.67	10
MT26	R1	Stream	algae	chronic	1.7	0.017	100.00	10
MT26	R2	Stream	algae	chronic	1.7	0.019	89.47	10
MT26	R3	Stream	algae	chronic	1.7	0.007	242.86	10
MT26	R4	Stream	algae	chronic	1.7	0.037	45.95	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value

FOCUS Step 4

Crop and rates: pre-emergent application to maize, 0.75 kg a.s./ha application in Northern Europe, 0.844 kg a.s./ha in Southern Europe.

Both spray drift and run-off mitigations have been included. Spray drift is included as a buffer zone of 5 or 10 m and runoff is a percentage reduction. Each group of organisms will be presented separately.

Two alternative mitigation options are shown:
5m + 50% means a 5m spray drift buffer zone plus 50% run-off mitigation in the runoff scenarios
10m + 90% means a 10m spray drift buffer zone plus 90% run-off mitigation in the runoff scenarios

Terbuthylazine

FOCUS Step 4: Acute risk to fish (and aquatic invertebrates) (terbuthylazine)

Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application (Northern Europe)								
R4	Stream	fish	acute	2200	5m + 50%	14.6	150.68	100
0.844 kg a.s./ha application (Southern Europe)								
R4	Stream	fish	acute	2200	5m + 50%	16.5	133.33	100

FOCUS Step 4: Chronic risk to fish (terbuthylazine)

Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application (Northern Europe)								
R1	Pond	fish	chronic	90	5m + 50%	0.217	414.75	10
R1	Stream	fish	chronic	90	5m + 50%	5.93	15.18	10
R4	Stream	fish	chronic	90	5m + 50%	14.6	**6.16**	10
0.844 kg a.s./ha application (Southern Europe)								
R1	Pond	fish	chronic	90	5m + 50%	0.243	370.37	10
R1	Stream	fish	chronic	90	5m + 50%	6.69	13.45	10
R2	Stream	fish	chronic	90	5m + 50%	5.13	17.54	10
R4	Stream	fish	chronic	90	5m + 50%	16.5	**5.45**	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value

Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application (Northern Europe)								
R4	Stream	fish	chronic	90	5m + 75%	7.75	11.61	10
0.844 kg a.s./ha application (Southern Europe)								
R4	Stream	fish	chronic	90	5m + 75%	8.74	10.30	10

Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application (Northern Europe)								
R4	Stream	fish	chronic	90	10m + 90%	3.22	27.95	10
0.844 kg a.s./ha application (Southern Europe)								
R4	Stream	fish	chronic	90	10m + 90%	3.63	24.79	10

FOCUS Step 4: Chronic risk to aquatic invertebrates (terbuthylazine)

Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application (Northern Europe)								
D3	Ditch	aq invert	chronic	19	5m + 50%	1.29	14.73	10
D4	Pond	aq invert	chronic	19	5m + 50%	0.154	123.38	10
D4	Stream	aq invert	chronic	19	5m + 50%	1.4	13.57	10
D5	Pond	aq invert	chronic	19	5m + 50%	0.202	94.06	10
D5	Stream	aq invert	chronic	19	5m + 50%	1.43	13.29	10
D6	Ditch	aq invert	chronic	19	5m + 50%	1.35	14.07	10
R1	Pond	aq invert	chronic	19	5m + 50%	0.217	87.56	10
R1	Stream	aq invert	chronic	19	5m + 50%	5.93	**3.20**	10
R2	Stream	aq invert	chronic	19	5m + 50%	4.54	**4.19**	10
R3	Stream	aq invert	chronic	19	5m + 50%	1.62	11.73	10
R4	Stream	aq invert	chronic	19	5m + 50%	14.6	**1.30**	10
0.844 kg a.s./ha application (Southern Europe)								
D3	Ditch	aq invert	chronic	19	5m + 50%	1.45	13.10	10
D4	Pond	aq invert	chronic	19	5m + 50%	0.173	109.83	10
D4	Stream	aq invert	chronic	19	5m + 50%	1.58	12.03	10
D5	Pond	aq invert	chronic	19	5m + 50%	0.228	83.33	10
D5	Stream	aq invert	chronic	19	5m + 50%	1.61	11.80	10
D6	Ditch	aq invert	chronic	19	5m + 50%	1.52	12.50	10
R1	Pond	aq invert	chronic	19	5m + 50%	0.243	78.19	10
R1	Stream	aq invert	chronic	19	5m + 50%	6.69	**2.84**	10
R2	Stream	aq invert	chronic	19	5m + 50%	5.13	**3.70**	10
R3	Stream	aq invert	chronic	19	5m + 50%	1.82	10.44	10
R4	Stream	aq invert	chronic	19	5m + 50%	16.5	**1.15**	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value

Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application (Northern Europe)								
R1	Pond	aq invert	chronic	19	10m + 90%	0.102	186.27	10
R1	Stream	aq invert	chronic	19	10m + 90%	1.24	15.32	10
R2	Stream	aq invert	chronic	19	10m + 90%	0.985	19.29	10
R4	Stream	aq invert	chronic	19	10m + 90%	3.22	**5.90**	10
0.844 kg a.s./ha application (Southern Europe)								
R1	Pond	aq invert	chronic	19	10m + 90%	0.115	165.22	10
R1	Stream	aq invert	chronic	19	10m + 90%	1.404	13.53	10
R2	Stream	aq invert	chronic	19	10m + 90%	1.11	17.12	10
R4	Stream	aq invert	chronic	19	10m + 90%	3.63	**5.23**	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value

FOCUS Step 4: Risk to algae (terbuthylazine)

Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application (Northern Europe)								
D3	Ditch	algae	chronic	12	5m + 50%	1.29	**9.30**	10
D4	Pond	algae	chronic	12	5m + 50%	0.154	77.92	10
D4	Stream	algae	chronic	12	5m + 50%	1.4	**8.57**	10
D5	Pond	algae	chronic	12	5m + 50%	0.202	59.41	10
D5	Stream	algae	chronic	12	5m + 50%	1.43	**8.39**	10
D6	Ditch	algae	chronic	12	5m + 50%	1.35	**8.89**	10
R1	Pond	algae	chronic	12	5m + 50%	0.217	55.30	10
R1	Stream	algae	chronic	12	5m + 50%	5.93	**2.02**	10
R2	Stream	algae	chronic	12	5m + 50%	4.54	**2.64**	10
R3	Stream	algae	chronic	12	5m + 50%	1.62	**7.41**	10
R4	Stream	algae	chronic	12	5m + 50%	14.6	**0.82**	10
0.844 kg a.s./ha application (Southern Europe)								
D3	Ditch	algae	chronic	12	5m + 50%	1.45	**8.28**	10
D4	Pond	algae	chronic	12	5m + 50%	0.173	69.36	10
D4	Stream	algae	chronic	12	5m + 50%	1.58	**7.59**	10
D5	Pond	algae	chronic	12	5m + 50%	0.228	52.63	10
D5	Stream	algae	chronic	12	5m + 50%	1.61	**7.45**	10
D6	Ditch	algae	chronic	12	5m + 50%	1.52	**7.89**	10
R1	Pond	algae	chronic	12	5m + 50%	0.243	49.38	10
R1	Stream	algae	chronic	12	5m + 50%	6.69	**1.79**	10
R2	Stream	algae	chronic	12	5m + 50%	5.13	**2.34**	10
R3	Stream	algae	chronic	12	5m + 50%	1.82	**6.59**	10
R4	Stream	algae	chronic	12	5m + 50%	16.5	**0.73**	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value

Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Annex VI trigger
D3	Ditch	algae	chronic	12	10m + 90%	0.683	17.57	10
D4	Pond	algae	chronic	12	10m + 90%	0.114	105.26	10
D4	Stream	algae	chronic	12	10m + 90%	0.745	16.11	10
D5	Pond	algae	chronic	12	10m + 90%	0.162	74.07	10
D5	Stream	algae	chronic	12	10m + 90%	0.767	15.65	10
D6	Ditch	algae	chronic	12	10m + 90%	0.747	16.06	10
R1	Pond	algae	chronic	12	10m + 90%	0.102	117.65	10
R1	Stream	algae	chronic	12	10m + 90%	1.24	**9.68**	10
R2	Stream	algae	chronic	12	10m + 90%	0.985	12.18	10
R3	Stream	algae	chronic	12	10m + 90%	0.859	13.97	10
R4	Stream	algae	chronic	12	10m + 90%	3.22	**3.73**	10
0.844 kg a.s./ha application (Southern Europe)								
D3	Ditch	algae	chronic	12	10m + 90%	0.769	15.60	10
D4	Pond	algae	chronic	12	10m + 90%	0.128	93.75	10
D4	Stream	algae	chronic	12	10m + 90%	0.839	14.30	10
D5	Pond	algae	chronic	12	10m + 90%	0.183	65.57	10
D5	Stream	algae	chronic	12	10m + 90%	0.863	13.90	10

Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Annex VI trigger
D6	Ditch	algae	chronic	12	10m + 90%	0.843	14.23	10
R1	Pond	algae	chronic	12	10m + 90%	0.115	104.35	10
R1	Stream	algae	chronic	12	10m + 90%	1.404	**8.55**	10
R2	Stream	algae	chronic	12	10m + 90%	1.11	10.81	10
R3	Stream	algae	chronic	12	10m + 90%	0.966	12.42	10
R4	Stream	algae	chronic	12	10m + 90%	3.63	**3.31**	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value

FOCUS Step 4: Risk to higher aquatic plants (terbuthylazine)

Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application (Northern Europe)								
D3	Ditch	aq plants	chronic	12.8	5m + 50%	1.29	**9.92**	10
D4	Pond	aq plants	chronic	12.8	5m + 50%	0.154	83.12	10
D4	Stream	aq plants	chronic	12.8	5m + 50%	1.4	**9.14**	10
D5	Pond	aq plants	chronic	12.8	5m + 50%	0.202	63.37	10
D5	Stream	aq plants	chronic	12.8	5m + 50%	1.43	**8.95**	10
D6	Ditch	aq plants	chronic	12.8	5m + 50%	1.35	**9.48**	10
R1	Pond	aq plants	chronic	12.8	5m + 50%	0.217	58.99	10
R1	Stream	aq plants	chronic	12.8	5m + 50%	5.93	**2.16**	10
R2	Stream	aq plants	chronic	12.8	5m + 50%	4.54	**2.82**	10
R3	Stream	aq plants	chronic	12.8	5m + 50%	1.62	**7.90**	10
R4	Stream	aq plants	chronic	12.8	5m + 50%	14.6	**0.88**	10
0.844 kg a.s./ha application (Southern Europe)								
D3	Ditch	aq plants	chronic	12.8	5m + 50%	1.45	**8.83**	10
D4	Pond	aq plants	chronic	12.8	5m + 50%	0.173	73.99	10
D4	Stream	aq plants	chronic	12.8	5m + 50%	1.58	**8.10**	10
D5	Pond	aq plants	chronic	12.8	5m + 50%	0.228	56.14	10
D5	Stream	aq plants	chronic	12.8	5m + 50%	1.61	**7.95**	10
D6	Ditch	aq plants	chronic	12.8	5m + 50%	1.52	**8.42**	10
R1	Pond	aq plants	chronic	12.8	5m + 50%	0.243	52.67	10
R1	Stream	aq plants	chronic	12.8	5m + 50%	6.69	**1.91**	10
R2	Stream	aq plants	chronic	12.8	5m + 50%	5.13	**2.50**	10
R3	Stream	aq plants	chronic	12.8	5m + 50%	1.82	**7.03**	10
R4	Stream	aq plants	chronic	12.8	5m + 50%	16.5	**0.78**	10

TERs highlighted in **bold** are less than the respective Annex VI trigger value

Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Annex VI trigger
0.75 kg a.s./ha application (Northern Europe)								
D3	Ditch	aq plants	chronic	12.8	10m + 90%	0.683	18.74	10
D4	Pond	aq plants	chronic	12.8	10m + 90%	0.114	112.28	10
D4	Stream	aq plants	chronic	12.8	10m + 90%	0.745	17.18	10
D5	Pond	aq plants	chronic	12.8	10m + 90%	0.162	79.01	10
D5	Stream	aq plants	chronic	12.8	10m + 90%	0.767	16.69	10
D6	Ditch	aq plants	chronic	12.8	10m + 90%	0.747	17.14	10
R1	Pond	aq plants	chronic	12.8	10m + 90%	0.102	125.49	10

Scenario	Water body type	Test organism	Time scale	Toxicity (µg/L)	Buffer zone distance	PEC (µg/L)	TER	Annex VI trigger
R1	Stream	aq plants	chronic	12.8	10m + 90%	1.24	10.32	10
R2	Stream	aq plants	chronic	12.8	10m + 90%	0.985	12.99	10
R3	Stream	aq plants	chronic	12.8	10m + 90%	0.859	14.90	10
R4	Stream	aq plants	chronic	12.8	10m + 90%	3.22	**3.98**	10
0.844 kg a.s./ha application (Southern Europe)								
D3	Ditch	aq plants	chronic	12.8	10m + 90%	0.769	16.64	10
D4	Pond	aq plants	chronic	12.8	10m + 90%	0.128	100.00	10
D4	Stream	aq plants	chronic	12.8	10m + 90%	0.839	15.26	10
D5	Pond	aq plants	chronic	12.8	10m + 90%	0.183	69.95	10
D5	Stream	aq plants	chronic	12.8	10m + 90%	0.863	14.83	10
D6	Ditch	aq plants	chronic	12.8	10m + 90%	0.843	15.18	10
R1	Pond	aq plants	chronic	12.8	10m + 90%	0.115	111.30	10
R1	Stream	aq plants	chronic	12.8	10m + 90%	1.404	**9.12**	10
R2	Stream	aq plants	chronic	12.8	10m + 90%	1.11	11.53	10
R3	Stream	aq plants	chronic	12.8	10m + 90%	0.966	13.25	10
R4	Stream	aq plants	chronic	12.8	10m + 90%	3.63	**3.53**	10

TERs highlighted in bold are less than the respective Annex VI trigger value

Groundwater

Metabolite TERs for aquatic organisms when groundwater becomes surface water. Calculated for the Piacenza scenario, assuming a 0.844 kg a.s./ha application of terbuthylazine in Southern Europe.

Time scale	Organism	Toxicity endpoint µg/L		Diluted ground water PEC µg/L[2]	TER	Annex VI trigger value
MT1 (desethyl-terbuthylazine)						
Acute	Fish	LC_{50}	18000	0.1429	125962	100
Acute	Aquatic invertebrate	EC_{50}	42000	0.1429	293912	100
	Algae	E_bC_{50}	140	0.1429	980	10
MT13 (2-hydroxy-terbuthylazine)						
Acute	Fish	LC_{50}	>2500	1.283	>1949	100
Acute	Aquatic invertebrate	EC_{50}	>2800	1.283	>2182	100
	Algae	E_rC_{50}	>3800	1.283	>2962	10
MT14 (desethyl-hydroxy-terbuthylazine, GS 28620)						
Acute	Fish	LC_{50}	15000[1]	0.3627	41356	100
Acute	Aquatic invertebrate	EC_{50}	15000[1]	0.3627	41356	100
	Algae	E_bC_{50}	15000[1]	0.3627	41356	10

[1] The study authors proposed the acute fish and *Daphnia magna* L/EC_{50} for MT14 was >100 mg/L and the EC_{50} to algae to be 30.7 mg/L. However, these values are greater than the water solubility of MT14 (18 mg/L) and therefore the Rapporteur has reservations in accepting quantified toxicity endpoints. The water solubility of MT14 is 18 mg/L and therefore to assume the saturation level (the amount of MT14 in solution under the conditions of the study) of 15 mg a.s./L is not unreasonable. Assuming the acute fish LC_{50}, acute *Daphnia*

magna EC_{50} and the algae EC_{50} are 15 mg/L a TER of 2617.3 is calculated which clearly demonstrates that metabolite MT14 does not pose a high risk to fish, aquatic invertebrates and algae

[2] Diluted groundwater PEC for Piacenza scenario (found to be worst case). Calculated assuming a 0.844 kg a.s./ha application in Southern Europe and a dilution factor of 10 (as stated in SANCO/3268 (Section 6.4.2 (4))

Bioconcentration			
	Active substance	MT1 (desethyl-terbuthylazine)	MT13 (2-hydroxy-terbuthylazine
$\log P_{O/W}$	3.4	2.3	1.6
Bioconcentration factor (BCF)[1] ‡	34*	Not required	Not required
Annex VI Trigger for the bioconcentration factor	100	-	-
Clearance time (days) (CT_{50})[2]	0.8 days (whole fish) 0.68 days (edibles) 0.93 (non-edibles)		

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

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. (terbuthylazine)	>22.6 µg a.s./bee (SYN)	>32 µg a.s./bee (OXON)
'Gardo Gold' (A-9476 C)	>100 µg 'Gardo Gold'/bee (SYN)	>100 µg 'Gardo Gold'/bee (SYN)
'Terbuthylazine 500 g/L SC'	>117.5 µg 'Terbuthylazine 500 g/L SC'/bee (OXON)	>100 µg 'Terbuthylazine 500 g/L SC'/bee (OXON)
Field or semi-field tests: not required		

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

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s. (terbuthylazine)	Contact	<31.25[1]	50
a.s. (terbuthylazine)	oral	<44.25[1]	50
'Gardo Gold' (A-9476 C)	Contact	<48.7[2]	50
'Gardo Gold' (A-9476 C)	oral	<48.7[2]	50
'Terbuthylazine 500 g/L SC'	Contact	<18.7[3]	50

Test substance	Route	Hazard quotient	Annex VI Trigger
‘Terbuthylazine 500 g/L SC’	oral	<22.0[3]	50

[1] Following a 1 kg/ha application of terbuthylazine
[2] Following a 4.5 L formulation/ha application of ‘Gardo Gold’ (A-9476 C)
[3] Following a 2.0 L formulation/ha application of ‘Terbuthylazine 500 g/L SC’

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
Typhlodromus pyri ‡	‘Terbuthylazine 500 g/L SC’	Mortality	LR_{50} > 0.75 kg a.s./ha (> 1.5 L form.n/ha) OXON
Aphidius rhopalosiphi ‡		Mortality	LR_{50} > 0.75 kg a.s./ha (> 1.5 L form.n/ha) OXON

1 x 1.00 kg terbuthylazine/ha on maize and sorghum

Test substance	Species	HQ in-field	HQ off-field*	Trigger
‘Terbuthylazine 500 g/L SC’	*Typhlodromus pyri*	< 1.33	< 0.0369	2
	Aphidius rhopalosiphi	< 1.33	< 0.0369	2

* Using a default drift rate of 2.77% for field crops

Further laboratory and extended laboratory studies ‡

Species	Life stage	Substrate and duration	Dose (g tba /ha)	Lethal effects (control corrected)	Sublethal effects (% reduction)	Trigger value
‘Gardo Gold’ SYN						
Aphidius rhopalosiphi	Adult	Barley plants, 48 hours (mortality assessed), plus 11 days (fecundity assessed)	34 844	0 % 0 %	Parasitism: -16.4 % -15.1 %	50 %
Typhlodro-mus pyri	Proto-nymph	Bean leaves, 7 days (mortality assessed) plus a further 7 days (fecundity assessed)	34 844	11.2 % 16.9 %	Egg production: 30 % **75 %**	50 %

Species	Life stage	Substrate and duration	Dose (g tba /ha)	Lethal effects (control corrected)	Sublethal effects (% reduction)	Trigger value
T. pyri	Proto-nymph	Bean leaves, 7 days (mortality assessed) plus a further 7 days (fecundity assessed)	 4.8 2.4 1.2 0.6 0.4 0.2	 6 3 0 0 0 0	eggs/female **76** **52** 22 -12 -22 -19	50%
Aleochara bilineata	Proto-nymph	Quartz sand, 28 days	34 844	15.3 % 8.4 %	Parasitism: 7 % 7 %	50 %
Poecilus cupreus	Proto-nymph	Quartz sand, 14 days	34 844	0 % 0 %	Food consumption: -2.14 % -50 %	50 %
'Terbuthylazine 500 g/L SC' OXON						
Poecilus cupreus	Adult	Moist sand, 15 days	750	0 %	Food consumption: 1.6 %	50 %
Aleochara bilineata	Adult	Moist sand, 35 days	750	Not reported	Parasitism: 0 %	50 %
Chrysoperla carnea	Larvae	Glass-plate, 14 day exposure period, 8 day hatching period, 4 week oviposition period.	750	0	E/f: 4.2 % Lh: 48.3 % Fe/f: 36.7 %	50 %
Chrysoperla carnea	Larvae	Bean leaves, 19 day exposure period, 12 day hatching period, 1 week oviposition period	Fresh residues:			
			10.39	13.6 %	E/f: 2.16 % Lh: 14.2 %	50 %
			750	11.4 %	E/f: -9.57 % Lh: 4.72 %	
			Aged residues (7 DAT):			
			10.39	-4.9 %	E/f: -15.8 % Lh: -21.4 %	50 %
			750	-7.3 %	E/f: -22.7 % Lh: -29.2 %	

Note: negative values indicate a higher survival, food consumption or reproduction than in the control treatment
E/f = eggs per female, Lh = larvae hatched, Fe/f = fertile eggs per female

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
Earthworms – acute toxicity			
Eisenia foetida	a.s. ‡	Acute 14 days	$LC_{50\ corr}$ > 141.7 mg tba/kg soil dw [OXON]
Eisenia foetida	Preparation - ‘Gardo Gold’	Acute 14 days	$LC_{50\ corr}$ = 44.1 mg tba/ kg soil dw [SYN]
Eisenia foetida	Preparation - ‘Terbuthylazine 500 g/L SC’	Acute 14 days	$LC_{50\ corr}$ > 500 mg tba/ kg soil dw [OXON]
Eisenia foetida	Metabolite MT1 (desethyl-terbuthylazine)	Acute 14 days	$LC_{50\ corr}$ = 120 mg/kg soil dw [SYN]
Eisenia foetida	Metabolite MT13 (hydroxy-terbuthylazine)	Acute 14 days	LC_{50} > 1000 mg/kg soil dw [SYN & OXON]
Eisenia foetida	Metabolite MT14 (desethyl-hydroxy-terbuthylazine)	Acute 14 days	LC_{50} > 1000 mg/kg soil dw [SYN]
Earthworms – chronic toxicity			
Not applicable	Preparation - ‘Gardo Gold’ (‘A-9476 C’)	Field study – 1 yr (Denmark)	No significant ecologically adverse effects at 4.5 L form.n/ha (844 g tba/ha) after 1 yr [SYN]
Not applicable		Field study – 1 yr (Germany)	**Significant adverse effects on biomass of Epilobous juveniles at 4.0 & 4.5 L form.n/ha (750 & 844 g tba/ha) after 1 yr.** No other significant ecologically adverse effects found [SYN]
Eisenia foetida	Preparation - ‘Gardoprim Plus Gold’ (‘A-9476 B’)	Chronic, 56 days (lab)	$NOEC_{corr}$ = 0.563 mg tba/ kg soil [SYN]
Not applicable	Preparation - ‘Gardoprim’ /‘GS 13529 SC 500’ (‘A-5435 E’)	Field study – 1 yr (Denmark)	No significant ecologically adverse effects at 1.69 L form.n/ha (844 g tba/ha) after 1 yr SYN (Oxon acess)
Not applicable		Field study – 1 yr (Germany)	No significant ecologically adverse effects at 1.69 L form.n/ha (844 g tba/ha) after 1 yr [SYN] (Oxon acess)

Test organism	Test substance	Time scale	End point
Eisenia foetida	Preparation - 'Terbuthylazine 500 g/L SC'	Chronic, 56 days	$NOEC_{corr}$ < 0.5 mg tba/ kg soil dw [OXON]
Not applicable		Field study – 1 yr	No significant ecologically adverse effects at 1.5 L form.n/ha (750 g tba/ha) after 1 yr. [OXON *]
Eisenia foetida	Metabolite MT1 (desethyl-terbuthylazine)	Chronic, 56 days	$NOEC_{corr}$ 2.8 mg/ kg soil dw
Eisenia foetida	Metabolite MT13 (hydroxy-terbuthylazine)	Chronic, 56 days	NOEC 7 mg/kg soil dw
Other soil macro-organisms			
Collembola	Preparation - 'Gardoprim Plus Gold'	28 days	$NOEC_{corr}$ = 21.12 mg tba/ kg soil dw [SYN]
Litter bag study	terbuthylazine desethyl-terbuthylazine 2-hydroxy-terbuthylazine	Field study (1 yr)	no significant impact on organic matter breakdown at applications considered to cover an application of terbuthylazine of 1 kg/ha, plus any long term accumulation [OXON]

* Note: this study was conducted on established grassland; no correction for levels of ground interception has been made

Test substance	Max PEC_{soil} (accum.) mg/kg soil dw	End point
Soil micro-organisms (nitrogen and carbon mineralisation)		
a.s. ‡	1.125	No significant effects of > 25 % on carbon mineralisation or nitrogen transformation up to a max tested concentration of 10.9 mg/kg soil dw
Metabolite MT1 (desethyl-terbuthylazine)	0.325	No effects of > 25 % on carbon mineralisation or nitrogen transformation up to a max tested concentration of 1.84 mg/kg soil dw
Metabolite MT13 (hydroxy-terbuthylazine)	0.357	No effects of > 25 % on carbon mineralisation or nitrogen transformation up to a max tested concentration of 3.45 mg/kg soil dw
Metabolite MT14 (desethyl-hydroxy-terbuthylazine)	n.c.	No effects of > 25 % on carbon mineralisation or nitrogen transformation up to a max tested concentration of 0.52 mg/kg soil dw

n.c. = Not calculated

Note: PEC_{soil} not calculated for desethyl-hydroxy-terbuthylazine, as this is a minor metabolite, present at only 1.9 % AR

Toxicity/exposure ratios for soil organisms

Test organism	Test substance	Time scale	Max PEC_{soil} mg/kg soil dw	TER	Trigger
Earthworms					
1 x 0.844 kg terbuthylazine/ha on maize [SYN]					
Eisenia foetida	'Gardo Gold'	Acute	1.125	39.2	10
Eisenia foetida	'Gardoprim Plus Gold'	Chronic	1.125	**0.50**	5
Eisenia foetida	a.s. ‡	Acute	1.125	>125.96	10
Eisenia foetida	Desethyl-terbuthylazine (MT1)	Acute	0.325	369.23	10
Eisenia foetida	Hydroxy-terbuthylazine (MT13)	Acute	0.357	>2801	10
1 x 0.75 kg terbuthylazine/ha on maize [SYN]					
Eisenia foetida	'Gardo Gold'	Acute	1	44.1	10
Eisenia foetida	'Gardoprim Plus Gold'	Chronic	1	**0.563**	5
Other soil macro-organisms					
1 x 0.844 kg terbuthylazine/ha on maize [SYN]					
Collembola	'Gardoprim Plus Gold'	Chronic	1.125	18.8	5

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

Laboratory dose response tests

Most sensitive species	Growth stage at treatment	Endpoint (mL form.n/ha)	Exposure scenario	Drift rate * (mL form.n/ha)	TER	Trigger
'Gardoprim Plus Gold' – 1 x 0.844 kg terbuthylazine/ha on maize SYN						
Lettuce	Pre-emergence	EC_{50} = 321	Drift (at 1 m)	124.7	**2.57**	5
			Drift (at 5 m)	25.65	12.51	
	Post-emergence	EC_{50} = 439	Drift (at 1 m)	124.4	**3.52**	
			Drift (at 5 m)	25.65	17.12	
'Terbuthylazine 500 g/L SC' – 1 x 1.00 kg terbuthylazine/ha on maize and sorghum OXON						
Sugar beet	Pre-emergence	EC_{50} = 16.0	Drift (at 1 m)	55.4	**0.29**	5
			Drift (at 5 m)	11.4	**1.40**	
			Drift (at 10 m)	5.8	**2.76**	
			Drift (at 20 m)	3.0	5.33	
Tomato	Post-emergence	EC_{50} = 164.61	Drift (at 1 m)	55.4	**2.97**	
			Drift (at 5 m)	11.4	14.4	

* According to Rautmann *et al.* 2001

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

Test type/organism	end point
Activated sludge	NOEC = 100 mg terbuthylazine/L SYN & OXON

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

Compartment	
soil	Terbuthylazine
water	Terbuthylazine, metabolite MT26 (terbutryn), desethyl terbuthylazine,
sediment	Terbuthylazine
groundwater	None

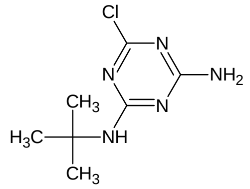
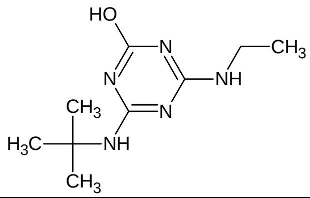
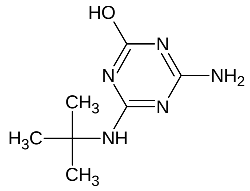
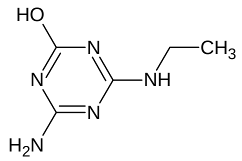
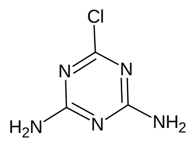
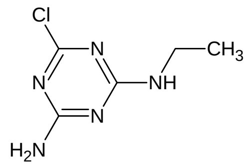
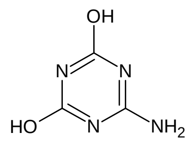
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

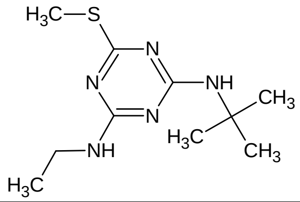
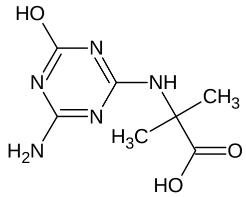
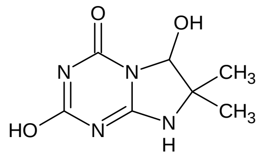
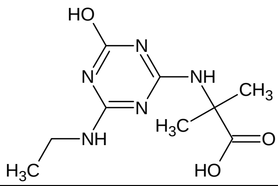
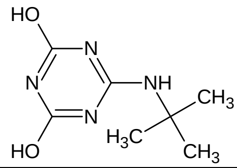
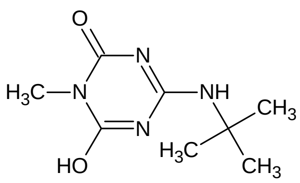
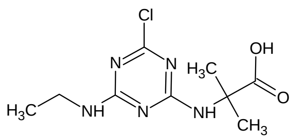
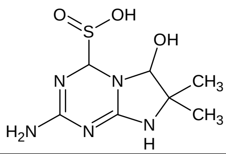
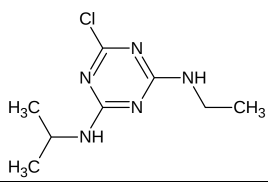
	RMS/peer review proposal
Active substance	N Dangerous to the environment R50/ R53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment S60/ S61 This material and its container must be disposed of as hazardous waste / Avoid release to the environment.

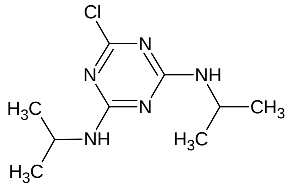
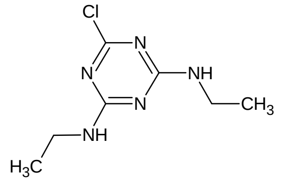
	RMS/peer review proposal
Preparation 'GARDO® GOLD®' (SYN)	N Dangerous to the environment R50/ R53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment S35 or S60 This material and its container must be disposed in a safe way or This material and its container must be disposed of as hazardous waste and S57 or S61 Use appropriate container to avoid environmental contamination or Avoid release to the environment.

	RMS/peer review proposal
Preparation 'Terbuthylazine 500 g/L SC' (OXON)	N Dangerous to the environment R50 Very toxic to aquatic organisms S35 or S60 This material and its container must be disposed in a safe way or This material and its container must be disposed of as hazardous waste and S57 or S61 Use appropriate container to avoid environmental contamination or Avoid release to the environment.

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name (IUPAC)**	Structural formula**
MT1 desethyl-terbuthylazine (GS 26379)	*N-tert*-butyl-6-chloro-1,3,5-triazine-2,4-diamine	
MT13 Hydroxy-terbuthylazine or 2-hydroxy-terbuthylazine GS 23158	4-(*tert*-butylamino)-6-(ethylamino)-1,3,5-triazin-2-ol or 6-hydroxy -N^2-ethyl-N^4- *tert*-butyl-1,3,5-triazine-2,4-diamine	
MT14 desethyl-hydroxy-terbuthylazine or desethyl-2-hydroxy terbuthylazine GS 28620	4-amino-6-(*tert*-butylamino)-1,3,5-triazin-2-ol or *N-tert*-butyl-6-hydroxy-1,3,5-triazine-2,4-diamine	
MT19 De-t-butyl-hydroxy-terbuthylazine or atrazine-desisopropyl-2-hydroxy	4-amino-6-(ethylamino)-1,3,5-triazin-2-ol or *N*-ethyl-6-hydroxy-1,3,5-triazine-2,4-diamine	
MT20 diamino-chlorotriazine or atrazine-desethyl desisopropyl	6-chloro-1,3,5-triazine-2,4-diamine	
MT22 de-t-butyl-terbuthylazine or atrazine-desisopropyl-2-hydroxy (G 28279)	6-chloro-*N*-ethyl-1,3,5-triazine-2,4-diamine	
MT24 LM1 amino-dihydroxy-triazine GS 35713	6-amino-1,3,5-triazine-2,4-diol	

Code/Trivial name	Chemical name (IUPAC)**	Structural formula**
terbutryn MT26 GS 14260	*N*[2]-*tert*-butyl-*N*[4]-ethyl-6-methylthio-1,3,5-triazine-2,4-diamine	
MT28 LM2 CSAA036479 CGA046571	*N*-(4-amino-6-hydroxy-1,3,5-triazin-2-yl)-2-methylalanine	
LM3 SM9 CSCD692760 *SYN546009*	2,6-dihydroxy-7,7-dimethyl-7,8-dihydroimidazo[1,2-*a*][1,3,5]triazin-4(6*H*)-one	
LM4 SM4 CSAA404949 *GS40436*	*N*-[4-(ethylamino)-6-hydroxy-1,3,5-triazin-2-yl]-2-methylalanine	
MT23 LM5 SM12 GS 16984	6-(*tert*-butylamino)-1,3,5-triazine-2,4-diol	
LM6 SM6 CSCD648241 *SYN545666*	4-(*tert*-butylamino)-6-hydroxy-1-methyl-1,3,5-triazin-2(1*H*)-one	
LM7	*N*-[4-chloro-6-(ethylamino)-1,3,5-triazin-2-yl]-2-methylalanine 2-amino-6-hydroxy-7,7-dimethyl-1,4,6,7-tetrahydroimidazo[1,2-*a*][1,3,5]triazine-4-sulfinic acid	 
atrazine	6-chloro-*N*[2]-ethyl-*N*[4]-isopropyl-1,3,5-triazine-2,4-diamine	

propazine	6-chloro-N^2,N^4-diisopropyl-1,3,5-triazine-2,4-diamine	
simazine	6-chloro-N^2,N^4-diethyl-1,3,5-triazine-2,4-diamine	

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

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
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 Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DDD	defined daily dose
DFOP	double first order in parallel kinetics
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use

g	gram
GAP	good agricultural practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-NPD	gas chromatography with nitrogen phosphorous selective detector
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high performance liquid chromatography – mass spectrometry
HPLC-MS/MS	liquid performance with tandem mass spectrometry
HPLC-UV	high performance liquid chromatography with ultra violet detector
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	millinewton
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
nm	nanometre
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	Pascal
PAT	pesticide application timer
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in groundwater
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})
POEM	predictive operator exposure model
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
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
WHO	World Health Organisation
wk	week
yr	year