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STATEMENT



# Statement on the refined environmental risk assessment and impact of the new classification for captan

**European Food Safety Authority (EFSA)** 

Correspondence: pesticides.peerreview@efsa.europa.eu

## Abstract

On 24 July 2020, the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance captan drawn in the context of the renewal of approval of the active substance captan conducted in accordance with Commission Implementing Regulation (EC) No 844/2012 was approved. In December 2023, the European Commission asked EFSA to provide a statement on its view as regards the RMS's revised environmental risk assessment concerning some uses in pome fruits and cherries and the potential impact of the recent new classification recommended by RAC on the toxicological reference values of captan stated in the EFSA Conclusion. The current statement contains the conclusions of the considerations related to the environmental revised risk assessment performed by the RMS, Austria, and to the new classification proposed by RAC on the toxicological reference values.

#### K E Y W O R D S

Captan, classification, ecotoxicology assessment, environmental fate and behaviour, fungicide, peer review, pesticide

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# SUMMARY

Captan is an active substance covered by the third stage of the renewal programme for pesticides ('AIR3') in accordance with Commission Implementing Regulation (EU) No 844/2012.

The rapporteur Member State (RMS), Austria, and co-rapporteur Member State (co-RMS), Italy, received an application from ADAMA Agriculture BV (on behalf of ADAMA Makhteshim Ltd.) and Arysta LifeScience S.A.S. for the renewal of approval of the active substance captan. In addition, the applicant submitted a maximum residue level (MRL) application form for the evaluation of confirmatory data following review according to Article 12 of Regulation (EC) No 396/2005. An initial evaluation of the dossier on captan was provided by the RMS in the renewal assessment report (RAR), and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by the European Food Safety Authority (EFSA) in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659.

The EFSA conclusion on the peer review of the pesticide risk assessment of the active substance captan was approved on 24 July 2020. The EFSA conclusion identified, among other concerns, risks from field uses to birds and mammals (longterm), aquatic organisms and honeybees (chronic adults and larvae).

Following several discussions at the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) between March 2021 and July 2023, the RMS sent to the Commission a revised risk assessment, indicating that certain outdoor uses would lead to acceptable risks provided that a number of conditions are respected.

Furthermore, on 14 September 2023, the ECHA Risk Assessment Committee (RAC) has adopted an opinion to classify captan, in addition to the existing categories, also as toxic to reproduction Category 2, STOT RE1 and Aquatic Chronic Category 1.<sup>1</sup>

Subsequently, EFSA received a mandate by Commission in December 2023 to provide its view by 15 January 2024, as regards:

- the RMS's revised risk assessment concerning the uses in pome fruits, 6 × 1.2 kg a.s./ha (BBCH 51–85) and cherries, 2 × 1.8 kg a.s./ha (BBCH 53–87).<sup>2</sup>
- the potential impact of the new classification on the toxicological reference values (TRVs) stated in the EFSA Conclusion (2020).

The current statement presents the conclusions of the considerations related to the environmental revised risk assessment performed by the RMS, Austria, and to the new classification proposed by RAC.

A refined aquatic exposure assessment for captan application in orchards has been submitted. The new predicted environmental concentration (PEC) in surface water are based on a 60.7% reduction in application rates measured in a field test using precision spraying. However, the study's applicability to different orchards cannot be considered acceptable due to varied conditions. In addition, the proposed additional ground loss reduction of 20% used to refine the long-term risk to mammals is not considered applicable as not scientifically substantiated.

As regards non-target organisms, it is considered that a low risk to wild mammals, to bees and to aquatic organisms is not demonstrated by the available risk assessments.

Finally, as concerns the new classification of captan as toxic to reproduction Category 2, no impact on the toxicological reference values (TRVs) established in the EFSA conclusion is identified. However, according to the EFSA Conclusion (EFSA, 2020), the metabolites THPI and THPAM are found at > 0.1  $\mu$ g/L in the majority of the FOCUS groundwater scenarios for all the uses. As a consequence of the new classification of captan, the groundwater metabolites THPI and THPAM should become toxicologically relevant since their potential for reproductive toxicity has not been investigated.

# 1 | INTRODUCTION

Captan is an active substance covered by the third stage of the renewal programme for pesticides ('AIR3') in accordance with Commission Implementing Regulation (EU) No 844/2012.<sup>3</sup> In accordance with Article 1 of the Regulation, the rapporteur Member State (RMS), Austria, and co-rapporteur Member State (co-RMS), Italy, received an application from ADAMA Agriculture BV (on behalf of ADAMA Makhteshim Ltd.) and Arysta LifeScience S.A.S. for the renewal of approval of the active substance captan. In addition, the applicant submitted a maximum residue level (MRL) application form for the evaluation of confirmatory data following review according to Article 12 of Regulation (EC) No 396/2005.<sup>4</sup> An initial evaluation of the dossier on captan was provided by the RMS in the renewal assessment report (RAR) which was received by EFSA on 4 December 2017.

<sup>2</sup>The current EFSA Conclusion demonstrated that these two uses are safe for birds.

<sup>&</sup>lt;sup>1</sup>https://echa.europa.eu/documents/10162/61dcb37e-ab22-e25e-9891-181ae09413ef

<sup>&</sup>lt;sup>3</sup>Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.

<sup>&</sup>lt;sup>4</sup>Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

Subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by the European Food Safety Authority (EFSA) in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659.<sup>5</sup>

The EFSA conclusion on the peer review of the pesticide risk assessment of the active substance captan was approved on 24 July 2020. The EFSA conclusion identified among other concerns, risks from field uses to birds and mammals (longterm), aquatic organisms and honeybees (chronic adults and larvae).

Multiple discussions at the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) were held between March 2021 and July 2023. Regulatory decision-making could not be completed due to disagreements among Member States as many of them considered that safe field uses were possible by applying certain risk mitigation measures and refinements, including in particular also more realistic scenarios as regards pesticide application techniques within the representative uses referred to above.

In February 2023, the Rapporteur Member State (RMS) offered to refine the risk assessment for bird and mammals, bees and aquatic organisms. On 25 July 2023, the RMS sent to the Commission the results of the revised risk assessment (Austria, 2023), indicating that certain outdoor uses would lead to acceptable risks provided that a number of conditions are respected.

Furthermore, on 14 September 2023, the ECHA risk assessment committee (RAC) has adopted an opinion to classify captan, in addition to the existing categories, also as toxic to reproduction Category 2, STOT RE1 and Aquatic Chronic Category 1 (ECHA, 2023).

This statement presents the conclusions of the considerations related to the environmental revised risk assessment performed by the RMS, Austria, and the potential impact of the new classification adopted by RAC on the toxicological reference values (TRVs).

Given the importance of the revised risk assessment provided by the RMS, Austria, this document is considered as background document to this statement and thus is made publicly available.

# 1.1 | Background and terms of reference as provided by the requestor

EFSA was mandated by the European Commission on 5 December 2023 to provide a statement containing its view as regard:

- the RMS's revised risk assessment concerning the uses in Pome fruits, 6×1.2 kg a.s./ha (BBCH 51–85) and Cherries, 2×1.8 kg a.s./ha (BBCH 53–87).<sup>6</sup>
- the potential impact of the new classification on the TRVs stated in the EFSA Conclusion (EFSA, 2020).

EFSA was requested to complete this mandate by 15 January 2024.

# 2 | ASSESSMENT

# 2.1 Revised environmental risk assessment

The RMS, Austria, conducted a higher tier risk assessment for mammals (long term), honey bees (chronic adult honey bees and honey bee larvae) and aquatic organisms taking into account a reduced application rate due to optimisation of application techniques used in orchards. For reasons of completeness also the long-term risk for birds was included by the RMS. This last assessment was not further considered by EFSA as not part of the mandate received.

Furthermore, the RMS provided the environmental risk assessment for other uses in addition to the two representative uses specified in the mandate and EFSA did not consider these additional ones in its present statement.

The RMS conducted the higher tier risk assessment taking into account the reduced application rates, other refinement options on the top of the refinements agreed in the course of the peer review for the renewal of captan.

# 2.1.1 | Environmental fate and behaviour

#### Surface water exposure assessment

The RMS provided a refined risk assessment considering the reduction of the application rate by using specific application techniques based on literature data. An optimisation of the application rate by using precision spraying systems was

<sup>5</sup>Commission Implementing Regulation (EU) No 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No844/2012 in view of the scientific criteria for the determination of endocrine-disrupting properties introduced by Regulation (EU) 2018/605.

<sup>6</sup>The current EFSA Conclusion demonstrated that these two uses are safe for birds.

presented that resulted in a GAP defined application rates reduction by 60.7%, based on a published paper (Xun et al., 2022<sup>7</sup>), with this being the average of several values that were presented in the paper for a range of plant protection product categories that were investigated in the field trials reported. In this paper, the dose rate reduction for fungicides was seen at 55%. This outcome is based on field tests carried out in one Spanish orchard of 4.3 ha growing two apple varieties with a density of 2849 trees per ha and a row distance of 3.9 m with tree heights of 3.17–4 m. The spray distributions over the canopy were evaluated at three specific BBCH growth stages over the whole season. Taking into consideration the great variability in orchard crops characteristics (e.g. crop variety, training systems, pruning practices) and spraying systems, it seems therefore quite uncertain this application rate reduction might be duplicated for other apple orchards and cherry orchards. This conclusion is supported by the results from other literature data (Xun et al., 2023<sup>8</sup>) considered in the RMS's evaluation (Austria, 2023), where lower reduction rates of applied volume/pesticide were observed in very similar field experiments with apple tree plots in Spain. Indeed, in this research, a reduction of only 12% with the optimised spraying system following the best management practices, and a reduction of 43% with the precise system were observed.

Overall, based on the available information, a reduction of 60.7% of the application rates for the representative uses applied for is not justified for a regulatory exposure assessment at the EU level.

It should also be noted that no-spray buffer zones of 30 m, 40 m and 50 m applied in FOCUS Step 4 predicted environmental concentration in surface water ( $PEC_{SW}$ ) calculations would result in a reduction of drift of more than 95% which is beyond the limit recommended by the FOCUS landscape and mitigation guidance (FOCUS, 2007).

In conclusion, the refined PEC<sub>SW</sub> as proposed by the RMS cannot be considered acceptable.

#### Refinement of ground loss

The refined risk assessment to herbivorous mammals submitted by the RMS considered *'in addition to the deposition factors according to FOCUS an additional ground loss reduction of 20% due to the application techniques briefly described above was taken into account based on the available literature'.* However, neither the RMS's evaluation nor the submitted open literature provide information on how this specific drift reduction value of 20% in ground drift depositions was derived or elaborated. The scientific paper evaluating the spray drift potential of three spraying systems in an apple orchard at BBCH 72 and 99 (Xun et al., 2023) shows that the two advanced spraying systems exhibited a drift reduction when compared with the conventional system evaluated in the specific field tests: 23.3%–70.9% in ground drift, and 26.2%–84.6% in airborne drift. However, when the results are compared with the standard spray drift values used in the EU regulatory aquatic risk assessment, no significant ground loss reductions can be demonstrated taking into consideration the standard spray drift value of 15.7% at 3 m for pome/stone fruit, late applications as defined by FOCUS (2001) as updated in 2015.

In conclusion, the proposed additional ground loss reduction of 20% used to refine the long-term risk to mammals is not considered applicable and should be scientifically substantiated by additional information/data.

# 2.1.2 Amended environmental risk assessment for non-target organisms

#### Amended long-term risk assessment for mammals

The risk assessments considering the reduced application rate by 60.7% resulted in high risk for both representative uses of captan (6 applications of 1.2 kg a.s./ha at BBCH 51–85 to pome fruits and 2 applications of 1.8 kg a.s./ha at BBCH 53–87 to cherries). Additional refinement options were considered: (1) 20% reduction of spray volume deposition to ground vegetation, and (2) RUD values according to the EFSA's Guidance Document on Birds and Mammals (EFSA, 2023). With these refinements, a low risk was demonstrated for the two representative uses under reconsiderations. It is noted that – as explained in Section 2.1.1 above – the consideration to the additional 20% loss of spray volume deposition was not explicitly described in the available literature studies; therefore, the basis and the credibility of this value could not be examined. As regards the used RUD values, the Guidance Document on Birds and Mammals from 2023 has not been noted yet, therefore has not been used for risk assessments for active substances or plant protection products (PPPs).

A tabulated summary of the assessments is presented in Table 1, below.

#### Amended chronic risk assessment for honey bees (adult and larvae)

Risk assessments considering reduced application rate by 60.7% were provided for honey bees (for both the chronic adult and chronic larva risk cases) for both representative uses under reconsiderations. The risk assessments indicated high risk for several scenarios for both uses. Further considerations for the off-field scenarios (field margin, adjacent crop) were necessary for the use in pome fruit orchards. The exposure estimations were recalculated taking into account the use of drift reducing application techniques or no-spray buffer zones. The risk for these scenarios would be considered as low

<sup>&</sup>lt;sup>7</sup>Xun, L., Garcia-Ruiz, F., Fabregas, F. X., & Gil, E. (2022). Pesticide dose based on canopy characteristics in apple trees: Reducing environmental risk by reducing the amount of pesticide while maintaining pest and disease control efficacy, Science of the Total Environment, 826.

<sup>&</sup>lt;sup>8</sup>Xun, L., Campos, J., Salas, B., Fabregas, F. X., Zhu, H., & Gil, E. (2023). Advanced spraying systems to improve pesticide saving and reduce spray drift for apple orchards, Precision Agriculture, 24, 1526–1546.

provided if at least 65% drift reduction was achieved (besides the application rate reduction by 60.7%). Alternatively, it was indicated that a no-spray buffer zone of 30 m could be considered. As regards the treated crop scenario and the weeds in the treated field scenario, risk mitigation measures (i.e. SPe8 phrases that may be considered for PPP authorisation at member states level) were proposed for both uses. It should be noted that the effectiveness of these possible mitigation measures was not demonstrated. No refined calculations or risk mitigation measures were considered for the succeeding crop scenario, which represented a high risk for adult bees for both uses (but low risk for larvae). Furthermore, it should be noted that the available laboratory endpoints bear some uncertainties. The hazard might be overestimated by the available chronic adult endpoint, while the available larval study may underestimate the effects on brood development.

A tabulated summary of the assessments is presented in Table 1, below.

#### Amended risk assessment for aquatic organisms

According to the peer review from 2020 (EFSA, 2020), due to the degradation profile of captan in water bodies, only the acute scenario needs to be considered in the aquatic risk assessment. Even considering mitigation measures (FOCUS step 4 level), a high acute risk was concluded for fish and aquatic invertebrates for both representative uses under evaluation of the current mandate.

A laboratory study on fish was considered by the peer review to be suitable for a tier 2C risk assessment. In tier 2C, the exposure profile of the study needs to be compared to the exposure profile predicted by the FOCUS models. Refined FOCUS calculations considering reduced application rate by 60.7% were provided. In addition, non-spray buffer zones up to 50 m and a 20-m vegetated buffer strips mitigating water run-off was considered for these calculations. The exposure profiles predicted by these simulations were compared with the regulatory acceptable concentration (RAC) value derived from the above-mentioned study for fish. With the exemption of two scenarios (D3 and R2) for the representative use on cherry (and some partial scenarios for both uses), the predicted exposure profile was not fully covered by the exposure profile of the fish study (indicating that a high risk for those scenarios could not be excluded). Nevertheless, the RMS proposed that a low risk could be concluded for many other scenarios considering that the RAC and the no observed effect concentration (NOEC) derived from the study were significantly higher than the height of a single peak predicted by the FOCUS models (even if other dimensions of the peaks were not covered). However, when the assessment factor of 100 is considered for the NOEC (which would be justified), the margin of safety (the factor between the height of the peaks) is no longer significant. Moreover, the uncertainties identified in the peer review in 2020 should also be noted (e.g. lack of information on TK/TD). In addition, it should be noted that the FOCUS simulations considered risk mitigation measures that are beyond the recommended maximum mitigation level (see in Section 2.1.1 above). Therefore, the presented risk assessments for fish did not follow the agreed recommendations as described in the Aquatic guidance document (EFSA PPR Panel, 2013) and in FOCUS (2007).

No risk assessment addressing the identified acute risk for aquatic invertebrates was provided. The RMS considered that the acute risk for aquatic invertebrates should be covered by the risk assessment for fish, considering that the RAC for fish is lower than the RAC for aquatic invertebrates. However, this comparison considers only the endpoints, but does not include comparison of the exposure profiles. Nevertheless, the available endpoints indeed indicate that captan has a lower toxicity to aquatic invertebrates compared to fish. The comparison of the acute endpoints, however, bears some uncertainties because different design (static vs. semi-static) and different test items were used. Also, the available chronic endpoint for aquatic invertebrates indicated a lower toxicity; however, the exposure profile of captan in this study indicated a faster dissipation compared to the acute fish study.

A tabulated summary of the assessments is presented in Table 1, below.

	Representative use on pome fruits (6 × 1.2 kg a.s./ha at BBCH 51–85)	Representative use on cherries (2 × 1.8 kg a.s./ha at BBCH 53–87)
Wild mammals (critical scenario: small herbivorous mammals)	<ul> <li>20% reduction of spray volume deposition to ground vegetation, which was not sufficiently substantiated</li> <li>RUD values according to a not yet noted Guidance Document</li> </ul>	<ul> <li>20% reduction of spray volume deposition to ground vegetation, which was not sufficiently substantiated</li> <li>RUD values according to a not yet noted Guidance Document</li> </ul>
Bees (critical risk case: adult bees)	<ul> <li>Off-field scenarios: drift reduction that can be considered as feasible</li> <li>Treated crop and weed scenario: SPe8 phrases with no demonstration of their efficiency</li> <li>Succeeding crop scenario: none (high risk remains)</li> <li>Uncertainties regarding the used toxicity endpoints remained</li> </ul>	<ul> <li>Off-field scenarios: none (low risk remains)</li> <li>Treated crop and weed scenario: SPe8 phrases with no demonstration of their efficiency</li> <li>Succeeding crop scenario: none (high risk remains)</li> <li>Uncertainties regarding the used toxicity endpoints remained</li> </ul>

TABLE 1 Summary of the refinement options and risk mitigation measures considered by the RMS on the top of the application rate reduction of 60.7%

	Representative use on pome fruits (6 × 1.2 kg a.s./ha at BBCH 51–85)	Representative use on cherries (2 × 1.8 kg a.s./ha at BBCH 53–87)
Aquatic organisms (critical risk cases: acute fish and acute aquatic invertebrates)	<ul> <li>Fish</li> <li>Drift reduction that are beyond the recommended maximum mitigation level</li> <li>Expert judgement that was not considered suitable by EFSA; in addition, uncertainties were identified <u>Aquatic invertebrates</u></li> <li>Chronic endpoints for aquatic invertebrates and the risk assessment for fish were considered that approach was not considered suitable by EFSA</li> </ul>	<ul> <li>Fish</li> <li>Drift reduction that are beyond the recommended maximum mitigation level</li> <li>Expert judgement that was not considered suitable by EFSA (the expert judgement was not necessary for scenarios D3 and R2); in addition, uncertainties were identified</li> <li>Aquatic invertebrates</li> <li>Chronic endpoints for aquatic invertebrates and the risk assessment for fish were considered that approach was not considered suitable by EFSA</li> </ul>

Note: Safe scenarios are indicated in bold.

# 2.2 New classification

In the EFSA conclusion (EFSA, 2020), no potential for reproductive toxicity was identified. Agreed TRVs were as follows:

	Value mg/kg bw (per day)	Study	NOAEL mg/kg bw per day	LOAEL mg/kg bw per day	UF
ADI	0.25	Rat, 2-year, and rat, multigeneration (parental and offspring NOAEL)	25	100	100
ARfD	0.9	Rat, developmental	90	450	100
AOEL	0.25	Rat, multigeneration (parental and offspring NOAEL)	25	100	100
AAOEL	0.9	Rat, developmental	90	450	100

Abbreviations: AAOEL, acute acceptable operator exposure level; ADI, acceptable daily intake; AOEL, acceptable operator exposure level; ARfD, acute reference dose; UF, uncertainty factor.

Captan has been proposed to be classified as toxic to reproduction Category 2 based on the effects observed in pubertal developmental studies at 100 and 200 mg/kg bw per day in males and 300 and 600 mg/kg bw per day in females (ECHA, 2023).

The same studies were evaluated by the peer review experts in the context of the ED assessment according to the ECHA/ EFSA Guidance (ECHA-EFSA, 2018). Indeed, in determining whether captan interacts with the oestrogen, androgen and steroidogenesis (EAS) and thyroid (T) mediated pathways, the number and type of effects induced, and the magnitude and pattern of responses observed across studies were considered. Additionally, the conditions under which effects occur were considered, in particular, whether or not endocrine-related responses occurred at dose(s) that also resulted in overt toxicity. The ED assessment therefore provides a weight-of-evidence analysis of the potential interaction of captan with the EAS and T signalling pathways using the available evidence in the data set.

In the male and female pubertal studies, EAS-mediated adverse effects were observed at doses exerting systemic toxicity and considered to possibly exceed the maximum tolerated dose (MTD). Therefore, the findings observed in these studies were not considered as sufficient evidence of an EAS-mediated pattern of adversity.

The no observed adverse effect level (NOAEL) for reproductive toxicity was established at 500 mg/kg bw per day, based on the multigeneration study in rat in which no effects were observed up to the highest tested dose. It is noted that while many parameters evaluated in the pubertal studies were not investigated in the multigeneration study, some limitations on the use of pubertal studies (oral gavage administration, two tested doses only, sensitivity of the population to systemic toxicity effects) were considered in not using these studies for setting the TRVs, but only as part of the weight of evidence for ED assessment. Based on this, the established TRVs of captan are still considered appropriate even when taking into account the new classification proposed by RAC.

Finally, according to the EFSA Conclusion (EFSA, 2020), the metabolites THPI and THPAM are found at > 0.1  $\mu$ g/L in the majority of the FOCUS groundwater scenarios for all the uses. As a consequence of the new classification of captan, the groundwater metabolites THPI and THPAM should become toxicologically relevant since their potential for reproductive toxicity has not been investigated.

# 3 | CONCLUSIONS

A refined aquatic exposure assessment for captan application in orchards has been submitted. The new PEC in surface water are based on a 60.7% reduction in application rates measured in a field test using precision spraying. However, the study's applicability to different orchards cannot be considered acceptable due to varied conditions. The proposed risk assessment for herbivorous mammals incorporates a 20% ground loss reduction due to insufficient scientific support.

As regards non-target organisms, it is considered that a low risk to wild mammals, to bees and to aquatic organisms is not demonstrated by the available risk assessments considering the guidance documents in place.

Finally, as concerns the new classification of captan as toxic to reproduction Category 2, no impact on the TRVs established in the EFSA conclusion is identified. However, according to the EFSA Conclusion (EFSA, 2020), the metabolites THPI and THPAM are found at > 0.1  $\mu$ g/L in the majority of the FOCUS groundwater scenarios for all the uses. As a consequence of the new classification of captan, the groundwater metabolites THPI and THPAM should become toxicologically relevant since their potential for reproductive toxicity has not been investigated.

# 4 | DOCUMENTATION AS PROVIDED TO EFSA

Austria (2023).

# ABBREVIATIONS

a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
bw	body weight
EAST	oestrogen, androgen, steroidogenesis and thyroid modalities
ECHA	European Chemicals Agency
ED	Endocrine Disruptor
GAP	Good Agricultural Practices
LOAEL	lowest observable adverse effect level
MRL	maximum residue level
MTD	maximum tolerated dose
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
PAFF Committee	Standing Committee on Plants, Animals, Food and Feed
PEC <sub>sw</sub>	predicted environmental concentration in surface water
PPP	Plant Protection Product
RAC	regulatory acceptable concentration
RAC	Committee for Risk Assessment
RMS	Rapporteur Member State
RAR	Renewal Assessment Report
RUD	residue per unit dose
TK/TD	toxicokinetic/toxicodynamic
TRV	toxicological reference value
UF	Uncertainty factor

# **CONFLICT OF INTEREST**

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

# REQUESTOR

European Commission

# **QUESTION NUMBER**

EFSA-Q-2023-00879

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