

## SCIENTIFIC OPINION

# Safety of a feed additive consisting of diclazuril (Clinacox® 0.5%) for chickens for fattening and chickens reared for laying (Elanco GmbH)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) | Roberto Edoardo Villa | Giovanna Azimonti | Eleftherios Bonos | Henrik Christensen | Mojca Durjava | Birgit Dusemund | Ronette Gehring | Boet Glandorf | Maryline Kouba | Marta López-Alonso | Francesca Marcon | Carlo Nebbia | Alena Pechová | Miguel Prieto-Maradona | Katerina Theodoridou | Antonio Finizio | Thomas Poiger | Ivana Teodorovic | Maria Vittoria Vettori | Jaume Galobart | Orsolya Holczknecht

**Correspondence:** [Ask a Question](#)

The declarations of interest of all scientific experts active in EFSA's work are available at <https://open.efsa.europa.eu/experts>.

**Abstract**

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety of the coccidiostat diclazuril (Clinacox® 0.5%) for chickens for fattening and chickens reared for laying. The FEEDAP Panel has recently adopted an opinion on Clinacox® 0.5% for the renewal of its authorisation. In that opinion, the safety of the additive for the target species, consumer and user, as well as the efficacy was confirmed; however, no conclusions could be made on the safety for the environment due to major data gaps. Based on the new data submitted, it can be concluded that the use of diclazuril from Clinacox® 0.5% in complete feed for chickens for fattening and chickens reared for laying at a maximum level of 1 mg/kg complete feed does not pose a risk for the terrestrial and aquatic compartments, including sediment. No concern for groundwater is expected. No risk for secondary poisoning is identified.

**KEYWORDS**

chickens, Clinacox® 0.5%, coccidiostats, diclazuril, environment, safety

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs](#) License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

© 2026 European Food Safety Authority. *EFSA Journal* published by Wiley-VCH GmbH on behalf of European Food Safety Authority.

## CONTENTS

Abstract.....	1
1. Introduction .....	3
1.1. Background and Terms of Reference as provided by the requestor.....	3
2. Data and Methodologies.....	3
2.1. Data.....	3
2.2. Methodologies.....	3
3. Assessment.....	3
3.1. Safety for the environment.....	4
3.1.1. Phase I.....	4
3.1.1.1. Physico-chemical properties .....	4
3.1.1.2. Fate and behaviour.....	4
3.1.1.2.1. Fate in soil.....	4
3.1.1.3. Phase I predicted environmental concentrations.....	5
3.1.2. Phase II.....	6
3.1.2.1. Exposure assessment.....	6
3.1.2.1.1. Ecotoxicity studies.....	6
3.1.2.1.2. Risk characterisation (PEC/PNEC ratio).....	8
3.1.2.1.3. Risk of secondary poisoning.....	8
3.1.3. Conclusions on safety for the environment .....	9
4. Conclusions.....	9
Abbreviations .....	9
Acknowledgements.....	9
Requestor.....	9
Question number.....	9
Copyright for non-EFSA content.....	10
Panel members.....	10
Legal notice .....	10
References.....	10

## 1 | INTRODUCTION

### 1.1 | Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003 establishes the rules governing the Union authorisation of additives for use in animal nutrition; in particular, Article 9 defines the terms of the authorisation by the Commission. The applicant is seeking a Union authorisation of the feed additive described in [Table 1](#).

**TABLE 1** Description of the substances.

Category of additive	Coccidiostats and histomonostats
Functional group of additive	–
Description	Diclazuril (Clinacox® 0.5%)
Target animal category	Chickens for fattening and chickens reared for laying
Applicant	Elanco GmbH
Type of request	New opinion – Request for scientific opinion pursuant to Article 29(1)(a) of Regulation (EC) No 178/2002

On 27.6.2024, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), in its opinion on the safety and efficacy of a feed additive consisting of diclazuril (Clinacox® 0.5%) as coccidiostats and histomonostats for chickens for fattening and chickens reared for laying, could not conclude on the safety for the environment of diclazuril from Clinacox® 0.5% due to major data gaps in the dossier submitted.

The European Commission gave the possibility to the applicant to submit supplementary information and data to complete the assessment and to allow a revision of the EFSA opinion.

The new supplementary information and data have been transmitted by the applicant using the E-Submission Food Chain Platform (application number FEED-2025-00660).<sup>1</sup>

In view of the above and in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002, the European Commission requests EFSA to deliver a new scientific opinion on the feed additive consisting of diclazuril (Clinacox® 0.5%) for chickens for fattening and for chickens reared for laying under the conditions of Regulation (EC) No 1831/2003, based on the supplementary information and data submitted by the applicant.

## 2 | DATA AND METHODOLOGIES

### 2.1 | Data

The present assessment is based on data submitted by the applicant in the form of supplementary information<sup>2</sup> to a previous application on the same product.<sup>3</sup> The dossier was received on 21 November 2025 and the general information and supporting documentation are available on Open.EFSA at <https://open.efsa.europa.eu/questions/EFSA-Q-2025-00660>.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' knowledge, to deliver the present output.

### 2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety of diclazuril (Clinacox® 0.5%) is in line with the principles laid down in Regulation (EC) No 429/2008<sup>4</sup> and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019).

## 3 | ASSESSMENT

The additive under assessment diclazuril (Clinacox® 0.5%) is currently authorised as a coccidiostat in chickens for fattening and chickens reared for laying (up to 16 weeks) at a level of 1 mg diclazuril/kg complete feed.

<sup>1</sup>The E-Submission Food Chain Platform (<https://webgate.ec.europa.eu/esfc>).

<sup>2</sup>Dossier reference: FEED-2025-36604.

<sup>3</sup>Dossier reference: EFSA-Q-2020-00201 and EFSA-Q-2020-00203 (FAD-2019-0087 and FEED-2020-0015).

<sup>4</sup>Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

In a previous opinion on the renewal of the authorisation of Clinacox 0.5% (EFSA FEEDAP Panel, 2024), the safety of the additive for the target species, consumer and user as well as the efficacy was confirmed; however, no conclusions could be made on the safety for the environment due to major data gaps (EFSA FEEDAP Panel, 2024).

The applicant has submitted additional data to cover the limitations identified in the previous opinion which are assessed below.

### 3.1 | Safety for the environment

#### 3.1.1 | Phase I

##### 3.1.1.1 | Physico-chemical properties

The physico-chemical properties used for the environmental risk assessment of diclazuril are summarised in Table 2 (EFSA FEEDAP Panel, 2024).

**TABLE 2** Physico-chemical properties of diclazuril used for the assessment.

Property	Value
<b>Molecular weight (g/mol)</b>	407.64
<b>Dissociation constant pKa</b>	5.92
	< 10 <sup>-6</sup> g/L (distilled water)
	< 10 <sup>-3</sup> (pH 1.1)
<b>Solubility<sup>(1)</sup> (g/L)</b>	< 10 <sup>-3</sup> (pH 6.0)
	10 <sup>-3</sup> (pH 8.0)
	10 <sup>-2</sup> (pH 10.2)
<b>Octanol/water partition coefficient (log K<sub>ow</sub>)<sup>(2)</sup></b>	4.01 (pH 5)
	4.41 (pH 7)
	4.54 (pH 8)
	0.78 × 10 <sup>-4</sup> (10°C)
<b>Vapour pressure (Pa)</b>	1.85 × 10 <sup>-4</sup> (20°C)
	4.10 × 10 <sup>-4</sup> (30°C)

<sup>(1)</sup>Shake flask method.

<sup>(2)</sup>Measured at 25°C based on OECD Test Guideline 107, (shake flask method).

##### 3.1.1.2 | Fate and behaviour

In its former opinion, the FEEDAP Panel was not in the position to derive reliable adsorption/desorption constant (K<sub>OC</sub>) and degradation time (DT<sub>50</sub>) values due to the limitations of the studies submitted. In the same assessment, information was submitted on the fate in manure and water. New studies on the fate in soil, submitted for the current application, are assessed below.

###### 3.1.1.2.1 | Fate in soil

###### Adsorption

The applicant submitted an adsorption/desorption study conducted in accordance with OECD Testing Guideline (TG) 106. The test was performed using five mineral soils covering a wide range of pH (about 4–7.5), texture and organic carbon.<sup>5</sup> Validity criteria were met: control mass balances were about 89%–95%, soil mass balances in Tier 1 mostly 90%–110%, limit of quantification of the analytical method was well below test concentrations, recoveries were within established criteria and equilibrium times were justified by kinetics. The test item concentration in the aqueous phases and soil extracts was analysed by LC-MS/MS. The adsorption equilibrium was reached after 24 h. During Tier 2 and 3, to allow for an accurate determination of adsorption, the direct method was chosen for LabSoil F by determining the amount of test items in the aqueous phase as well as in the soil extract. For all the other soil types, result evaluation was based on the indirect method by calculating the test item amount in the soil phase based on the amount determined in the aqueous phase. The adsorption values and corresponding adsorption (K<sub>d</sub> and K<sub>OC</sub>) coefficients are given in Table 3.

<sup>5</sup>Annex III\_04\_33\_Publ ELA241459-1763732261604.

**TABLE 3** Adsorption of diclazuril in different soils.

Soil	Texture class	Adsorption (L/kg)	
		$K_d$	$K_{oc}$
2.1	Sand	47.96	6851
2.4N	Clay loam	130.70	5732
6S	Clay	85.95	5178
LabSoil B1	Sandy loam	289.83	12,939
LabSoil F	Silt loam	1058.84	15,480
<b>Geometric mean</b>			<b>8356</b>

Diclazuril exhibits strong sorption to soil organic carbon, indicating low mobility.

### Degradation

The aerobic transformation rate and route of [ $^{14}$ C] diclazuril in soil were investigated in four different soil types in accordance with OECD TG 307.<sup>6</sup> The study shows that diclazuril is degraded slowly, primarily forming non-extractable residues and moderate mineralisation. No degradation products with >5% applied radioactivity (AR) were observed. The overall mass balance was 95.7% AR at the end of the test. The soil characteristics and the degradation time (DT<sub>50</sub>) calculated according to the most appropriate kinetics are reported in Table 4.

**TABLE 4** Diclazuril DT<sub>50</sub> values in four different soils at a test temperature of 20°C.

Soil	Texture class	pH	C <sub>org</sub>	DT <sub>50</sub> (days)	Kinetics
2.1	Sand	4.9	0.8	326	SFO
2.2	Sandy loam	5.6	1.8	235	SFO
2.3	Sandy loam	5.7	0.8	349	DFOP (slow phase)
6S	Clay	7.3	1.7	140	SFO
<b>Geometric mean</b>				<b>247</b>	

Abbreviations: DFOP, Double first-order in parallel kinetics; SFO, Single first-order kinetics.

No pH dependency was observed; therefore, the geometric mean DT<sub>50</sub> normalised to 12°C results in a value of 524 days, which will be used for further assessment.

### Conclusions on fate and behaviour

The following values will be used for exposure assessment:  $K_{oc}$  of 8356 L/kg and a DT<sub>50</sub> of 524 days (at 12°C).

#### 3.1.1.3 | Phase I predicted environmental concentrations

The Phase I predicted environmental concentrations (PECs) are reported in Table 5.

**TABLE 5** Phase I PECs for diclazuril.

Input	Value
Dose (mg diclazuril/kg feed)	1
Molecular weight	407.64
Vapour pressure (Pa)	$1.85 \times 10^{-4}$
Solubility (mg/L)	1
$K_{oc}$ (L/kg)	8356
DT <sub>50</sub> at 12°C (days)	524
<b>Output</b>	
PEC <sub>soil</sub> (µg/kg)	15
PEC <sub>groundwater</sub> (µg/L)	0.02

<sup>6</sup>Annex III\_04\_34\_Publ ELA241460.

No concern is expected for groundwater when diclazuril is used according to the requested dose. The trigger of Phase I is not respected for soil; therefore, a Phase II is needed.

### 3.1.2 | Phase II

#### 3.1.2.1 | Exposure assessment

Considering the persistence of diclazuril ( $DT_{50}$  at 12°C = 524 days), the PECs were refined for accumulation (Table 6).

**TABLE 6** Refined predicted environmental concentration of diclazuril.

Input	Value
Dose (mg diclazuril/kg feed)	1
Molecular weight	407.64
Vapour pressure (Pa)	$1.85 \times 10^{-4}$
Solubility (mg/L)	1
$K_{OC}$ (L/kg)	8356
$DT_{50}$ at 12°C (days)	524
<b>Output</b>	
PEC <sub>soil plateau</sub> (µg/kg)	39
PEC <sub>groundwater</sub> (µg/L)	0.06
PEC <sub>surface water</sub> (µg/L)	0.02
PEC <sub>sediment</sub> (µg/kg)	16

##### 3.1.2.1.1 | Ecotoxicity studies

In its former opinion, the FEEDAP Panel was not in a position to conclude on the effects of diclazuril in terrestrial plants and aquatic organisms due to the limitations of the studies submitted. In the same assessment, information was evaluated on the effects of diclazuril on earthworms and soil microorganisms. The new information on the effect of diclazuril on terrestrial and aquatic organisms is assessed below.

#### Toxicity to soil organisms

##### Effects on plants

A new Terrestrial Plant Seedling Emergence and Seedling Growth Test with diclazuril was performed following OECD TG 208.<sup>7</sup> The study was declared to be good laboratory practice (GLP) compliant. Diclazuril was tested for effects on seedling emergence and seedling growth of eight plant species from eight different plant families, six dicotyledonous (turnip, radish, common bean, wild carrot, cucumber, tomato) and two monocotyledonous species (perennial ryegrass, onion), in five test concentrations (range from 62.5 to 1000 mg/kg). The test item was mixed with fine quartz sand, and the mixture was added to soil (sandy loam) and thoroughly mixed. The analytical recovery rate of the test substance in the treated soil samples was between 94% and 110% of the nominal value. The study was well performed, valid and the results are reliable. No statistically significant reduction in emergence rate, survival or growth (fresh weight) was observed for any plant species at any treatment tested. No relevant phytotoxic effects were observed for any species tested. Therefore, the no observed effect concentration (NOEC) of > 1000 mg/kg has been selected for the risk assessment.

##### Effects on earthworms

The acute toxicity of diclazuril to *Eisenia foetida* and to the earthworm *Lumbricus terrestris* was evaluated in the previous FEEDAP opinion (EFSA FEEDAP Panel, 2024). In the first study, the lethal concentration ( $LC_{50}$ ) at day 14 was > 1000 mg/kg dry weight (dw). In the second study, there was no significant difference in weight change or survival between control and treated groups at an exposure rate of 1100 mg/kg dw soil.

<sup>7</sup>Annex III\_04\_35\_Publ ELA241464.

### Soil microorganisms

The effects of diclazuril on soil microorganisms were evaluated by the FEEDAP Panel in 2024 (EFSA FEEDAP Panel, 2024). The study is considered valid for the current assessment since the tested concentrations were higher than  $PEC_{\text{soil plateau}}$  (39  $\mu\text{g}/\text{kg}$ ) and  $10 \times PEC_{\text{soil plateau}}$ , and all values remained within a 10% limit when expressed as a reduction with respect to the control.

### Toxicity to aquatic organisms.

#### Effects on algae

The effect of diclazuril on the green algae *Pseudokirchneriella subcapitata* was evaluated in a study performed in line with OECD TG 201, OECD TG 23 and SANTE/2020/12830<sup>8</sup> and claimed to be in line with GLP principles. The algal species was exposed to nominal concentrations of 38.8, 85.4, 188, 413, 909 and 2000  $\mu\text{g}$  test item/L (each prepared in 100  $\mu\text{L}$  dimethylformamide (DMF)/L), with three replicates per test concentration. In addition, both a control and a solvent control (six replicates each) were included. The test duration was 72 h. To assess the stability of the test item, concentrations of diclazuril in the test media were measured at test start (101% of nominal) and after 72 h (97% of nominal), confirming adequate stability. Consequently, biological endpoints were evaluated using nominal concentrations. All validity criteria were fulfilled. Under the conditions of the study, the 72-h  $E_rC_{50}$  for *P. subcapitata* was  $> 2000 \mu\text{g}/\text{L}$ .

#### Effects on crustaceans

The acute toxicity of diclazuril to *Daphnia magna* under static conditions was evaluated in a GLP-compliant study conducted according to OECD TG 202, OECD TG 23 and SANTE/2020/12830.<sup>9</sup> Neonate daphnids ( $< 24$  h old) were exposed to nominal concentrations of 229, 366, 586, 938 and 1500  $\mu\text{g}$  test item/L (each prepared in 100  $\mu\text{L}$  DMF/L), alongside a solvent control (100  $\mu\text{L}$  DMF/L) and an untreated control. The test duration was 48 h, with four replicates for each test concentration as well as for the solvent and untreated controls. Mortality and immobilisation were inspected and recorded at 24-h intervals throughout the 48-h exposure period. All validity criteria were fulfilled. Under the conditions of the study, the 48-h  $EC_{50}$  of diclazuril for *D. magna* was 826  $\mu\text{g}/\text{L}$ .

#### Effects on fish

The acute toxicity of diclazuril to rainbow trout (*Oncorhynchus mykiss*) was investigated in a GLP-compliant study conducted in accordance with OECD TG 202, OECD TG 23 and SANTE/2020/12830.<sup>10</sup> The test was performed under static exposure conditions for 96 h. Juvenile rainbow trout were exposed to nominal concentrations of 19.1, 34.3, 61.7, 111 and 200  $\mu\text{g}/\text{L}$  of diclazuril, each prepared in 100  $\mu\text{L}$  DMF/L, together with a solvent control (100  $\mu\text{L}$  DMF/L). To assess the stability of the test item, concentrations in the test media were measured at the start and end of the exposure. As the measured concentrations deviated by more than  $\pm 20\%$  from the initial values, endpoints were evaluated using time-weighted average concentrations. The study met all validity criteria, and the 96-h  $LC_{50}$  for diclazuril was 69.2  $\mu\text{g}/\text{L}$ .

#### Effects on sediment-dwelling organisms

In the former opinion, the FEEDAP Panel assessed a study on the effects of diclazuril on sediment-dwelling organisms using *Chironomus tentans* according to ASTM 1992 standard guide for conducting sediment toxicity tests with freshwater invertebrates. NOECs for the emergence and development rate were determined as 7.31 mg diclazuril/kg dry soil and 7.31 mg/kg dry sediment, respectively (EFSA FEEDAP Panel, 2024).

A new study was submitted for the current application to assess the effects of diclazuril in a sediment-water toxicity test using spiked sediment on *Chironomus riparius*.<sup>11</sup> The study presents several shortcomings that prevent its use to support the environmental safety assessment. Recoveries were very low (12%–41%), and exposure concentrations were not maintained throughout the test (4.13 mg/kg on Day 0; 1.16 mg/kg on Day 28). The study itself suggests that a non-homogeneous distribution of diclazuril in the sediment may have contributed to these inconsistencies, thereby potentially compromising actual organism exposure. Consequently, the study is considered invalid and cannot be used for risk assessment.

Considering that the first study is rather old and the limitations in the second study, the FEEDAP Panel considered it more appropriate to assess the risk for the sediment through the equilibrium partitioning approach (EFSA FEEDAP Panel, 2019).

<sup>8</sup>Annex III\_04\_36\_Publ ELA241461.

<sup>9</sup>Annex III\_04\_37\_Publ ELA241462.

<sup>10</sup>Annex III\_04\_38\_Publ ELA241463.

<sup>11</sup>Annex III\_04\_40\_Publ 036-007.

## 3.1.2.1.2 | Risk characterisation (PEC/PNEC ratio)

The risk characterisation ratios between the PECs and the predicted no effects concentrations (PNECs) for terrestrial and freshwater compartments are reported in Tables 7 and 8.

**TABLE 7** Risk characterisation (PEC/PNEC ratio) for the terrestrial compartment.

Taxa	PEC <sub>soil</sub> (µg/kg)	LC <sub>50</sub> or NOEC (mg/kg)	AF	PNEC (µg/kg)	PEC/PNEC
Earthworms	39	> 1000 <sup>(1)</sup>	1000	1000	0.039
Plants		> 1000 <sup>(2)</sup>	10	100,000	0.00039

Abbreviation: AF, assessment factor.

<sup>(1)</sup>LC<sub>50</sub>.

<sup>(2)</sup>NOEC.

**TABLE 8** Risk characterisation (PEC/PNEC ratio) for the freshwater compartment.

Taxa	PEC <sub>surface water</sub> (µg/L)	E <sub>(r)</sub> (L)C <sub>50</sub> (µg/L)	AF	PNEC (µg/L)	PEC/PNEC
Algae	0.02	> 2000 <sup>(1)</sup>	1000	0.0692	0.3
Aquatic invertebrates		826 <sup>(2)</sup>			
Fish		69.2 <sup>(3)</sup>			

Abbreviation: AF, assessment factor.

<sup>(1)</sup>E<sub>r</sub>C<sub>50</sub>.

<sup>(2)</sup>EC<sub>50</sub>.

<sup>(3)</sup>LC<sub>50</sub>.

For the sediment compartment, the PNEC was derived from the PNEC of surface water by the equilibrium partitioning method (EFSA FEEDAP Panel, 2019). Considering the PNEC<sub>surface water</sub> of 0.0692 µg/L, the PNEC<sub>sediment</sub> is 61 µg/kg. Taking this value into account, the risk characterisation for the sediment compartment is reported in Table 9.

**TABLE 9** Risk characterisation (PEC/PNEC ratio) for the sediment compartment.

PEC <sub>sediment</sub> (µg/kg)	PNEC (µg/kg) <sup>(1)</sup>	PEC/PNEC
16	61	0.3

<sup>(1)</sup>Calculated from PNEC<sub>surface water</sub> with the equilibrium partitioning method.

## 3.1.2.1.3 | Risk of secondary poisoning

Based on the logK<sub>ow</sub> of 4.54 (see Table 2), diclazuril has the potential to bioaccumulate; therefore, the risk of secondary poisoning has to be assessed. In the former opinion, the FEEDAP Panel could not conclude on this aspect due to lack of data (EFSA FEEDAP Panel, 2024). In the current assessment, the applicant submitted new information that allowed the evaluation of the risk of secondary poisoning.

To assess the risk of secondary poisoning for worm/fish-eating birds and mammals via the food web chain, the method proposed in the relevant Guidance from the European Medicines Agency (EMA) has been considered (EMA, 2016). The highest logK<sub>ow</sub> value of 4.54 at pH 8 was used for the assessment.

The lowest no observed adverse effect level (NOAEL) of 2.9 mg/kg body weight (bw) per day, based on non-specific liver changes observed in a 2-year chronic toxicity/carcinogenicity study in mice (EFSA FEEDAP Panel, 2024), was used to calculate a NOEC of 24.1 mg/kg feed, applying a conversion factor of 8.3 for mice. By applying an assessment factor of 30, the corresponding PNEC<sub>oral,predator</sub> was determined to be 0.80 mg/kg feed.

For the determination of the bioconcentration factor (BCF) in fish, a study performed according to OECD TG 305 and claimed to be GLP compliant was submitted.<sup>12</sup> All validity criteria were met, and the study is considered reliable. The kinetic bioconcentration factor for fish (BCF<sub>fish,k</sub>) was 160 L/kg, exceeding the threshold for bioaccumulation potential (BCF < 100 L/kg) (ECHA, 2023). Although the lipid content of the test species (bluegill sunfish) was not reported, a lipid fraction of approximately 5% is typical for this species.

The estimated concentration in fish (PEC<sub>fish (oral,predator)</sub>), based on a PEC<sub>sw</sub> of 0.06 µg/L and an experimentally determined BCF<sub>fish,k</sub> of 160 L/kg, is 0.0064 mg/kg. The PEC<sub>fish (oral,predator)</sub> is lower than the PNEC<sub>oral,predator</sub> and the risk of secondary poisoning can be excluded for fish-eating birds and mammals.

The estimated concentration in earthworms (PEC<sub>earthworm (oral,predators)</sub>), based on a PEC<sub>gw</sub> of 0.06 µg/L, a PEC<sub>soil</sub> of 39 µg/kg and a BCF<sub>earthworm</sub> of 416 L/kg, is 0.026 mg/kg. The BCF<sub>earthworm</sub> was estimated using a QSAR calculation implemented in

<sup>12</sup>Annex III\_04\_31 ERA Clinacox 2025.

the FERA calculation tool. The  $PEC_{\text{earthworm (oral,predator)}}$  is lower than the  $PNEC_{\text{oral,predator}}$  and the risk of secondary poisoning can therefore be excluded for worm-eating birds and mammals.

No risk of secondary poisoning is expected for birds and mammals through the terrestrial or aquatic food chains.

### 3.1.3 | Conclusions on safety for the environment

The use of diclazuril from Clinacox® 0.5% in complete feed for chickens for fattening and chickens reared for laying at a maximum level of 1 mg/kg complete feed does not pose a risk for the terrestrial and aquatic compartments nor to sediment. No concern for groundwater is expected. No risk of secondary poisoning is identified.

## 4 | CONCLUSIONS

Based on the new data submitted, it can be concluded that the use of diclazuril from Clinacox® 0.5% in complete feed for chickens for fattening and chickens reared for laying at a maximum level of 1 mg/kg complete feed does not pose a risk for the terrestrial and aquatic compartments including sediment. No concern for groundwater is expected. No risk for secondary poisoning is identified.

### ABBREVIATIONS

AF	assessment factor
AR	applied radioactivity
ASTM	American Society for Testing of Materials
BCF	bioconcentration factor
$BCF_{\text{fish,k}}$	bioconcentration factor for fish calculated using the kinetic method
bw	body weight
DFOP	Double First-Order in Parallel kinetics
DMF	dimethylformamide
$DT_{50}$	time to degradation of 50% of original concentration of the compound in the tested soils
$EC_{50}$	the concentration of a test substance which results in 50% of the test organisms being adversely affected, i.e. both mortality and sublethal effects
ECHA	European Chemicals Agency
EMA	European Medicines Agency
$E_rC_{50}$	the concentration of a test substance which results in a 50% of inhibition of algal growth rate
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
$K_d$	sorption/desorption coefficient
$K_{oc}$	organic carbon–water partitioning coefficient
$LC_{50}$	the concentration of a test substance which results in a 50% mortality of the test species
LC-MS/MS	Liquid chromatography tandem mass spectrometry
$\text{Log } K_{ow}$	logarithm of octanol–water partition coefficient
MW	molecular weight
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PNEC	predicted no effect concentration
QSAR	quantitative structure–activity relationship
SFO	Single First Order kinetics
TG	Testing Guideline
UF	uncertainty factor

### ACKNOWLEDGEMENTS

The Panel wishes to thank the following for the support provided to this scientific output: Jordi Tarrés-Call and Petr Letocha.

### REQUESTOR

European Commission

### QUESTION NUMBER

EFSA-Q-2025-00660

## COPYRIGHT FOR NON-EFSA CONTENT

EFSA may include images or other content for which it does not hold copyright. In such cases, EFSA indicates the copyright holder and users should seek permission to reproduce the content from the original source.

## PANEL MEMBERS

Roberto Edoardo Villa, Giovanna Azimonti, Eleftherios Bonos, Henrik Christensen, Mojca Durjava, Birgit Dusemund, Ronette Gehring, Boet Glandorf, Maryline Kouba, Marta López-Alonso, Francesca Marcon, Carlo Nebbia, Alena Pechová, Miguel Prieto-Maradona, Katerina Theodoridou.

## LEGAL NOTICE

Relevant information or parts of this scientific output have been blackened in accordance with the confidentiality requests formulated by the applicant pending a decision thereon by the European Commission. The full output has been shared with the European Commission, EU Member States and the applicant. The blackening will be subject to review once the decision on the confidentiality requests is adopted by the European Commission.

## REFERENCES

- ECHA (European Chemicals Agency). (2023). *Guidance on information requirements and chemical safety assessment: Chapter R.7c: Endpoint specific guidance, version 4.0*. European Chemicals Agency.
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Bastos, M., Christensen, H., Dusemund, B., Kouba, M., Kos Durjava, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Sanz, Y., Villa, R. E., Woutersen, R., Brock, T., ... Azimonti, G. (2019). Guidance on the assessment of the safety of feed additives for the environment. *EFSA Journal*, 17(4), 5648. <https://doi.org/10.2903/j.efsa.2019.5648>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Durjava, M., Dusemund, B., Kouba, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Villa, R. E., Woutersen, R., Bories, G., Brantom, P., ... Holczknecht, O. (2024). Assessment of the feed additive consisting of diclazuril (Clinacox® 0.5%) for chickens for fattening and chickens reared for laying for the renewal of its authorisation (Elanco GmbH). *EFSA Journal*, 22(8), 8908. <https://doi.org/10.2903/j.efsa.2024.8908>
- EMA (European Medicines Agency). (2016). Revised guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL38, Rev. 1 (EMA/CVMP/ERA/418282/2005-Rev.1).

**How to cite this article:** EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Villa, R. E., Azimonti, G., Bonos, E., Christensen, H., Durjava, M., Dusemund, B., Gehring, R., Glandorf, B., Kouba, M., López-Alonso, M., Marcon, F., Nebbia, C., Pechová, A., Prieto-Maradona, M., Theodoridou, K., Finizio, A., Poiger, T., Teodorovic, I., ... Holczknecht, O. (2026). Safety of a feed additive consisting of diclazuril (Clinacox® 0.5%) for chickens for fattening and chickens reared for laying (Elanco GmbH). *EFSA Journal*, 24(2), e9930. <https://doi.org/10.2903/j.efsa.2026.9930>