CONCLUSION ON PESTICIDE PEER REVIEW



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Peer review of the pesticide risk assessment for the active substance thiabendazole in light of confirmatory data submitted

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Abstract

The conclusions of the EFSA following the peer review of the initial risk assessment carried out by the competent authority of the rapporteur Member State, Spain, for the pesticide active substance thiabendazole are reported. The context of the peer review was that requested by the European Commission following the submission and evaluation of confirmatory information with regard to the endocrine disruption potential of the substance. The conclusions were reached on the basis of the evaluation of the representative uses of thiabendazole as a fungicide on seed potato, apple and pear and citrus. Assessments not finalised together with the missing information identified as being required by the mandate are listed. Concerns are identified.

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Keywords: thiabendazole, peer review, confirmatory data, risk assessment, pesticide, fungicide

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Summary

The approval of the active substance thiabendazole was renewed on 1 April 2017 in accordance with Regulation (EC) No 1107/2009 by Commission Implementing Regulation (EU) 2017/157 of 30 January 2017. It was a specific provision of the approval that the applicant was required to submit to the European Commission further information investigating the potential for endocrine-mediated effects of thiabendazole by 31 March 2019.

In accordance with the specific provision, the applicant, Syngenta Ltd, submitted an updated dossier in March 2019, which was evaluated by the designated rapporteur Member State (RMS), Spain, in the form of an addendum to the renewal assessment report. In compliance with the guidance document SANCO 5634/2009-rev.6.1, the RMS distributed the addendum to Member States, the applicant and EFSA for comments on 18 November 2019. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 2 April 2020. EFSA added its scientific views on the specific points raised during the commenting phase, leading to the Technical Report finalised on 28 April 2020.

Following consideration of the conclusions of the Technical Report, in June 2021 the European Commission requested EFSA to arrange a further peer review, including expert discussion where appropriate, to further assess the endocrine-disrupting properties of thiabendazole on the basis of the available information and, if applicable, to establish which additional test(s) would be needed to conclude on such properties both for human health and the environment under consideration of the scientific criteria established by Commission Regulation 2018/605.

Thiabendazole is considered to meet the criteria for endocrine disruption for humans for the thyroid (T)-modality according to point 3.6.5 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605, leading to a critical area of concern. The assessment of the endocrine-disrupting properties of thiabendazole according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 could not be finalised based on the available data for non-target organisms.



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Background

The approval of the active substance thiabendazole was renewed on 1 April 2017 in accordance with Regulation (EC) 1107/2009¹ by Commission Implementing Regulation (EU) 2017/157² of 30 January 2017. EFSA previously finalised a Conclusion on this active substance on 23 October 2014 in the EFSA Journal (EFSA, 2014).

It was a specific provision of the approval that the applicant was required to submit by 31 March 2019 to the European Commission, the Member States and EFSA Level 2 tests as indicated in the OECD Conceptual Framework (2012, updated in 2018) investigating the potential for endocrine-mediated effects of thiabendazole.

In accordance with this requirement, the applicant, Syngenta Ltd., submitted an updated dossier in March 2019, which was evaluated by the designated rapporteur Member State (RMS), Spain, in the form of an addendum to the renewal assessment report (Spain, 2019). In compliance with the guidance document SANCO 5634/2009-rev.6.1 (European Commission, 2013), the RMS distributed the addendum to the other Member States, the applicant and the EFSA for comments on 18 November 2019. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 2 April 2020. EFSA added its scientific views on the specific points raised during the commenting phase, leading to the Technical Report finalised on 28 April 2020 (EFSA, 2020). The technical report from EFSA indicated that the confirmatory information submitted was not sufficient to conclude on the endocrine potential of thiabendazole neither for human health nor for non-target organisms and that further data may be required before concluding on the endocrine-disrupting (ED) properties of thiabendazole. It was also proposed to discuss in an additional experts' consultation the assessment of the ED properties of thiabendazole both for humans and non-target organisms and to identify which additional tests are needed to conclude on the ED properties.

Following consideration of the conclusions of the Technical Report, on 29 June 2021 the European Commission requested EFSA to arrange a further peer review, including expert discussion where appropriate, to further assess the ED properties of thiabendazole on the basis of the available information and, if applicable, to establish which additional test(s) would be needed to conclude on such properties both for human health and the environment under consideration of the scientific criteria established by Commission Regulation 2018/605³.

In order to facilitate the further review, Spain as the designated RMS has provided to EFSA a revised confirmatory data addendum on the ED properties according to the ECHA/EFSA (2018) guidance on 7 June 2021 (Spain, 2021).

Following a commenting round with Member States, EFSA and the applicant conducted in July 2021, the RMS assessment and the reporting table with the compiled comments were considered at the Pesticides Peer Review Experts' Teleconference TC 68 on Mammalian Toxicology and Ecotoxicology joint session on ED in January 2022. Advice was also provided by the EFSA ED Working Group. Details of the issues discussed, together with the outcome of these discussions were presented in the report of the scientific consultation with Member State experts (EFSA, 2022).

A final consultation on the conclusions arising from the peer review took place with Member States via a written procedure in February 2022.

The conclusions laid down in this report were reached on the basis of the peer review of the RMS's evaluation of the confirmatory data submitted in relation to the ED properties of thiabendazole. A key supporting document to this conclusion is the peer review report (EFSA, 2022), comprising of the following documents, in which all views expressed during the course of the confirmatory data peer review, including minority views, if applicable, can be found:

- the comments received on the confirmatory data addendum;
- the report of the scientific consultation with Member State experts;
- the comments received on the draft EFSA conclusion.

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

² Commission Implementing Regulation (EU) 2017/157 of 30 January 2017 renewing the approval of the active substance thiabendazole in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 25, 31.1.2017, p. 5–9.

³ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36



Given the importance of the RMS assessment (revised version of January 2022; Spain, 2022) and the peer review report, these documents are considered as background documents to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Thiabendazole is the ISO common name for 2-(thiazol-4-yl)-1H-benzimidazole (IUPAC).

The representative formulated product for the evaluation for the renewal of approval was 'TECTO 500 SC', a suspension concentrate (SC) containing 500 g/L thiabendazole. The representative uses were preplanting indoor using ultra low volume (ULV) or spinning disk spray applications to seed potatoes, and post-harvest indoor applications by dip or drench to apple, pear and citrus (see Appendix A in EFSA, 2014).

1. Conclusions of the evaluation

In March 2019, the applicant submitted confirmatory information as regards the potential for endocrine-mediated effects of thiabendazole. The assessment of the information was presented by the RMS in the form of a revised confirmatory data addendum (Spain, 2021).

The assessment of the endocrine disruption (ED) potential for thiabendazole was discussed at the Pesticides Peer Review Experts' Teleconference 68 on Mammalian Toxicology and Ecotoxicology joint session on ED in January 2022. Advice from the EFSA ED Working Group was also provided and taken into account in the conclusions reached.

With regard to the assessment of the ED potential of thiabendazole **for humans** according to the ECHA/EFSA guidance (2018), the number and type of effects induced, and the magnitude and pattern of responses observed across studies were considered to determine whether thiabendazole interacts with the oestrogen, androgen and steroidogenesis (EAS) and thyroid (T)-mediated pathways. Additionally, the conditions under which the effects occur were examined, in particular, whether or not endocrine-related responses occurred at dose(s) that also resulted in overt toxicity. This assessment therefore provides a weight-of-evidence analysis of the potential interaction of thiabendazole with the EAS and T signalling pathways using the available evidence in the data set.

The data set for the **T-modality** was considered complete. There is evidence of a pattern of T-mediated adversity (i.e. follicular cell hypertrophy and hyperplasia observed in several studies in rats and in dog, follicular cell adenomas observed in the carcinogenicity study in rat) and endocrine activity (i.e. increased thyroid stimulating hormone (TSH), decreased T3, increased T4 clearance and distribution), therefore the Scenario 1b of the EFSA/ECHA (2018) ED Guidance applies.⁴ The uncertainty analysis indicated that a mode of action (MoA) based on increase in T4 clearance and drop in T4 is a possibility, but the empirical support is limited, and uncertainties exist for the dose concordance. The ED criteria established by Commission Regulation (EU) 2018/605 for the T-modality are met based on evidence of adverse thyroid effects in multiple studies conducted in rat and dog.

The data set for the **EAS-modalities** was considered incomplete with regard to the A- and S-modalities. However, the E-modality was considered sufficiently investigated since a ToxCast oestrogen receptor (ER) model is available and negative, therefore in line with the EFSA/ECHA (2018) ED Guidance the ED criteria for the **E-modality** are not met for humans.

Thus, further data need to be generated before a conclusion on whether or not the ED criteria are met for the AS-modalities can be drawn (Scenario 2a(iii) of the EFSA/ECHA (2018) ED Guidance⁵). To investigate the **A- and S-modalities,** the following tests would be needed:

• **A-modality:** A study in line with OECD Test Guideline (TG) 458 (Stably Transfected Human Androgen Receptor Activation Assay (AR STTA) assay);

S-modality:

A study in line with OECD TG 456 (H295R Steroidogenesis Assay);

An Aromatase assay (human recombinant) OPPTS 890.1200 (US EPA 2009 In: Endocrine Disruptor Screening Program Test Guidelines. Office of Prevention, Pesticides and Toxic Substances (OPPTS), US EPA, Washington (DC);

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⁴ See Section 3.4.4.1 of the ECHA/EFSA (2018) guidance: Scenario 1b – Adversity indicated by 'EATS-mediated' parameters.

⁵ See Section 3.4.4.2 of the ECHA/EFSA (2018) guidance: Scenario 2a – No adversity indicated by the `EATS-mediated' parameters, iii) No endocrine activity, but not sufficiently investigated.



In case of OECD TG 458, 456 and OPPTS 890.1200 are negative, a study in line with OECD TG 441 (Hershberger Assay) is required.

If the above studies are negative, the scenario 2a(ii) applies and the ED criteria are not met for ASmodalities. However, if these studies are positive for at least one modality, the scenario 2a(i) applies and further data would be needed to support the MoA analysis: a study in line with OECD TG 443 (with cohort 1a/1b including the mating of cohort 1b to produce the F2 generation, OECD, 2018).

Based on the available information, thiabendazole was considered to meet the ED criteria for humans for the T-modality according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, leading to a critical area of concern.

The conclusion that thiabendazole meets the ED criteria for humans for the T-modality cannot be applied to wild mammals as non-target organisms as the population relevance of the identified adversity (i.e. change in thyroid histopathology) could not be confirmed⁶.

The outcome of the assessment reported above for the EAS-modalities for humans also applies to wild mammals as non-target organisms.

For non-target organisms other than mammals, neither the endocrine activity nor the endocrine adversity was sufficiently investigated for the EATS-modalities. Therefore, additional data would be needed to draw a conclusion on the ED properties of thiabendazole on non-target organisms and in particular, a test according to OECD TG 231 (Amphibian Metamorphosis Assay (AMA)) (T-modality) and a test according to OECD TG 230^7 (21-day fish screening assay) including an assessment of gonad histopathology (EAS-modalities). These tests are relevant to investigate potential EATS-mediated endocrine activity and, if negative, to exclude that thiabendazole has endocrine properties, according to the scientific criteria for the determination of endocrine-disrupting properties as set out in point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) No 2018/605. However, in case of positive result/s based on these tests for at least one modality, additional testing (i.e. a test according to OECD TG 241 (Larval Amphibian Growth and Development Assay (LAGDA)) and/or a test according to OECD TG 240 (Medaka Extended One Generation Reproduction Test (MEOGRT)) might be needed in order to further investigate the adversity.

Based on the available information on non-target organisms, the assessment of the endocrine disruption potential of thiabendazole according to point 3.8.2 of Annex II to Regulation (EC) No 1107/ 2009, as amended by Commission Regulation (EU) 2018/605, cannot be concluded (data gap and issue not finalised).

2. Concerns and related data gaps

2.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011 and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related:

- 1) The assessment of the ED properties of thiabendazole cannot be finalised for the T**modality** and additional data would be needed for non-target organisms:
 - a) A test according to OECD TG 231 (Amphibian Metamorphosis Assay).

⁶ See report from the Pesticides Peer Review Experts' Teleconference TC 68 (EFSA, 2022).

⁷ Considering the similarity between the OECD TG 229 and OECD TG 230 and that an impact on fecundity/fertility as a parameter observed in a level 3 study would need further testing to confirm the adversity, the experts at the Pesticides Peer Review Experts' Teleconference TC 68 (EFSA, 2022) considered that the applicant's proposal for conducting a test in line with OECD TG 230 instead of OECD TG 229 is reasonable.



If the test is negative, the active substance will not meet the ED criteria for the T-modality for non-target organisms. However, in case of positive results, additional testing would be needed, i.e. a test according to OECD TG 241 (LAGDA).

- 2) The assessment of the ED properties of thiabendazole cannot be finalised for the EAS⁸-modalities and additional data would be needed for both humans and non-target organisms:
 - a) A study in line with OECD Test Guideline (TG) 458 (Stably Transfected Human Androgen Receptor Activation Assay (AR STTA) assay);
 - b) An aromatase assay (human recombinant) OPPTS 890.1200 (US EPA 2009 In: Endocrine Disruptor Screening Program Test Guidelines. Office of Prevention, Pesticides and Toxic Substances (OPPTS), US EPA, Washington (DC);
 - c) A study in line with OECD TG 456 (H295R Steroidogenesis assay);
 - d) A study in line with OECD TG 441 (Hershberger Assay) in case OECD TG 456, OPPTS 890.1200 and OECD TG 458 are negative;
 - e) A test according to OECD TG 230 (21-day fish screening assay) including an assessment of gonad histopathology.

If the above tests are negative, the active substance will not meet the ED criteria for EAS-modalities for humans and/or non-target organisms. However, in case of positive result/s for at least one modality, additional testing would be needed:

- f) A test according to OECD TG 443 (with cohort 1a/1b including the mating of cohort 1b to produce the F2 generation, OECD, 2018);
- g) A test according to OECD TG 240 (Medaka Extended One Generation Test) for further investigating adversity in fish.

The data gaps/issues not finalised are not relevant for an overall conclusion on the endocrinedisrupting properties since the criteria are already met for the T-modality based on a complete data set with respect to humans.

2.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29 (6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:

3) Thiabendazole is considered to meet the criteria for endocrine disruption for humans for the T-modality according to point 3.6.5 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605 (see Section 1).

⁸ For humans, the endocrine activity for the E modality was sufficiently investigated and negative. The ER ToxCast model was available as explained in Section 1. Therefore, the E modality would need only to be further investigated for non-target organisms.



3. List of other outstanding issues

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant:

Other outstanding issues were not identified.

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Abbreviations

EATS oestrogen, androgen, thyroid, steroidogenic

ECHA European Chemicals Agency

ED endocrine disruption

EEC European Economic Community

FAO Food and Agriculture Organization of the United Nations

ISO International Organization for Standardization
IUPAC International Union of Pure and Applied Chemistry
LAGDA Larval Amphibian Growth and Development Assay

mm millimetre (also used for mean measured concentrations)
OECD Organisation for Economic Co-operation and Development

ppm parts per million (10^{-6}) r^2 coefficient of determination SC suspension concentrate

SMILES simplified molecular-input line-entry system

T-modality Thyroid-modality

TSH thyroid stimulating hormone (thyrotropin)
US EPA United States Environmental Protection Agency

WHO World Health Organization



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Appendix A – Consideration of cut-off criteria for thiabendazole according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties	Conclusion
Endocrine-disrupting properties	Thiabendazole is considered to meet the criteria for endocrine disruption for humans for the T-modality according to point 3.6.5 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605.
	The endocrine-disrupting properties of thiabendazole for non-target organisms according to point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 could not be concluded.



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Appendix B – Used compound codes

Code/trivial name	IUPAC name/SMILES notation/InChiKey ^(a)	Structural formula(b)
Thiabendazole	2-(thiazol-4-yl)-1 <i>H</i> -benzimidazole [NH]1c2cccc2nc1c1cscn1 WJCNZQLZVWNLKY-UHFFFAOYSA-N	NH S N N

⁽a): ACD/Name 2021.1.3 ACD/Labs 2021 Release (File version N15E41, Build 123232, 8 July 2021).

⁽b): ACD/ChemSketch 2021.1.3 ACD/Labs 2021 Release (File version C25H41, Build 123835, 29 August 2021).