Terbuthylazine
SANCO/11337/2011 rev 2
17 June 2011

Review report for the active substance terbuthylazine
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 17 June 2011
in view of the approval of terbuthylazine as active substances in accordance with Regulation (EC) No 1107/2009

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of terbuthylazine, made in the context of a new application by the data submitter after the non-inclusion of this substance to Annex I of Directive 91/414/EEC.

Terbuthylazine is a substance that was covered by the third stage of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market\(^1\), with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EC) No 451/2000\(^2\) and No 1490/2002\(^3\) lay down the detailed rules for the implementation of the third stage of the programme. In particular, Article 11e of Regulation (EC) No 1490/2002 sets specific conditions for the notifier to withdraw its support. All notifiers withdrew their support and terbuthylazine was not included through Commission Decision 2008/934/EC\(^4\).

In accordance with Article 13 of Regulation (EC) No 33/2008\(^5\), Syngenta Crop Protection AG and Oxon Italia S. p. a., the sole data submitters presented, on 10 June 2009 a request to the United Kingdoms, the rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

The United Kingdom finalised in January 2010 its examination, in the form of an additional report to the original Draft Assessment Report. This Report was received by the Commission and the European Food Safety Authority on 3 February 2010.

\(^1\) OJ No L 230, 19.8.1991
\(^2\) OJ No L 55, 29.2.2000
\(^3\) OJ No L 224, 21.8.2002
\(^4\) OJ No L 333, 11.12.2008
\(^5\) OJ No L 15, 18.1.2008
The EFSA organised the consultation on the draft assessment report and, in accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, on the additional report by all the Member States as well as by Syngenta Crop Protection AG and Oxon Italia S. p. a. on 4 February 2010 by making it available.

The EFSA organised a focused consultation of scientific experts from a certain number of Member States, to review the additional report and the comments received thereon (peer review).

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008 the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance terbuthylazine (issued on 20 December 2010)]\(^6\). This conclusion refers to background document A (draft assessment report and additional report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 21 of Regulation (EC) No 33/2008, the Commission referred a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 17 June 2011.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), these documents are also considered to be part of this review report.

2. **Purposes of this review report**

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Implementing Regulation (EU) No 820/2011\(^7\) concerning the approval of terbuthylazine as active substances under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing terbuthylazine they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the requirements of Regulation (EU) No 544/2011, submitted for the purpose of approval of the active substances, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 22 of Regulation (EC) No 33/2008, this review report will be made available for public consultation by any interested parties.

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\(^7\) OJ L 209, 17.8.2011, p. 18–23
The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Regulation (EC) No 1107/2009, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.


The overall conclusion from the evaluation is that it may be expected that plant protection products containing terbuthylazine will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 29 (1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each terbuthylazine containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 29 (1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

The following reference values have been finalised as part of this re-evaluation:

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ADI</td>
<td>0.004</td>
<td>mg/kg bw/day</td>
</tr>
<tr>
<td>ARfD</td>
<td>0.008</td>
<td>mg/kg bw</td>
</tr>
<tr>
<td>AOEL</td>
<td>0.0032</td>
<td>mg/kg bw/day</td>
</tr>
</tbody>
</table>

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The International Estimated Daily Intake (IEDI) is 10 % of the Acceptable Daily Intake (ADI), (WHO cluster B). The predicted levels of metabolites MT1, MT13 and MT14 in groundwater 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.

Estimates of acute dietary exposure of adults and children revealed that the Acute Reference Dose (ARfD) would not be exceeded (according to the EFSA PRIMo rev 2 less than 63 % for carrots as rotational crops).

The review has identified acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.
The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC.

4. **Identity**

The main identity of terbuthylazine is given in Appendix I.

The active substance shall comply with the FAO specification and there seem not to be reasons for deviating from that specification. The FAO specification is given in Appendix I of this report.

The review has established that for the active substance notified the manufacturing impurities propazine, atrazine, and simazine are considered to be of toxicological concern and a maximum level of 10 g/kg, 1 g/kg and 30 g/kg respectively are established.

5. **Endpoints and related information**

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA, and at section 3 of this report.

6. **Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing terbuthylazine**

On the basis of the proposed and supported uses (as listed in Appendix II), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted:

- the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;
- the long-term risk and the risk from secondary poisoning for mammals and the risk for earthworms.

Conditions of use shall include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate.

7. **List of studies to be generated**

Further studies were identified which were at this stage considered necessary in relation to the approval of terbuthylazine under the current approval conditions. In particular, information to further address:
(a) the specification of the technical material, as commercially manufactured including information on the relevance of the impurities;

(b) the equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicity dossiers;

(c) confirmatory information groundwater exposure assessment for the unidentified metabolites LM1, LM2, LM3, LM4, LM5 and LM6;

(d) If a decision on the classification of terbuthylazine under Regulation (EC) No 1272/2008 would identify the need for further information on the relevance of the metabolites MT1, MT13, MT14, and for the unidentified metabolites LM1, LM2, LM3, LM4, LM5 and LM6.

The notifier shall submit to the Member States, the Commission and the Authority the information set out in point (a) and (b) by 30 June 2012, the information set out in point (c) by 30 June 2013 and the information set out in point (d) by 6 months after the classification of terbuthylazine.

Some other endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. The list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusions (p 22).

8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13(1) to (4) of Directive 91/414/EEC and Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13(1) to (4) of the Directive 91/414/EEC and Article 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the approval conditions for terbuthylazine.
APPENDIX I

Identity
TERBUTHYLAZINE

<table>
<thead>
<tr>
<th>Common name (ISO)</th>
<th>Terbuthylazine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name (IUPAC)</td>
<td>$N^2$-tert-butyl-6-chloro-$N^4$-ethyl-1,3,5-triazine-2,4-diamine</td>
</tr>
<tr>
<td>Chemical name (CA)</td>
<td>6-chloro-N-(1,1-dimethylethyl)-$N'$-ethyl-1,3,5-triazine-2,4-diamine</td>
</tr>
<tr>
<td>CIPAC No</td>
<td>234</td>
</tr>
<tr>
<td>CAS No</td>
<td>5915-41-3</td>
</tr>
<tr>
<td>EEC No</td>
<td>227-637-9</td>
</tr>
<tr>
<td>Minimum purity</td>
<td>950 g/kg</td>
</tr>
</tbody>
</table>
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) | Propazine 10 g/kg  
Atrazine 1 g/kg  
Simazine 30 g/kg |
| Molecular formula                 | C9H16ClN5                                 |
| Molecular mass                    | 229.7 g/mol                               |
| Structural formula                | ![Structural formula](image)              |
## APPENDIX II

### List of uses supported by available data

**TERBUTHYLAZINE**

<table>
<thead>
<tr>
<th>Crop and/or situation</th>
<th>Member State, Country or Region</th>
<th>Product name</th>
<th>F or I</th>
<th>Pests or Group of pests controlled</th>
<th>Preparation</th>
<th>Application</th>
<th>Application rate per treatment (for explanation see the text in front of this section)</th>
<th>PHI (days)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maize</strong></td>
<td>N.EU.</td>
<td>GARD O® GOLD #</td>
<td>F</td>
<td>Dicot and monocot weeds</td>
<td>SE 187.5 g/L Terbutylazine 312.5 g/L S-metolachlor</td>
<td>Tractor - mounted sprayer  pre-emergence - 8 leaf</td>
<td>1</td>
<td>Not applicable 0.15-0.375 Terbutylazine 0.25-0.614 S-metolachlor 200-500 Max. 0.75 Terbutylazine Max. 1.228 S-metolachlor</td>
<td>0.15-0.375</td>
</tr>
<tr>
<td></td>
<td>S.EU.</td>
<td>GARD O® GOLD #</td>
<td>F</td>
<td>Dicot and monocot weeds</td>
<td>SE 187.5 g/L Terbutylazine 312.5 g/L S-metolachlor</td>
<td>Tractor - mounted sprayer  pre-emergence - 8 leaf</td>
<td>1</td>
<td>Not applicable 0.168-0.422 Terbutylazine 0.28-0.71 S-metolachlor 200-500 Max. 0.844 Terbutylazine Max. 1.415 S-metolachlor</td>
<td>0.168-0.422</td>
</tr>
<tr>
<td></td>
<td>Franc (N) Germany (N) The Netherlands (N)</td>
<td>Terbutylazine 500 g/l SC</td>
<td>F</td>
<td>Annual and perennial broad leaved weeds</td>
<td>SC 500 g/l</td>
<td>Spray  Pre-emergence Early post emergence (12-16)</td>
<td>1</td>
<td>- 0.15-0.5 200-500 0.75-0.844 n.r</td>
<td>0.15-0.5</td>
</tr>
<tr>
<td>Crop and/or situation</td>
<td>Member State, Country or Region</td>
<td>Product name</td>
<td>F/G/I</td>
<td>Type</td>
<td>Conc. of as</td>
<td>method kind</td>
<td>growth stage &amp; season</td>
<td>number min/max</td>
<td>interval between applications</td>
</tr>
<tr>
<td>-----------------------</td>
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<tr>
<td>(a) Sorghum</td>
<td>Italy (S) Spain (S)</td>
<td>Terbutylazine 500 g/l SC</td>
<td>F</td>
<td>SC</td>
<td>500 g/l</td>
<td>Spray</td>
<td>Pre-emergence Early post emergence (14)</td>
<td>1</td>
<td>-</td>
</tr>
</tbody>
</table>

**Remarks:**

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure).

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I).

(c) *e.g.* biting and sucking 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) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench.

(g) All abbreviations used must be explained.

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - 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) The minimum and maximum number of application possible under practical conditions of use must be provided.

(l) PHI - minimum pre-harvest interval.

(m) Remarks may include: Extent of use/economic importance/restrictions.