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REASONED OPINION

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Targeted review of maximum residue levels (MRLs) for dicofol

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Abstract

In accordance with Article 43 of Regulation (EC) 396/2005, EFSA received a request from the European Commission to review the existing maximum residue levels (MRLs) for the non-approved active substance dicofol in view of the possible lowering of the MRL. EFSA investigated the origin of the current EU MRLs. All existing EU MRLs reflect previously authorised uses in the EU or are based on obsolete Codex Maximum Residue Limits. Furthermore, in view of the limitations of the toxicological dataset and related uncertainties, the existing toxicological reference values derived at the EU level cannot be confirmed for dicofol. EFSA therefore proposed lowering all existing EU MRLs for dicofol to the limit of quantification.

KEYWORDS

consumer risk assessment, dicofol, MRL setting, non-approved active substance, residue definitions, toxicological evaluation

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SUMMARY

The European Commission submitted a request to EFSA for a targeted review of maximum residue limits (MRLs) for 10 active substances no longer approved in the EU, but for which MRLs greater than the limit of quantification (LOQ) are still in place and for which Member States have identified potential consumer health risks. Separate reasoned opinions should be provided in accordance with Article 43 of Regulation (EC) 396/2005, for each of the substances included in this mandate, one of them being dicofol.

In accordance with the terms of reference, EFSA investigated the origin of the current EU MRLs for dicofol, and whether they are sufficiently substantiated. An EU MRL is considered substantiated if it is sufficiently supported by data and established for uses still authorised or based on Codex Maximum Residue Limit (CXL) or import tolerance that are still in place and relevant. Accordingly, MRLs that were derived for previously authorised EU uses are obsolete and should be lowered to the LOQ. For those commodities for which the existing EU MRLs are based on a CXL, EFSA investigated whether the CXLs are still in place and whether they are sufficiently supported by data. Obsolete or insufficiently supported Codex MRLs are also candidates for being lowered to the LOQ. To identify possible import tolerances, EFSA consulted Member States on Good Agricultural Practices authorised in third countries that were evaluated at national level which might justify maintaining certain MRLs as import tolerances. Following this Member State consultation, EFSA concluded that none of the existing EU MRL for dicofol has been established as an import tolerance. EFSA also screened the quality of the toxicological reference values (TRVs) derived at EU level and by the Joint Meeting on Pesticide residues (JMPR). As EFSA identified critical issues related to the available toxicological database, EFSA organised an expert consultation (Pesticides Peer Review Teleconference 100) to discuss the toxicological profile and the TRVs for dicofol.

EFSA prepared a draft reasoned opinion that was shared with Member States and the European Reference Laboratories (EURLs) for consultation via a written procedure. Comments received were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of dicofol in plant and animal was previously investigated in the framework of the EU evaluation for inclusion in Annex I to Directive 91/414/EEC in 2006, in the framework of the MRL review in 2011, as well as by JMPR in 1992 and 1994. According to the results of the metabolism studies assessed, the residue definition for enforcement and risk assessment, both for plant and animal products, should be defined as the sum of o,p'-dicofol and p,p'-dicofol, the residue being fat soluble.

Analytical methods are available for the enforcement of the proposed residue definition in all four main plant matrices and tea with a summed LOQ of 0.02 mg/kg. Dicofol can be enforced in food of animal origin with an LOQ of 0.01–0.05 mg/kg for each isomer of dicofol. According to the EURLs, a quick, easy, cheap, effective, rugged, and safe (QuEChERS) multi-residue analytical method is available with a summed LOQ of 0.02 mg/kg for the routine analysis of dicofol in the four main matrix groups of plant origin, and a summed LOQ of 0.04 mg/kg in specific matrices (i.e. tea and cocoa). For high water, high acid content and dry commodities, even lower summed LOQ of 0.01 mg/kg were successfully validated. QuEChERS multi-residue analytical and SweEt based method are also available to monitor dicofol in commodities of animal origin (muscle, milk and liver) with a summed LOQ of 0.02 mg/kg. For these commodities an even lower summed LOQ of 0.01 mg/kg was successfully validated.

The origin of all current MRLs set for dicofol (based on formerly approved uses or on CXLs) was investigated, and all MRLs were identified as not sufficiently substantiated: EU MRLs on melons, cotton seeds, teas, hops, poultry commodities, milk and bird's eggs. No fall-back MRLs were identified for any of these crops or animal commodities.

A screening of the quality of the EU TRVs derived by the RMS Spain under Directive 91/414 and of those established by the JMPR was performed, and the set of toxicological studies used to derive these TRVs was assessed according to the current standards. As critical issues were identified, an experts' consultation with Member States was organised. The experts concluded that the TRVs cannot be confirmed or established for dicofol, since its mutagenic potential is inconclusive. In addition, the assessed database is incomplete and presents many uncertainties, particularly regarding its endocrine disrupting potential to define a reliable point of departure for this type of toxicity. Accordingly, the EU acceptable daily intake (ADI) and acute reference dose (ARfD) derived under Directive 91/414 do not comply with the current scientific standards. The following data would be required to finalise the toxicological assessment which is a pre-requisite to derive robust TRVs:

- complete the genotoxicity test battery to conclude on the mutagenic and aneugenic potential of dicofol;
- an assessment of the validity of analytical methods used in feed, body fluids and tissues, air and any additional matrices used in support of the toxicological studies;
- an assessment of the presence of toxicologically relevant impurities in the technical specification and in dicofol-treated commodities;
- comprehensive toxicokinetic studies, including the administration of a second dose level, repeated dosing and intravenous administrations;
- interspecies comparative in vitro metabolism study on animal species used in pivotal studies and on human material;
- an assessment of the carcinogenic potential of dicofol;
- additional toxicological data to perform an ED assessment according to the 2018 ECHA/EFSA Guidance;
- developmental neurotoxicity study;
- up-to-date search for published literature;

- full re-evaluation of the toxicological data package and reporting relevant details on the studies and the results in accordance with the current OECD test guidelines.

It cannot be assessed whether the same limitations concerning the genotoxicity data package are applicable to JMPR values since additional genotoxicity studies are mentioned in the 1992 monograph, but the report of these studies is not sufficiently detailed to perform an independent assessment.

Chronic and acute exposure calculations were performed using revision 3.1 of PRIMo, considering all CXLs/MRLs no longer substantiated at the appropriate LOQ, as well as all other commodities for which no GAP was reported under this review. The exposure derived by this conservative screening was compared to the current EU TRVs. The highest chronic exposure represented 124% of the ADI (Dutch toddler). In a refined scenario, considering the lowest summed LOQ achievable for milk (0.01 mg/kg instead of 0.02 mg/kg) reported by the EURLs, the highest chronic exposure represented 94% of the ADI (Dutch toddler). The highest acute exposure amounted to 2% of the ARfD (potatoes).

EFSA emphasises that as the toxicological assessment revealed deficiencies regarding the toxicological studies available for dicofol and considering that EU TRVs do not meet the current scientific standards, the risk assessment cannot be finalised, and results are presented in this review for indicative purposes only.

Furthermore, it is highlighted that dicofol is listed in Annex A of the Stockholm convention on persistent organic pollutants, which contains a list of chemicals for which parties to the Convention are required to prohibit and/or take measures to eliminate their production, use, import and export.

It is concluded that none of the existing EU MRLs/CXLs listed in the summary table below are recommended for inclusion in Annex II to the Regulation.

SUMMARY TABLE

Code[a]	Commodity	Existing MRL[b] (mg/kg)	Outcome of the review	
			MRL proposal (mg/kg)	Comment
Residue definition for enforcement (plants and animal products): Dicofol (sum of o,p' and p,p' isomers)[F]				
0233010	Melons	0.2	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0233010	Cotton seeds	0.1	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0610000	Tea	20	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0700000	Hops	50	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
1016010	Poultry, muscle	0.1	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
1016020	Poultry, fat	0.1	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
1016030	Poultry, liver	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
1016040	Poultry, kidney	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
1016050	Poultry, edible offals (others)	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
1020000	Milk	0.1	LOQ	The existing EU MRL is not substantiated The default LOQ for milk (0.02 mg/kg) leads to an exceedance of the ADI. Hence, risk managers may consider lowering the MRL to the lowest LOQ reported by the EURLs (0.01 mg/kg)
1030000	Birds eggs	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ

Abbreviations: ADI, acceptable daily intake; EURLs, European reference laboratories; LOQ, limit of quantification; MRL, maximum residue limit.

[F]Fat soluble.

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]MRL currently set under Regulation (EU) No 899/2012.

BACKGROUND

In March 2021, a Member State submitted to the European Commission the results of a screening performed on all maximum residue levels (MRLs) of active substances used in plant protection products that are not approved in the EU. The list contained 904 substances; for 297 of them, at least one MRL was set at a level above the limit of quantification (LOQ).

For 219 of these substances, the MRLs are not related to the uses of the substances in plant protection products (e.g. MRLs reflect the use of biocides or veterinary medical product, or MRLs are set to account for their occurrence in certain food due to environmental persistence, or their natural occurrence). For the other 78 substances, the MRLs were established either based on formerly approved uses in the EU, on import tolerance requests, or on Codex maximum residue limits (CXLs).

Some of these substances were never approved in the EU, or their approval was withdrawn before 2008, and therefore they did not fall within the scope of the systematic review of all existing MRLs under Article 12 of Regulation (EC) No 396/2005.[1]

A second Member State conducted additional analysis, identifying potential consumer risk for some of the MRLs set for these active substances.

Based on these analyses, the European Commission conducted a prioritisation exercise to identify substances for which existing MRLs should be reviewed with high priority. The prioritisation was also discussed and agreed with Member States during several meetings of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), section Phytopharmaceuticals – Pesticides residues (September 2021,[2] November 2021,[3] and February 2022[4]). The SCoPAFF agreed that ten active substances, for which potential consumer risks were identified, should be assessed by EFSA as a priority. One of the substances identified for being assessed with high priority is dicofol.

The European Commission proposed to mandate EFSA to provide a targeted review of MRLs for the substances concerned without delay. Due to the urgency of the subject, EFSA was invited to consider, if appropriate, delivering a separate reasoned opinion for each of the substances included in this mandate, as to be able to start providing outcomes to the Commission as soon as possible and successively. In this reasoned opinion EFSA covered the targeted review of the MRLs for dicofol.

TERMS OF REFERENCE (AS PROVIDED BY THE REQUESTOR)

EFSA was requested by the European Commission, according to Article 43 of Regulation (EC) No 396/2005, to prepare a reasoned opinion on dicofol. In particular, the following tasks should be performed:

1. to investigate the origin of the current EU MRLs (e.g. MRL based on formerly approved uses in the EU, on import tolerance requests, or on CXLs). This analysis should allow to verify if the CXLs/import tolerances are still justified[5] and to identify MRLs that do not correspond to import tolerances or currently established CXLs (non-verified CXL/import tolerances);
2. to consult Member States on information about Good Agricultural Practices authorised in third countries and already evaluated at MS level, which might support maintaining the existing import tolerances or setting of new (lowered) import tolerances, if this is necessary in view of consumer protection;
3. to identify fall-back MRLs for MRLs that do not correspond to a verified CXLs/import tolerance; these fall-back MRLs could be either a lower import tolerance or a lower CXL established more recently. If no fall-back MRL can be identified, the MRL should be considered for lowering to the appropriate LOQ;
4. to consult the EU Reference Laboratories (EURLs) on the LOQs achievable during routine analyses for all commodities;
5. to perform an indicative screening of the chronic and acute consumer exposure related to the existing EU MRLs reflecting the verified CXLs/import tolerances, fall-back MRLs and/or proposed revised LOQ MRLs, using the newest version of the Pesticide Residues Intake Model (PRIMo) based on the available residue definitions for risk assessment and, if not available, residue definitions for enforcement derived at EU level or by JMPR. The following scenarios should be calculated:

    a. Scenario 1:
        (i) Values at the appropriate LOQ: all MRLs that are based on former EU uses and all CXLs that were revoked by the Codex Committee on Pesticide Residues (CCPR) should be lowered to the appropriate LOQ;

[1]Regulation (EC) No 396/2005 of the 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.

[2]Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues 23-24 September 2021 (https://food.ec.europa.eu/system/files/2021-10/sc_phyto_20210923_ppr_sum.pdf).

[3]Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues 22–23 November 2021 (https://food.ec.europa.eu/system/files/2021-12/sc_phyto_20211122_ppr_sum_0.pdf).

[4]Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues 22–23 February 2022 (https://food.ec.europa.eu/system/files/2022-08/sc_phyto_20220222_ppr_sum.pdf).

[5]A CXL is considered justified if it is still in place (i.e., if it has not been withdrawn). An import tolerance is to be considered justified if the GAP in the country of origin is still authorised and the MRL in the country of origin is established at a level corresponding to the EU MRL (taking into account the potential difference in the RDs).

(ii) Non-LOQ values to be considered: CXLs that were previously taken over in EU legislation, CXLs that were covered by still existing (higher) EU MRLs to be considered at the value of the CXL, MRLs based on existing import tolerances;

b. Scenario 2:

(i) Like scenario 1, but lowering all CXLs that were evaluated by EFSA before and including 2009[6] and all import tolerances established before and including 2007[7]F, respectively, to the appropriate LOQ.

6. to derive the input values for commodities of animal origin for the consumer exposure calculation from the relevant assessment where the MRLs for animal products were derived. However, if the respective risk assessment values (HR/STMR) cannot be retrieved from the available sources, the exposure shall be calculated with the existing MRL. If the existing MRL is no longer justified and no fall-back MRL can be retrieved, the existing MRL should be considered for being lowered to the LOQ; in this case the risk assessment screening should be performed with the LOQ;
7. to examine the available information in order to screen the quality of the toxicological reference values (TRVs) set at EU level and of those established by JMPR. This screening should also consider the completeness of the set of toxicological studies used to derive the TRVs, as to assess if it would be acceptable according to the current standards. In case deficiencies are identified, these should be highlighted along with the resulting uncertainties;
8. to examine the available information in order to screen the quality of the residue definitions for risk assessment set at EU level and of those established by JMPR. In case deficiencies are identified, these should be highlighted along with the resulting uncertainties;
9. to compare the indicative chronic and acute dietary exposure to the toxicological reference values derived at EU level or, if not available, to the toxicological reference values derived by JMPR;
10. to report information on the classification of the substance under the CLP Regulation[8] and whether the active substance meets the criteria for endocrine disruptors;
11. to assess, in all cases, the contribution of MRLs at the LOQ to the exposure in all exposure scenarios;
12. to recommend MRLs that do not pose an unacceptable risk to consumers, where possible, and advise risk managers on alternative options. Where relevant, EFSA should indicate whether the achievable LOQs are sufficiently protective for consumers;
13. to share its draft reasoned opinion for consultation with Member States (MSs) and EURLs before finalising it.

EFSA accepted the mandate and to deliver its assessment by finalising separate reasoned opinions for each of the substances included in this mandate, including dicofol, by 22 May 2023. Subsequently, an extension of the deadline to 31 October 2023 was agreed with the European Commission.

ASSESSMENT

To address the complex Terms of Reference (ToR), EFSA used the following approach:

- In Section 1 (Regulatory background information on dicofol), information on classification of the active substance under CLP regulation and on endocrine properties is reported (addressing ToR 10).
- In Section 2.1 (Nature of residues and residue definitions), a screening of the quality of residue definitions is reported (addressing ToR 8).
- In Section 2.2 (Analytical methods for MRLs enforcement), information on analytical methods for MRLs enforcement provided by the EURLs on the LOQs achievable during routine residues analysis is reported (ToR 4). In addition, EFSA summarised the information on the analytical methods assessed previously by EFSA.
- In Section 2.3 (Existing MRLs), information on the origin of the current MRL is reported in tabular format (ToR 1). In the same section, information provided by MSs on good agricultural practices (GAPs) authorised in third countries and previously evaluated in view of setting import tolerances can be found (ToR 2). This information, together with information on existing CXLs, is used to derive possible fall-back MRLs (ToR 3) that are also reported in the table if available.
- In Section 3 (Toxicological reference values), the quality of the TRVs set in the EU and by JMPR is assessed (ToR 7).
- In Section 4 (Consumer risk assessment), an indicative screening of the chronic and acute consumer exposure is presented (ToR 5 and 6). The dietary exposure assessment Scenario 1 is performed as requested in ToR 5 (a). Scenario 2 (ToR 5 (b)) is not relevant for the assessment of dicofol, as all CXLs set in EU Regulation were implemented and evaluated by EFSA after 2009. Moreover, none of the existing MRLs was found to be substantiated (see Table 5). This section also addresses ToR 11 (contribution of MRLs at the LOQ to the total exposure) and ToR 9 (comparison of the dietary exposure with the TRV derived at EU and JMPR level), however, noting that following the experts' meeting on mammalian toxicology, it was concluded that the TRVs do not comply with the current scientific standards (see Section 3).

[6]The first EFSA scientific report in preparation of CCPR was prepared in 2010.

[7]The first evaluations of import tolerances under Regulation (EC) No 396/2005 which fully entered into force on 1.9.2008.

[8]Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

- In the Conclusions and recommendations section, EFSA presents the MRL proposals that are unlikely to pose an unacceptable risk to consumers, where possible, and the ones for which further consideration is required (ToR 12).

EFSA has based its assessment on the following documents:

- The Draft Assessment Report (DAR) (Spain, 2006);
- the review report on dicofol (European Commission, 2008);
- the Reports and Evaluations of the JMPR (FAO and WHO, 1992, 1994; FAO and WHO, 2012);
- the reports of the Codex Committee on Pesticide residues (CCPR, 1994, 1995, 2013);
- the previous reasoned opinion on the MRL review for dicofol (EFSA, 2011);
- the scientific report on the scientific support for preparing an EU position in the 45th Session of the Codex Committee on Pesticide Residues (CCPR) (EFSA, 2013).

As requested by the terms of reference (ToR 2), Member States were invited to submit by 18 October 2022 the GAPs that are authorised in third countries and already evaluated at national level, in the format of specific GAP forms, as well as the supporting residue data, in the format of an evaluation report. In the framework of this consultation seven Member States (CZ, DE, ES, IT, FR, NL and SE) provided feedback regarding dicofol and notified that no import tolerances were in place. The EU Reference Laboratories (EURLs) were also consulted (ToR 4) to provide an evaluation report on the availability of analytical methods for enforcement and the LOQs achievable during routine analysis in plants and animal commodities. The **EURLs report on analytical methods** (EURLs, 2022) submitted during the collection of data is considered as main supporting document to this reasoned opinion. In addition, an expert consultation in the area of mammalian toxicology was conducted in April 2023; the **peer review meeting report TC 100** (EFSA, 2023a) is also considered as main supporting document.

On the basis of the data submitted by the MSs, the EURLs, the data available in the JMPR Evaluation reports and taking into account the conclusions derived by EFSA in previous opinions and the screening of the available toxicological data with regards to their completeness and quality according to current standards, EFSA prepared a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure during August and September 2023. Comments received by 8 September 2023 were considered during the finalisation of this reasoned opinion (ToR 13).

Further supporting document to this reasoned opinion is the **Member States consultation report** (EFSA, 2023b). All the supporting documents prepared in the framework of this assessment and mentioned above are made publicly available as background document to this reasoned opinion. The exposure calculations for all crops reported in the framework of this review performed using the EFSA **PRIMo** are also key supporting documents made publicly available.

1 | REGULATORY BACKGROUND INFORMATION ON DICOFOL

The key events concerning the regulatory history of dicofol, the background information, together with the relevant published documents are summarised in Table 1.

TABLE 1 Background information.

Process	Status	Comments, references
Approval status	Not approved	Decision on non-inclusion of dicofol in Annex I of Council Directive 91/414/EEC[b] by Decision 2008/764/EC[c]
EFSA conclusion available	No	–
MRL review performed	Yes, see comments	EFSA (2011) Legally implemented by Regulation (EU) No 899/2012[d]
EU MRL applications or other EU assessments	Yes, see comments	Codex MRL assessment (Art. 43): EFSA Scientific support for preparing an EU position in the 45th Session of the Codex Committee on Pesticide Residues (CCPR) (EFSA, 2013)
Classification under CLP Regulation	See comments	Acute Tox 4[a], H302 'harmful if swallowed'; Acute Tox 4[a], H312 'harmful in contact with skin'; Skin Irrit. 2, H315 'causes skin irritation'; Skin Sens. 1, H317 'may cause an allergic skin reaction' (CLP00[e]) Dicofol does not fall under cut off criteria
Endocrine effects of a.s.	Not assessed	ED assessment according to ECHA and EFSA guidance (ECHA and EFSA, 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[f]) has not been performed. Additional data would be needed to carry it out

(continues)

TABLE 1 (Continued)

Process	Status	Comments, references
Other relevant information	–	Technical dicofol is a mixture composed of p,p'-dicofol (also known as dicofol), typically constituting > 80% of the mixture, its o,p´-isomer (also known as o,p´-dicofol) typically constituting < 15% of the mixture, and various impurities (mainly DDT and derivatives, as DDT is an intermediate in dicofol production). Dicofol is listed in Annex A of the Stockholm convention on persistent organic pollutants,[g] which contains a list of chemicals for which parties to the Convention are required to prohibit and/or take measures to eliminate the production, use, import and export. Dicofol, as a persistent organic pollutant, is included in Annex I Part A to Regulation (EU) 2019/1021.[h]

Abbreviations: a.s, active substance; CLP, classification, labelling and packaging; CCPR, Codex Committee on Pesticide Residues; ED, endocrine disruptor; MRL, maximum residue limit.

[a]Indicates a minimum classification that must be classified in a more severe hazard category in the event that further information is available which shows that the hazard(s) meet the criteria for classification in the more severe category (see Annex VI, section 1,2,1 of CLP Regulation).

[b]Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

[c]Commission Decision 2008/764/EC of 30 September 2008 concerning the non-inclusion of dicofol in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. C(2008) 5105). OJ L 262, 1.10.2008, p. 40–41.

[d]Commission Regulation (EU) No 899/2012 of 21 September 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acephate, alachlor, anilazine, azocyclotin, benfuracarb, butylate, captafol, carbaryl, carbofuran, carbosulfan, chlorfenapyr, chlorthal-dimethyl, chlorthiamid, cyhexatin, diazinon, dichlobenil, dicofol, dimethipin, diniconazole, disulfoton, fenitrothion, flufenzin, furathiocarb, hexaconazole, lactofen, mepronil, methamidophos, methoprene, monocrotophos, monuron, oxycarboxin, oxydemeton-methyl, parathion-methyl, phorate, phosalone, procymidone, profenofos, propachlor, quinclorac, quintozene, tolylfluanid, trichlorfon, tridemorph and trifluralin in or on certain products and amending that Regulation by establishing Annex V listing default values. OJ L 273, 6.10.2012, p. 1–75.

[e]Annex VI of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

[f]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.

[g]https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:22006A0731(01)

[h]Commission Delegated Regulation (EU) 2020/1204 of 9 June 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of dicofol OJ L 270, 18.8.2020, p. 4–6.

2 | RESIDUE DEFINITIONS AND EXISTING EU MRLS

2.1 | Nature of residues and residue definitions

As requested in point 8 of the Terms of Reference, EFSA summarised in this section the information used to derive the residue definitions for plant and animal products. Table 2 covers the studies submitted in the framework of the EU evaluation for inclusion in Annex I to Directive 91/414/EEC and assessed previously by EFSA to propose EU residue definitions (EFSA, 2011), as well as studies assessed by JMPR in the framework of the setting of CXLs (FAO and WHO, 1992, 1994).

TABLE 2 Available metabolism studies.

Primary crops	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/Source
	Fruit crops	Apple	Indoor, foliar (leaf spot appl.), 1.26 mg a.s./L	3, 7, 14	^{14}C-p,p'-dicofol ring labelled (EFSA, 2011; FAO and WHO, 1992; Spain, 2006)
			Indoor, soil (drench appl.) 11.2 kg a.s./ha	3, 7, 14	Translocation study on seedlings Study considered not valid by the RMS (Spain, 2006)
		Grapefruit	Outdoor, 1 local appl. on fruits, 4.8 g a.s./L (volume not specified)	7, 30, 60, 90, 120, 150	^{14}C-p,p'-dicofol ring labelled (EFSA, 2011; FAO and WHO, 1992; Spain, 2006) Only considered valid for additional information by the RMS (Spain, 2006)
		Orange	Indoor, local appl. on leaf, 0.89 a.s./kg	0, 7, 14, 28, 56, 78	^{14}C-p,p'-dicofol ring labelled (EFSA, 2011; FAO and WHO, 1992; Spain, 2006)
			Indoor, 1 soil appl., 4.8 kg a.s./ha	0, 7, 14, 28, 56, 78	Translocation study on seedlings Study considered not valid by the RMS (Spain, 2006)
		Tomato	Outdoor, 2 foliar appl. (int. of 7 days), total rate of 2.7 kg a.s./ha	10, 16, 21	^{14}C-p,p'-dicofol and ^{14}C-o,p'-dicofol ring labelled (EFSA, 2011; FAO and WHO, 1992; Spain, 2006)
	Leafy crops	–	–	–	Study not available but relevant for the existing MRL on tea
	Pulses/ oilseeds	Beans	Indoor, foliar (leaf spot appl.), 1.26 mg a.s./L	3, 7, 14	^{14}C-p,p'-dicofol ring labelled (EFSA, 2011; FAO and WHO, 1992; Spain, 2006)
			Indoor, soil (drench appl.) 11.2 kg a.s./ha	3, 7, 14	Translocation study on seedling Some clarifications were requested to the notifier as identification and quantification of metabolites raised several concerns (Spain, 2006)

TABLE 2 (Continued)

Primary crops	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/Source
		Cotton seeds	Indoor, 2 foliar appl. (int. of 7 days), total rate of 5.7 kg a.s./ha	72, 49, 15 treatment-to-harvest interval and at harvest	^{14}C-p,p′-dicofol and ^{14}C-o,p′-dicofol ring labelled (EFSA, 2011; FAO and WHO, 1992; Spain, 2006) Study considered not valid by the RMS (Spain, 2006)
Livestock	**Animal**		**Dose**	**Duration (day)**	**Comment/Source**
	Laying hen		0.1, 1 and 10 mg/kg	7	^{14}C- dicofol (EFSA, 2011, FAO and WHO, 1992, Spain, 2006)
	Ruminant, goat		1.5 mg a.s./kg and 15 mg a.s./kg in the diet	7	^{14}C-p,p′-dicofol ring labelled (EFSA, 2011, FAO and WHO, 1992, Spain, 2006) Metabolism of o,p′-dicofol not investigated. Only considered valid for additional information by the RMS (Spain, 2006)
	Pigs		–	–	No study available. Similarity of metabolisms in rat and in ruminant was not discussed in available assessments

Abbreviations: a.s., active substance; DAT, days after treatment.

Metabolism studies on grapefruits, tomato and cotton as well as translocation studies on apples, oranges and beans were assessed in the framework of the EU evaluation (Spain, 2006) for inclusion in Annex I to Directive 91/414/EEC, in the framework of the MRL review (EFSA, 2011) and in the framework of JMPR evaluation (FAO and WHO, 1992). Although some of the studies were considered not valid by the RMS (Spain, 2006), overall, the available plant metabolism and translocation studies demonstrate that dicofol remains on the surface and does not translocate. In all plant types investigated, the major residue related to dicofol consists of parent compound, the o,p′- and p,p′-isomers of dicofol. No metabolites contribute significantly to the residue in plants. Only in the metabolism studies conducted in tomato and cottonseeds behaviour of both dicofol isomers was investigated but the cottonseeds metabolism study did not provide sufficient information due to the low amount of %TRR identified.

Isomers of dicofol were found to be chemically instable in solution leading by hydrolyse to their corresponding dichlorobenzophenones (DCBP) and the chromatographic methods used to identify and quantify residues were considered inadequate to quantify separately the residues of parent compound present in the samples and the DCBP that could have been formed during the extraction from crop matrix (Spain, 2006). Consequently, it was concluded at EU level that the residue definition for enforcement and risk assessment in crops belonging to the groups 'fruit crops' and 'pulses and oilseeds' should be defined as the sum of o,p′-dicofol, p,p′-dicofol and their corresponding DCBP expressed as dicofol (EFSA, 2011; Spain, 2006).

It is underlined that this residue definition was finally not legally implemented in Regulation (EC) No 396/2005 where the residue definition for enforcement is set as dicofol (sum of o,p′-dicofol, p,p′-dicofol). Moreover, according to the information notified by the EURLs under the present assessment, analytical methods are available that minimise and/or compensate for the dicofol decomposition during analysis, especially during GC-analysis. DCBP formed during analysis is thus irrelevant. Consequently, the inclusion of DCBP is considered not any longer necessary and the residue definition in plant commodities can be simplified as the sum of o,p′-dicofol, p,p′-dicofol for both enforcement and risk assessment, in line with the residue definition proposed by JMPR (FAO and WHO, 1992, 1994) and implemented in Regulation (EC) No 396/2005.

Among the commodities under assessment, it is noted that no metabolism study is available to cover the use on tea.

The nature of dicofol residues in livestock was investigated and assessed in the framework of the EU evaluation (Spain, 2006) for inclusion in Annex I to Directive 91/414/EEC, in the framework of the MRL review (EFSA, 2011) and in the framework of the JMPR evaluations (FAO and WHO, 1992, 1994).

Metabolism study of p,p′-dicofol in lactating ruminant and metabolism study of dicofol (sum of o,p′ and p,p′ isomers) in laying hens assessed by JMPR showed extensive metabolism of dicofol to polar metabolites, namely 2,2-dichloro-1,1-bis(4-chlorophenyl)ethanol (dichloro-dicofol, FW 152), p,p′-dichlorobenzophenone (DCBP) and p,p′-dichlorobenzhydrol (DCBH), which were detected in tissues, organs, milk and eggs. As residues of FW 152 may constitute a significant proportion of the total radioactive residue in milk, eggs and tissues of ruminants and hens, JMPR derived a definition in products of animal origin, as the sum of dicofol (sum of o,p′ and p,p′ isomers) and 1-(2-chlorophenyl)-1-(4′-chlorophenyl)-2,2-dichloroethanol (FW 152), expressed as dicofol (FAO and WHO, 1994), the residue being fat soluble. In the framework of the periodic re-evaluation in 2012, this residue definition was revoked and deemed not required in animal commodities (FAO and WHO, 2012).

At EU level, considering that the metabolism of o,p′-dicofol in lactating ruminant was not investigated and that the metabolism study of p,p′-dicofol was considered valid as additional information only due to the lack of some data, no residue definition was proposed for livestock commodities (EFSA, 2011; Spain, 2006). The residue set in Regulation (EC) No 396/2005 for animal commodities is dicofol (sum of o,p′ and p,p′ isomers) and is different from what was concluded in the framework of JMPR assessments.

Table 3 below summarises the residue definitions derived at EU level and by JMPR.

TABLE 3 Residue definitions derived at EU level and by JMPR.

Type of residue definition (RD)	Commodity group	EU residue definition	JMPR residue definitions
RD for enforcement	Plant products	Reg. 396/2005: Dicofol (sum of o,p′ and p,p′ isomers) RMS (Spain, 2006) and EFSA (EFSA, 2011) proposal: sum of o,p′-dicofol, p,p′-dicofol and their corresponding dichlorobenzophenones (DCBP) expressed as dicofol	Dicofol (sum of o,p′ and p,p′ isomers) (FAO and WHO, 1992, 1994)
	Animal products	Reg. 396/2005: Dicofol (sum of o,p′ and p,p′ isomers) The residue is fat soluble. RMS (Spain, 2006) and EFSA (EFSA, 2011) proposal: no residue definition proposed	In 1994, JMPR initially derived a residue definition as the (sum of o,p′ and p,p′ isomers) and 1-(2-chlorophenyl)-1-(4′-chlorophenyl)-2,2-dichloroethanol (FW 152), expressed as dicofol. In 2012, JMPR revoked the previous Codex residue definition for animal products, as in the context of the periodic re-evaluation no metabolism data on livestock were provided. JMPR also noted that for future uses on plant commodities that are livestock feedstuffs, animal metabolism studies would be necessary (FAO and WHO, 2012)
RD for risk assessment	Plant products	RMS (Spain, 2006) and EFSA (EFSA, 2011) proposal: sum of o,p′-dicofol, p,p′-dicofol and their corresponding dichlorobenzophenones (DCBP) expressed as dicofol	Dicofol (sum of o,p′ and p,p′ isomers) (FAO and WHO, 1992, 1994)
	Animal products	RMS (Spain, 2006) and EFSA (EFSA, 2011) proposal: no residue definition proposed	See JMPR residue definition for enforcement for animal products

Comments: The residue definition for plant products set in Reg. (EC) 396/2005 is identical with the one proposed in the framework of JMPR assessments. The inclusion of metabolite DCBP in the EU residue definition for plants was mainly driven by the fact that analytical methods used to identify and quantify dicofol residues lead to the formation of DCBP. Considering that the analytical methods proposed by the EURLs minimise and/or compensate for the dicofol decomposition during analysis, DCBP formed during analysis is irrelevant and its inclusion in the plant residue definition is considered not any longer necessary. The residue definition for animal products set in Reg. (EC) 396/2005 is different from what was concluded in the framework of JMPR assessments.

Abbreviations: JMPR, Joint FAO/WHO Meeting on Pesticide Residues; RMS, Rappourter Member State.

2.2 | Analytical methods for MRLs enforcement

Analytical methods for the determination of dicofol residues were assessed in the framework of the EU evaluation (Spain, 2006) for inclusion in Annex I to Directive 91/414/EEC and in the framework of the MRL review (EFSA, 2011). However, none of the assessed methods were sufficiently validated and it was concluded that no analytical methods were available to enforce residue of dicofol in plant and animal products according to the residue definition as sum of o,p′-dicofol, p,p′-dicofol and their corresponding dichlorobenzophenones (DCBP), expressed as dicofol (EFSA, 2011).

Analytical methods were assessed in the framework of JMPR evaluations (FAO and WHO, 1992; FAO and WHO, 2012). According to the JMPR, analytical methods are available to enforce residue of dicofol in the four main plant matrices with an LOQ of 0.01 mg/kg for each isomers of dicofol (p,p'-dicofol and o,p'-dicofol). Analytical method is available to enforce dicofol (sum of isomers) in specific matrices, i.e. tea with an LOQ of 0.02 mg/kg. It is noted that in the analytical methods available to the JMPR, diclofop isomers are analysed following degradation to the corresponding dichlorobenzophenone isomer (FAO and WHO, 1992; FAO and WHO, 2012).

Analytical methods are available to enforce residue of dicofol in animal commodities with an LOQ of 0.01–0.05 mg/kg for each isomer of dicofol, DCBP and FW-152 in all animal matrices (FAO and WHO, 1992; FAO and WHO, 2012).

During the data collection, the EURLs provided information on a QuEChERS multi-residue analytical method using gas chromatography with tandem mass spectrometry (GC–MS/MS) technique, for the routine analysis of p,p'-dicofol and o,p'-dicofol with an LOQ of 0.01 mg/kg each, in high-water, high-acid and high-oil content commodities. Thus, resulting in a summed LOQ of 0.02 mg/kg. For dry commodities, only p,p'-dicofol was validated and an LOQ of 0.01 mg/kg is achievable, but based on analytical experience via GC, this LOQ can be extrapolated to o,p'dicofol, resulting in a summed LOQ of 0.02 mg/kg. For high-water, high-acid content and dry commodities, even lower levels were successfully validated for p,p'-dicofol (down to 0.005 mg/kg) which, due to the similar analytical behaviour of the two dicofol isomers, may also be applied to the o,p´-isomer, resulting in a summed LOQ of 0.01 mg/kg. Analytical method is available for the analysis of p,p'-dicofol and o,p'-dicofol with an LOQ of 0.02 mg/kg each, in specific matrices (i.e. tea and cocoa) thus, resulting in a summed LOQ of 0.04 mg/kg. According to the EURLs, in commodities of animal origin (muscle, milk and liver) p,p'-dicofol can be monitored with a default LOQ of 0.01 mg/kg. Based on analytical experience via GC, this LOQ can be extrapolated to o,p'dicofol, resulting in a summed LOQ of 0.02 mg/kg for milk, muscle and liver (EURLs, 2022). For these commodities even lower summed LOQ of 0.01 mg/kg was successfully validated. The analytical methods proposed by the EURLs minimise and/or compensate for the dicofol decomposition during analysis. DCBP formed during analysis

is thus irrelevant. The EURLs also informed that analytical standards for p,p'-dicofol and o,p'-dicofol are commercially available (EURLs, 2022).

Therefore it is concluded that analytical methods are available for the enforcement of dicofol (sum of o,p' and p,p' isomers) in all commodities under assessment, except for hops. Table 4 provides an overview of the analytical methods available for the enforcement of the residue definition currently included in Regulation 396/2005 and their respective LOQs.

TABLE 4 Analytical methods available.

Commodity group		Analytical method available	LOQ (mg/kg)	Source
Plant commodities	High water	Yes (GLC-ECD)	0.02[a]	FAO and WHO (1992)
		Yes (QuEChERS method with GC–MS/MS)	0.02[b]	EURLs (2022)
	High oil	Yes (GLC-ECD)	0.02[a]	FAO and WHO (1992)
		Yes (QUEChERS/QuOil method with GC–MS/MS)	0.02[b]	EURLs (2022)
	High-acid content	Yes (GLC-ECD)	0.02[a]	FAO and WHO (1992)
		Yes (QUEChERS method with GC–MS/MS)	0.02[b]	EURLs (2022)
	Dry	Yes (GLC-ECD)	0.02[a]	FAO and WHO (1992)
		Yes (QUEChERS method with GC–MS/MS)	0.02[b]	EURLs (2022)
	Other: difficult matrices (tea)	Yes (GLC-ECD)	0.02	FAO and WHO (1992)
	Other: difficult matrices (tea, cocoa)	Yes (QUEChERS method with GC–MS/MS)	0.04[b]	EURLs (2022)
Animal commodities	Muscle	Yes (RP-HPLC-UV)	0.01–0.05[c]	FAO and WHO (1992)
		Yes (GLC-ECD)	0.01–0.05[c]	FAO and WHO (1992)
		Yes (SweEt method with GC–MS/MS)	0.02[b]	EURLs (2022)
	Kidney	Yes (RP-HPLC-UV)	0.01–0.05[c]	FAO and WHO (1992)
		Yes (GLC-ECD)	0.01–0.05[c]	FAO and WHO (1992)
	Liver	Yes (RP-HPLC-UV)	0.01–0.05[c]	FAO and WHO (1992)
		Yes (GLC-ECD)	0.01–0.05[c]	FAO and WHO (1992)
		Yes (QUEChERS method with GC–MS/MS)	0.02[b]	EURLs (2022)
	Fat	Yes (RP-HPLC-UV)	0.01–0.05[c]	FAO and WHO (1992)
		Yes (GLC-ECD)	0.01–0.05[c]	FAO and WHO (1992)
	Milk	Yes (RP-HPLC-UV)	0.01–0.05[c]	FAO and WHO (1992)
		Yes (GLC-ECD)	0.01–0.05[c]	FAO and WHO (1992)
		Yes (QUEChERS method with GC–MS/MS)	0.02[b]	EURLs (2022)
	Eggs	Yes (RP-HPLC-UV)	0.01–0.05[c]	FAO and WHO (1992)
		Yes (GLC-ECD)	0.01–0.05[c]	FAO and WHO (1992)
	Other	–	–	–

Abbreviations: GLC-ECD, gas liquid chromatography with electron capture detector; GC–MS/MS, gas chromatography with tandem mass spectrometry; LOQ, limit of quantification; QUEChERS, Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); RP-HPLC-UV, reverse phase high-performance liquid chromatography UV method; SweEt, Swedish ethyl acetate method.

[a]Summed LOQ (individual LOQ of p,p'-dicofol and o,p'-dicofol as corresponding DCBP isomer are equal to ½ of the summed LOQ).

[b]Summed LOQ (individual LOQ of p,p'-dicofol and o,p'-dicofol are equal to ½ of the summed LOQ).

[c]LOQ of 0.01–0.05 mg/kg for each isomer of dicofol, for each isomer of DCBP and for each isomer of FW-152.

2.3 | Existing MRLs

The EU MRLs for dicofol are established in Annex II and IIIb of Regulation (EC) No 396/2005. For a number of food products, Codex Maximum Residue Limits (CXLs) have been taken over in the EU legislation. It should be noted that in the framework of the current review, Member States/UK did not notify any import tolerance.

EFSA reported in Table 5, the existing EU MRLs set above the LOQ for the respective plant and animal commodities, including information on the source of the MRLs together with the relevant GAPs and the references to the assessment where the MRL proposal was derived. In response to ToR 1 which requests to provide an analysis whether the existing EU MRL, the CXL or the import tolerance established for a crop is sufficiently substantiated, EFSA applied the following criteria:

A CXL is considered substantiated if:

- it is still in place (CXL has not been withdrawn from the Codex system);
- the CXL is sufficiently supported by data;
- the enforcement residue definition is identical with the EU residue definition.

An import tolerance is considered substantiated if:

- the GAP in the country of origin is still authorised;
- the import tolerance is sufficiently supported by data;
- the MRL in the country of origin is established at a level corresponding to the EU MRL (taking into account the potential difference in the RDs);
- in case the residue definition in the country of origin is different, the import tolerance is substantiated if sufficient information is available to derive an MRL for the EU RD.

An existing EU MRLs is not substantiated if:

- it is based on a previously authorised EU use;
- it is based on a previous CXL that has been revoked/withdrawn;
- it is based on an import tolerance that is no longer relevant as the use in the country of origin is not confirmed.

In order to address ToR 3, 5 and 6, in cases where the current CXLs or import tolerances are not sufficiently substantiated, Table 5 includes information on potential fall-back GAPs and the associated calculated fall-back MRLs. In the last column of this table, additional considerations relevant for taking risk management decisions are also reported.

TABLE 5 Background information on current MRLs for dicofol established at a level above the LOQ, and verification whether these values are sufficiently substantiated.

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)	Fall-back GAP	Fall-back MRL (mg/kg)	Comment
Melons	0.2	CXL (CAC, 1995)	USA: Foliar appl., 3 × 0.62 kg a.s./ha, PHI 2 days	N	No fall-back GAP identified	–	In 1992, JMPR proposed a CXL of 0.2 mg/kg on melons. The proposed CXL was adopted by CCPR 26/CAC in 1995. The proposed CXL was legally implemented in Regulation (EU) No 899/2012 following MRL review. The CXL on melons was revoked in 2013 (CCPR, 2013). Existing EU MRL is not substantiated as no IT use is in place and as CXL was revoked
Cotton seeds	0.1	CXL (CAC, 1995)	USA: Foliar appl., 2 × 1.66 kg a.s./ha, PHI 30d	N	No fall-back GAP identified	–	In 1992, JMPR proposed a CXL of 0.1 mg/kg on cotton seeds. The proposed CXL was adopted by CCPR 26/CAC in 1995. The proposed CXL was legally implemented in Regulation (EU) No 899/2012 following MRL review. The CXL on cotton seeds was revoked in 2013 (CCPR, 2013). Existing EU MRL is not substantiated as no IT use is in place and as CXL was revoked
Tea	20	See comments	See comments	N	No fall-back GAP identified	–	Existing EU MRL was legally implemented in Regulation (EC) 149/2008[b] and has never been modified. The origin of this MRL is unknown. In 2012, JMPR proposed a CXL of 40 mg/kg. The proposed CXL was adopted by CCPR 45/CAC in 2013 noting the reservations expressed[a] at EU level (CCPR, 2013; EFSA, 2013). Consequently, the CXL proposal has not been legally implemented. Existing EU MRL is not substantiated as no IT uses in place and as reservations were expressed for the implementation of the in force CXL on tea. Moreover, a metabolism study on leafy crops is not available to support the existing MRL
Hops	50	CXL (CAC, 1995)	Germany: Foliar appl., 2 × 1.6 kg a.s./ha, PHI 28 days USA: Foliar appl., 2 × 1.28 kg a.s./ha, PHI 7 days	N	No fall-back GAP identified	–	In 1992, JMPR proposed a CXL of 50 mg/kg on hops. The proposed CXL was adopted by CCPR 26/CAC in 1995. The proposed CXL was legally implemented in Regulation (EU) No 899/2012 following MRL review. The CXL on hops was revoked in 2013 (CCPR, 2013). Existing EU MRL is not substantiated as no IT use is in place and as CXL was revoked
Poultry, muscle	0.1	CXL (CAC, 1995)	Based on a residue of 0.1 mg of dicofol/ kg of feed (FAO and WHO, 1994)	N	No fall-back GAP identified	–	In 1994 JMPR proposed a CXL of 0.1 mg/kg on poultry meat. The proposed CXL was adopted by CCPR 27/CAC in 1995. The proposed CXL was legally implemented in Regulation (EU) No 899/2012 following MRL review. The CXL on poultry meat was revoked in 2013 (CCPR, 2013). Existing EU MRL is not substantiated as no IT use is in place and as CXL was revoked
Poultry, fat	0.1	CXL (CAC, 1995)	Based on a residue of 0.1 mg of dicofol/ kg of feed (FAO and WHO, 1994)	N	No fall-back GAP identified	–	In 1994 JMPR proposed a CXL of 0.1 mg/kg on poultry fat. The proposed CXL was adopted by CCPR 27/CAC in 1995. The proposed CXL was legally implemented in Regulation (EU) No 899/2012 following MRL review. The CXL on poultry fat was revoked in 2013 (CCPR, 2013). Existing EU MRL is not substantiated as no IT use is in place and as CXL was revoked.

(Continues)

TABLE 5 (Continued)

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)	Fall-back GAP	Fall-back MRL (mg/kg)	Comment
Poultry, liver	0.05	CXL (CAC, 1995)	Based on a residue of 0.1 mg of dicofol/ kg of feed (FAO and WHO, 1994)	N	No fall-back GAP identified	–	In 1992 JMPR proposed a CXL of 0.05[c] mg/kg on poultry edible offal. The proposed CXL was adopted by CCPR 26/CAC in 1995. The proposed CXL was legally implemented in Regulation (EU) No 899/2012 following MRL review. The CXL on poultry edible offal was revoked in 2013 (CCPR, 2013). Existing EU MRL is not substantiated as no IT use is in place and as CXL was revoked.
Poultry, kidney	0.05	CXL (CAC, 1995)	Based on a residue of 0.1 mg of dicofol/ kg of feed (FAO and WHO, 1994)	N	No fall-back GAP identified	–	In 1992 JMPR proposed a CXL of 0.05[c] mg/kg on poultry edible offal. The proposed CXL was adopted by CCPR 26/CAC in 1995. The proposed CXL was legally implemented in Regulation (EU) No 899/2012 following MRL review. The CXL on poultry edible offal was revoked in 2013 (CCPR, 2013). Existing EU MRL is not substantiated as no IT use is in place and as CXL was revoked.
Poultry, edible offals (others)	0.05	CXL (CAC, 1995)	Based on a residue of 0.1 mg of dicofol/ kg of feed (FAO and WHO, 1994)	N	No fall-back GAP identified	–	In 1992 JMPR proposed a CXL of 0.05[c] mg/kg on poultry edible offal. The proposed CXL was adopted by CCPR 26/CAC in 1995. The proposed CXL was legally implemented in Regulation (EU) No 899/2012 following MRL review. The CXL on poultry edible offal was revoked in 2013 (CCPR, 2013). Existing EU MRL is not substantiated as no IT use is in place and as CXL was revoked.
Milk	0.1	CXL (CAC, 1995)	Based on a residue of 3 mg of dicofol/ kg of feed (FAO and WHO, 1994)	N	No fall-back GAP identified	–	In 1994 JMPR proposed a CXL of 0.1 mg/kg on milk. The proposed CXL was adopted by CCPR 27/CAC in 1995. The proposed CXL was legally implemented in Regulation (EU) No 899/2012 following MRL review. The CXL on milk was revoked in 2013 (CCPR, 2013). Existing EU MRL is not substantiated as no IT use is in place and as CXL was revoked.
Birds eggs	0.05	CXL (CAC, 1995)	Based on a residue of 0.1 mg of dicofol/ kg of feed (FAO and WHO, 1994)	N	No fall-back GAP identified	–	In 1992 JMPR proposed a CXL of 0.05 mg/kg on eggs. The proposed CXL was adopted by CCPR 26/CAC in 1995. The proposed CXL was legally implemented in Regulation (EU) No 899/2012 following MRL review. The CXL on poultry edible offal was revoked in 2013 (CCPR, 2013). Existing EU MRL is not substantiated as no IT use is in place and as CXL was revoked

Abbreviations: a.s., active substance; CAC, Codex Alimentarius Commission; CCPR, Codex committee on pesticide residues; CXL, Codex maximum residue limit; GAP, good agricultural practice; cGAP, critical good agricultural practice; IT, import tolerance; MRL, maximum residue limit; PHI, pre-harvest interval.

[a]There is evidence that dicofol is unstable under processing and is expected to produce degradation products which could also generate chloroform.

[b]Commission Regulation (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto. OJ L 58, 1.3.2008, p. 1–398.

[c]Indicates that the CXL is set at the limit of quantification.

3 | TOXICOLOGICAL REFERENCE VALUES

EFSA was mandated to examine the available information in order to screen the quality of the TRVs set at EU level and of those established by the JMPR and to assess the completeness of the set of toxicological studies used to derive the TRVs according to the current standards. In case deficiencies are identified, these should be highlighted along with the resulting uncertainties (ToR 7).

The TRVs for dicofol reported in Table 6 were derived by the RMS in 2006 (Spain, 2006) under Directive 91/414; the TRVs were not formally adopted by the European Commission and the active substance was withdrawn from the European Market (European Commission, 2008; Commission Decision, 2008[9]). In 1992, the JMPR derived an ADI that was confirmed in 2011 and an ARfD was set in 2011 (FAO and WHO, 1992, 2011) which can be found in Table 7.

The ARfD and ADI values derived by the RMS and JMPR are based on the same studies and on the same no observed adverse effect levels (NOAELs); the difference in values are due to rounding.

TABLE 6 Toxicological reference values (TRVs) derived at EU level.

TRV	Value	Reference	Comments
ADI	0.0022 mg/kg bw per day	Spain (2006)	Based on a NOAEL of 0.22 mg/kg bw per day for liver toxicity (increased liver weights, increases in hepatic mixed function oxides activity, focal discolouration and prominent lobular architecture at necropsy and histological changes) in a 2-year study in rats and applying an UF of 100
ARfD	0.15 mg/kg bw	Spain (2006)	Based on a NOAEL of 15 mg/kg bw for reduced body weights and feed consumption, and urine-stained or faecal-stained fur observed in an acute neurotoxicity study in rats and applying an UF of 100

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; UF, uncertainty factor.

TABLE 7 Toxicological reference values (TRVs) set by the JMPR.

TRV	Value	Reference	Comments
ADI	0.002 mg/kg bw per day	FAO and WHO (1992, 2011)	Based on a NOAEL of 0.2 mg/kg bw per day for histopathological changes in the liver and adrenal gland in a 2-year toxicity and carcinogenicity study in rats, applying an UF of 100
ARfD	0.2 mg/kg bw	FAO and WHO (2011)	Based on a NOAEL of 15 mg/kg bw for decreased body weight and decreased feed intake in an acute neurotoxicity study in rats and applying an UF of 100. The ARfD is supported by the NOAEL of 15 mg/kg bw for decreased feed intake and hypertrophy of adrenal zona fasciculata in a single-dose oral toxicity study in rats.

Abbreviations: ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; UF, uncertainty factor.

EFSA screened the completeness and the quality of the toxicological studies that were used to derive EU and JMPR TRVs, focussing on the question whether the studies meet current scientific standards. EFSA did not undertake a full review of the original studies, the basis of the TRV derivation was scrutinised based on the available data reported mainly in the original DAR (Spain, 2006).

During this scrutiny, EFSA identified critical issues related to the available toxicological database which were discussed with Member State experts in mammalian toxicology in the Pesticides Peer Review Teleconference 100 in April 2023 (EFSA, 2023a).

The discussions with the Member State experts focussed on the following two critical points:

- the genotoxicity data set;
- the robustness of the available data to derive toxicological reference values, i.e. the ADI, the ARfD and respective UF.

The genotoxicity data package for dicofol contains studies assessing two of the three critical genotoxicity endpoints, i.e. gene mutation in bacterial and mammalian cells (in vitro) and clastogenicity (in vitro and in vivo); aneugenicity was not investigated (either in vitro or in vivo). In addition, an in vitro unscheduled DNA synthesis (UDS) assay is reported, whose TG (TG 482) was deleted in the meantime).[10]

The studies for gene mutation and chromosome aberration showed negative results. The studies were conducted in the 80s; two Ames tests presented important limitations: one of them was assessed as not acceptable due to the low purity of the test substance (34.8% pure) and the other was only considered acceptable when tested with metabolic activation since inappropriate positive controls were used without metabolic activation. In addition, the latter test used only four strains of Salmonella Typhimurium (instead of five or including a strain of *E. coli* WP2 uvrA), so that strains detecting point mutation at the A-T sites were not included. All experts agreed that the gene mutation in mammalian cells test was insufficient to

[9]Commission Decision of 30 September 2008 concerning the non-inclusion of dicofol in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. OJ L 262, 1.10.2008, p. 40–41.

[10]See experts' consultation point 2.1 at the Pesticide Peer Review Teleconference 100 (EFSA, 2023a,b).

cover the weaknesses identified in the Ames tests and either a new Ames test or in silico analysis would be needed to conclude on this endpoint. It is noted that additional genotoxicity studies that may address this data gap are mentioned in the 1992 JMPR monograph, however the short report of these studies is insufficient to perform an independent assessment. Chromosome aberration was tested in vitro and in vivo. A number of limitations were identified in the in vivo study, such as a low number of metaphases analysed per animal, only one dose level was used in males and mitotic index was not measured; however, taking into account the negative results obtained in vitro in an adequate range of dose levels according to cell survival, it was agreed that no concern is raised regarding the clastogenic potential of dicofol. With regards to aneugenicity, an additional study such as an in vitro micronucleus test, is needed to address this endpoint.

Overall, the data package available is insufficient to conclude on the genotoxicity potential of dicofol regarding gene mutation and aneugenicity.

With regards to the toxicological data package needed to derive an ADI and ARfD for dicofol according to the current data requirements,[11] the main following data gaps were identified[12]:

- an assessment of the validity of analytical methods used in feed, body fluids and tissues, air and any additional matrices used in support of the toxicological studies is not available;
- the presence of toxicologically relevant impurities in the technical specification and in dicofol-treated commodities cannot be assessed. In particular, insufficient information is available on the presence of dichlorodiphenyltrichloroethane (DDT), DDT-derivatives and dicofol isomers, known as dicofol-related impurities;
- the toxicokinetic studies were performed only with a single oral dose, missing a second dose level, repeated dosing and intravenous administration;
- an interspecies in vitro comparative metabolism study performed on animal species used in pivotal studies and on human material is not available to determine the relevance of the toxicological animal data to humans and whether additional testing of potential unique human metabolites would be required;
- the carcinogenic potential of dicofol has not been fully investigated as the available carcinogenicity study in mice showing an increase in liver tumours was not considered acceptable due to many deviations from the OECD test guideline (TG 451). In rats, no carcinogenic effects were observed up to 11.34 mg/kg bw per day (highest dose tested);
- an assessment of the endocrine disruptive potential of dicofol cannot be performed since insufficient investigations of the ED parameters are available according to the current ECHA/EFSA Guidance (ECHA and EFSA et al., 2018), while dicofol chemical structure is similar to DDT that has been identified as an endocrine disruptor in the published literature. In addition, it is noted that the US EPA reports dicofol as an endocrine disruptor;
- a developmental neurotoxicity (DNT) study is not available and is required since dicofol belongs to the chemical class of organochlorine pesticides presenting a neurotoxic mode of action and neurotoxicity effects were observed in adult rats in the acute and 90-day neurotoxicity studies;
- an up-to-date search for published literature is missing.

Additional uncertainties were highlighted on the available dicofol assessment. The summaries of the studies reported in the DAR are not sufficiently detailed (e.g. with tabulated results), as it would be expected in current standards, and an independent review of their reliability and findings cannot be fully undertaken. The a.s. has the potential to accumulate in adipose tissues in mammals, but this has not been fully investigated in the limited toxicokinetic studies. In 1998 the US EPA derived a chronic reference dose of 0.0004 mg/kg bw per day, lower than the EU and the JMPR ADI. The US EPA chronic reference dose was based on a NOAEL of 0.12 mg/kg bw per day for inhibition of adrenocorticotropic hormone (ACTH) – stimulated release of cortisol in male and female dogs in a 1-year toxicity study. This study was partially available to the RMS (i.e. only a 6-month interim report of the 1-year dog study was reported). The EPA applied an additional UF of 3 to cover the lack of a DNT study; this additional UF was also applied to the ARfD, resulting in an ARfD value of 0.05 mg/kg bw (based on the NOAEL of 15 mg/kg bw from the acute neurotoxicity study in rats). Taking into account the ED concern for dicofol, the experts considered essential to assess the ED potential of dicofol to allow the setting of appropriate TRVs.

In view of the limitations of the toxicological dataset and related uncertainties, it was concluded that the existing TRVs derived at the EU level cannot be confirmed for dicofol. In addition, the inconclusive genotoxicity assessment with regards to gene mutation whose mode of action is not threshold-related precludes the use of additional uncertainty factors for the derivation of TRVs.

The JMPR values suffer from the same uncertainties as it appears to be based generally on the same toxicological studies.

4 | CONSUMER RISK ASSESSMENT

In order to address ToR 5 (a) (Scenario 1), ToR 6 and ToR 11, EFSA performed an indicative screening of the chronic and acute consumer exposure. None of the MRLs are substantiated (see Section 2.3) and the existing MRL should be lowered to the LOQ for all commodities under assessment. This screening is conservative, as based on the assumption that in all plant and animal commodities, dicofol residues are present at the LOQ. Therefore, an exposure calculation for the residue definition

[11]Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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. OJ L 93, 3.4.2013, p. 1-84.

[12]See experts' consultation point 2.2 at the Pesticide Peer Review Teleconference 100 (EFSA, 2023a,b).

for risk assessment previously proposed by EFSA for plant commodities (i.e. the sum of o,p'-dicofol, p,p'-dicofol and their corresponding DCBP expressed as dicofol [EFSA, 2011]) was considered not appropriate. For plant and animal commodities, the LOQ values used in the exposure assessment refer to the enforcement residue definition (i.e. the sum of residue of o,p'-dicofol and p,p'-dicofol expressed as dicofol). Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA et al., 2018, 2019). All input values included in the exposure calculations are summarised in Appendix C.

The following scenario was calculated (**Scenario 1A**):

- For commodities for which the CXLs/MRLs were revoked or are no longer substantiated, the appropriate LOQ was used as input value for the exposure calculation.
- All other commodities were included in the calculation with the appropriate LOQ.

The risk assessment scenario as described in ToR 5 (b) (i.e. Scenario 2) is not relevant for the assessment of dicofol, as all CXLs set in EU Regulation were implemented and evaluated by EFSA after 2009. Additionally, all CXLs and EU MRLs are either identified as not substantiated.

The exposure values calculated were compared with the EU TRVs for profenofos derived by the RMS in 2006 (Spain, 2006) which were never formally adopted by the European Commission, noting that during the experts' meeting on mammalian toxicology held in April 2023, the experts concluded that these TRVs do not comply with the current scientific standards (see Section 3).

Since the ARfD and ADI values derived by the RMS and JMPR are based on the same studies and on the same NOAELs being the slightly difference in values due to rounding (see section 3), no additional calculations were performed with the TRVs derived by the JMPR.

According to scenario 1A, the highest chronic exposure was calculated for Dutch toddler representing 124% of the ADI; the highest acute exposure was calculated for potatoes, representing 2% of the ARfD. It is noted that the assumptions made for the indicative exposure calculations in this scenario are very conservative, in particular for the chronic exposure, assuming that all commodities contain residues of dicofol (sum of o,p' and p,p' isomers) at the LOQ (See Appendix C). Considering that the active substance is no longer authorised for use as plant protection product, it is not expected that consumers are exposed to these levels. Therefore, EFSA performed an additional calculation (**scenario 1B**), considering for milk, which was identified as the major contributor to the chronic exposure, a lower LOQ that could be achieved by enforcement laboratories (0.01 mg/kg instead of 0.02 mg/kg, see section 2.2). In this refined scenario, the highest chronic exposure decreased to 94% of the ADI (Dutch toddler).

Screenshots of the report sheet of the indicative PRIMo calculations for scenario 1A and 1B are presented in Appendix B.

EFSA highlights that the toxicological assessment revealed deficiencies regarding the toxicological studies available for dicofol (see Section 3 and EFSA, 2023a). Therefore, considering the high level of uncertainty affecting the TRVs considered, the risk assessment requested in ToR 5 cannot be finalised and the results are presented in this review for indicative purposes only.

CONCLUSIONS AND RECOMMENDATIONS

The metabolism of dicofol in plant and animal was previously investigated in the framework of the EU evaluation (Spain, 2006) for inclusion in Annex I to Directive 91/414/EEC, in the framework of the MRL review (EFSA, 2011) as well as by JMPR (FAO and WHO, 1992, 1994). According to the results of the metabolism studies assessed, the residue definition for enforcement and risk assessment, both for plant and animal products, should be defined as the sum of o,p'-dicofol and p,p'-dicofol, the residue being fat soluble.

Analytical methods are available for the enforcement of the proposed residue definition in all four main plant matrices and tea with a summed LOQ of 0.02 mg/kg. Dicofol can be enforced in food of animal origin with an LOQ of 0.01–0.05 mg/kg for each isomer of dicofol. According to the EURLs, a QuEChERS multi-residue analytical method is available with a summed LOQ of 0.02 mg/kg for the routine analysis of dicofol in the four main matrix groups of plant origin, and a summed LOQ of 0.04 mg/kg in specific matrices (i.e. tea and cocoa). For high-water, high-acid content and dry commodities, even lower summed LOQ of 0.01 mg/kg were successfully validated. QuEChERS multi-residue analytical and SweEt based method are also available to monitor dicofol in commodities of animal origin (muscle, milk and liver) with a summed LOQ of 0.02 mg/kg. For these commodities an even lower summed LOQ of 0.01 mg/kg was successfully validated.

The origin of all current MRLs set for dicofol (based on formerly approved uses or on CXLs) was investigated, and all MRLs were identified as not sufficiently substantiated: EU MRLs on melons, cotton seeds, teas, hops, poultry commodities, milk and bird's eggs. No fall-back MRLs were identified for any of these crops or animal commodities.

A screening of the quality of the EU TRVs derived by the RMS Spain under Directive 91/414 and of those established by the JMPR was performed, and the set of toxicological studies used to derive these TRVs was assessed according to the current standards. As critical issues were identified, an experts' consultation with Member States was organised. The experts concluded that the TRVs cannot be confirmed or established for dicofol, since its mutagenic potential is inconclusive. In addition, assessed database is incomplete and presents many uncertainties, particularly regarding its endocrine disrupting potential to define a reliable point of departure for this type of toxicity. Accordingly, the EU ADI and ARfD derived under Directive 91/414 do not comply with the current scientific standards. The following data would be required to finalise the toxicological assessment which is a pre-requisite to derive robust TRVs:

- complete the genotoxicity test battery to conclude on the mutagenic and aneugenic potential of dicofol;
- an assessment of the validity of analytical methods used in feed, body fluids and tissues, air and any additional matrices used in support of the toxicological studies;
- an assessment of the presence of toxicologically relevant impurities in the technical specification and in dicofol-treated commodities;
- comprehensive toxicokinetic studies, including the administration of a second dose level, repeated dosing and intravenous administrations;
- interspecies comparative in vitro metabolism study on animal species used in pivotal studies and on human material;
- an assessment of the carcinogenic potential of dicofol;
- additional toxicological data to perform an ED assessment according to the 2018 ECHA/EFSA Guidance;
- DNT study;
- up-to-date search for published literature;
- full re-evaluation of the toxicological data package and reporting relevant details on the studies and the results in accordance with the current OECD test guidelines.

It cannot be assessed whether the same limitations concerning the genotoxicity data package are applicable to JMPR values since additional genotoxicity studies are mentioned in the 1992 monograph, but the report of these studies is not sufficiently detailed to perform an independent assessment.

Chronic and acute exposure calculations were performed using revision 3.1 of PRIMo, considering all CXLs/MRLs no longer substantiated at the appropriate LOQ, as well as all other commodities for which no GAP was reported under this review. The exposure derived by this conservative screening was compared to the EU TRVs. The highest chronic exposure represented 124% of the ADI (Dutch toddler). In a refined scenario, considering the lowest summed LOQ achievable for milk (0.01 mg/kg instead of 0.02 mg/kg) reported by the EURLs, the highest chronic exposure represented 94% of the ADI (Dutch toddler). The highest acute exposure amounted to 2% of the ARfD (potatoes).

EFSA emphasises that as the toxicological assessment revealed deficiencies regarding the toxicological studies available for dicofol and considering that EU TRVs do not meet the current scientific standards, the risk assessment cannot be finalised and results are presented in this review for indicative purposes only.

Furthermore, it is highlighted that dicofol is listed in Annex A of the Stockholm convention on persistent organic pollutants, which contains a list of chemicals for which parties to the Convention are required to prohibit and/or take measures to eliminate their production, use, import and export.

It is concluded that none of the existing EU MRLs/CXLs listed in the table below (Table 8) are recommended for inclusion in Annex II to the Regulation.

TABLE 8 Summary table.

			Outcome of the review	
Code[a]	**Commodity**	**Existing MRL[b] (mg/kg)**	**MRL proposal (mg/kg)**	**Comment**
Residue definition for enforcement (plants and animal products): Dicofol (sum of o,p′ and p,p′ isomers)[F]				
0233010	Melons	0.2	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0233010	Cotton seeds	0.1	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0610000	Tea	20	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0700000	Hops	50	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
1,016,010	Poultry, muscle	0.1	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
1,016,020	Poultry, fat	0.1	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
1,016,030	Poultry, liver	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
1016040	Poultry, kidney	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ.
1016050	Poultry, edible offals (others)	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
1020000	Milk	0.1	LOQ	The existing EU MRL is not substantiated The default LOQ for milk (0.02 mg/kg) leads to an exceedance of the ADI. Hence, risk managers may consider lowering the MRL to the lowest LOQ reported by the EURLs (0.01 mg/kg)
1030000	Birds eggs	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ

Abbreviations: ADI, acceptable daily intake; EURLs, European reference laboratories; LOQ, limit of quantification; MRL, maximum residue limit.

[F] Fat soluble.

[a] Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b] MRL currently set under Regulation (EU) No 899/2012.

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
cGAP	critical good agricultural practice
CXL	Codex maximum residue limit
DAT	days after treatment
DAR	draft assessment report (prepared under Council Directive 91/414/EEC)
DALT	days after last treatment
ECHA	European Chemicals Agency
ED	endocrine disruptor
EURLs	European Reference Laboratories
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC–MS	gas chromatography with mass spectrometry
GC–MS/MS	gas chromatography with tandem mass spectrometry
HR	highest residue
IT	import tolerance
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC–MS/MS	liquid chromatography - mass spectrometry
LOQ	limit of quantification (determination)
MRL	maximum residue limit
MS	Member States
NOAEL	no observed adverse effect level
OJ	Official Journal of the European Union
OECD	Organisation for Economic Co-operation and Development
PeF	peeling factor
PHI	pre-harvest interval
ppm	parts per million (10^{-6})
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RD	residue definition
RAC	(ECHA) Risk Assessment Committee
RMS	Rapporteur Member State
RP-HPLC-UV	reverse phase high-performance liquid chromatography UV method
SCoPAFF	Standing Committee on Plants, Animals, Food and Feed
STMR	supervised trials median residue
SweEt	Swedish ethyl acetate method
tbd	to be discussed
ToR	terms of reference
TRV	toxicological reference value
WHO	World Health Organization
UF	uncertainty factor

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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

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APPENDIX A

Summary of the fall-back GAPs collected from Member States

Not applicable, as Member States reported no import tolerances for dicofol.

APPENDIX B

Pesticide Residue Intake Model (PRIMo)

- PRIMo_EU_(Sc. 1A)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Dicofol (F)

LOQs (mg/kg) range from: 0.02 to: 0.10

Toxicological reference values

ADI (mg/kg bw per day):	0.002	ARfD (mg/kg bw):	0.15
Source of ADI:	ES	Source of ARfD:	ES
Year of evaluation:	2006	Year of evaluation:	2006

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
124%	NL toddler	2.47	60%	Milk: Cattle	11%	Apples	7%	Maize/corn	124%	
65%	NL child	1.31	24%	Milk: Cattle	8%	Sugar beet roots	6%	Apples	65%	
62%	DE child	1.24	20%	Milk: Cattle	12%	Apples	4%	Wheat	62%	
61%	UK infant	1.21	39%	Milk: Cattle	3%	Potatoes	3%	Wheat	61%	
55%	FR toddler 2 3 yr	1.09	29%	Milk: Cattle	3%	Apples	3%	Wheat	55%	
54%	FR child 3 15 yr	1.08	23%	Milk: Cattle	5%	Wheat	4%	Sugar beet roots	54%	
45%	UK toddler	0.89	21%	Milk: Cattle	4%	Wheat	3%	Potatoes	45%	
41%	GEMS/Food G11	0.83	8%	Milk: Cattle	4%	Potatoes	4%	Soyabeans	41%	
41%	DK child	0.82	13%	Milk: Cattle	6%	Rye	4%	Wheat	41%	
38%	GEMS/Food G06	0.76	7%	Wheat	4%	Tomatoes	2%	Milk: Cattle	38%	
38%	GEMS/Food G07	0.76	6%	Milk: Cattle	4%	Wheat	4%	Potatoes	38%	
38%	GEMS/Food G15	0.75	7%	Milk: Cattle	5%	Wheat	4%	Potatoes	38%	
38%	RO general	0.75	12%	Milk: Cattle	5%	Wheat	4%	Potatoes	38%	
38%	GEMS/Food G08	0.75	6%	Milk: Cattle	4%	Wheat	4%	Potatoes	38%	
37%	SE general	0.75	12%	Milk: Cattle	4%	Bovine: Muscle/meat	4%	Potatoes	37%	
37%	GEMS/Food G10	0.73	5%	Milk: Cattle	4%	Wheat	3%	Soyabeans	37%	
37%	DE women 14-50 yr	0.73	12%	Milk: Cattle	5%	Sugar beet roots	3%	Apples	37%	
36%	ES child	0.72	12%	Milk: Cattle	4%	Wheat	2%	Oranges	36%	
36%	DE general	0.71	12%	Milk: Cattle	4%	Sugar beet roots	2%	Apples	36%	
35%	FI adult	0.70	28%	Coffee beans	1%	Potatoes	0.7%	Rye	35%	
33%	IE adult	0.66	4%	Milk: Cattle	4%	Sweet potatoes	2%	Wheat	33%	
30%	NL general	0.59	8%	Milk: Cattle	3%	Sugar beet roots	2%	Potatoes	30%	
29%	FR infant	0.58	17%	Milk: Cattle	2%	Potatoes	2%	Apples	29%	
21%	FR adult	0.42	4%	Milk: Cattle	2%	Wine grapes	2%	Wheat	21%	
21%	PT general	0.42	5%	Potatoes	4%	Wheat	2%	Wine grapes	21%	
20%	ES adult	0.40	5%	Milk: Cattle	2%	Wheat	1%	Oranges	20%	
17%	FI 3 yr	0.34	5%	Potatoes	1%	Bananas	1%	Wheat	17%	
16%	IT toddler	0.33	7%	Wheat	2%	Other cereals	1%	Tomatoes	16%	
16%	DK adult	0.33	5%	Milk: Cattle	1%	Potatoes	1%	Wheat	16%	
16%	LT adult	0.32	4%	Milk: Cattle	3%	Potatoes	2%	Apples	16%	
15%	UK vegetarian	0.29	3%	Milk: Cattle	2%	Wheat	1%	Potatoes	15%	
14%	FI 6 yr	0.27	4%	Potatoes	1.0%	Wheat	0.8%	Bananas	14%	
14%	UK adult	0.27	3%	Milk: Cattle	2%	Wheat	1%	Potatoes	14%	
12%	IT adult	0.24	4%	Wheat	1%	Tomatoes	0.8%	Apples	12%	
10%	PL general	0.19	3%	Potatoes	2%	Apples	0.9%	Tomatoes	10%	
8%	IE child	0.16	4%	Milk: Cattle	1%	Wheat	0.6%	Potatoes	8%	

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 123.6 % of the ADI.
For 1 diet(s) the ADI is exceeded.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details - acute risk assessment/children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Potatoes	0.02/0.02	3.1
2%	Melons	0.02/0.02	3.0
2%	Pears	0.02/0.02	2.8
2%	Oranges	0.02/0.02	2.7
2%	Milk: Cattle	0.02/0.02	2.5
2%	Watermelons	0.02/0.02	2.4
1%	Apples	0.02/0.02	2.2
1%	Pineapples	0.02/0.02	2.0
1%	Bananas	0.02/0.02	1.9
1%	Peaches	0.02/0.02	1.9
1%	Mangoes	0.02/0.02	1.6
1%	Grapefruits	0.02/0.02	1.6
1.0%	Table grapes	0.02/0.02	1.5
0.9%	Cucumbers	0.02/0.02	1.3
0.8%	Carrots	0.02/0.02	1.3

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets
(IESTI calculation)

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.6%	Head cabbages	0.02/0.02	0.84
0.5%	Watermelons	0.02/0.02	0.81
0.5%	Melons	0.02/0.02	0.78
0.5%	Milk: Cattle	0.02/0.02	0.77
0.5%	Swedes/rutabagas	0.02/0.02	0.68
0.5%	Table grapes	0.02/0.02	0.68
0.4%	Oranges	0.02/0.02	0.61
0.4%	Pears	0.02/0.02	0.61
0.4%	Potatoes	0.02/0.02	0.60
0.4%	Pineapples	0.02/0.02	0.59
0.4%	Yams	0.02/0.02	0.57
0.4%	Apples	0.02/0.02	0.56
0.4%	Cucumbers	0.02/0.02	0.56
0.4%	Aubergines/egg plants	0.02/0.02	0.54
0.3%	Mangoes	0.02/0.02	0.52

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Sugar beets (root)/sugar	0.02/0.24	2.2
1%	Potatoes/fried	0.02/0.02	1.9
1%	Pumpkins/boiled	0.02/0.02	1.8
1%	Witloofs/boiled	0.02/0.02	1.8
1%	Broccoli/boiled	0.02/0.02	1.6
0.9%	Cauliflowers/boiled	0.02/0.02	1.4
0.9%	Escaroles/broad-leaved endives/boiled	0.02/0.02	1.3
0.8%	Potatoes/dried (flakes)	0.02/0.09	1.2
0.8%	Leeks/boiled	0.02/0.02	1.1
0.7%	Apples/juice	0.02/0.02	1.1
0.7%	Oranges/juice	0.02/0.02	1.1
0.7%	Turnips/boiled	0.02/0.02	1.0
0.7%	Parsnips/boiled	0.02/0.02	1.0
0.7%	Sweet potatoes/boiled	0.02/0.02	1.0
0.6%	Florence fennels/boiled	0.02/0.02	0.91

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Pumpkins/boiled	0.02/0.02	1.1
0.6%	Sugar beets (root)/sugar	0.02/0.24	0.88
0.6%	Cauliflowers/boiled	0.02/0.02	0.83
0.5%	Beetroots/boiled	0.02/0.02	0.78
0.5%	Celeries/boiled	0.02/0.02	0.68
0.4%	Apples/juice	0.02/0.02	0.67
0.3%	Broccoli/boiled	0.02/0.02	0.48
0.3%	Coffee beans/extraction	0.1/0.02	0.48
0.3%	Courgettes/boiled	0.02/0.02	0.46
0.3%	Parsnips/boiled	0.02/0.02	0.43
0.3%	Kohlrabies/boiled	0.02/0.02	0.43
0.3%	Wine grapes/juice	0.02/0.02	0.42
0.3%	Escaroles/broad-leaved	0.02/0.02	0.41
0.3%	Florence fennels/boiled	0.02/0.02	0.39
0.3%	Turnips/boiled	0.02/0.02	0.38

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Dicofol (F) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

- PRIMo_EU_(Sc. 1B)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Dicofol

LOQs (mg/kg) range from: 0.01 to: 0.10

Toxicological reference values

ADI (mg/kg bw per day):	0.002	ARfD (mg/kg bw):	0.15
Source of ADI:	ES	Source of ARfD:	ES
Year of evaluation:	2006	Year of evaluation:	2006

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : --

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	94%	NL toddler	1.87	30%	Milk: Cattle	11%	Apples	7%	Maize/corn	94%	
	53%	NL child	1.06	12%	Milk: Cattle	8%	Sugar beet roots	6%	Apples	53%	
	52%	DE child	1.04	12%	Apples	10%	Milk: Cattle	4%	Wheat	52%	
	42%	FR child 3 15 yr	0.85	11%	Milk: Cattle	5%	Wheat	4%	Sugar beet roots	42%	
	41%	UK infant	0.83	19%	Milk: Cattle	3%	Potatoes	3%	Wheat	41%	
	40%	FR toddler 2 3 yr	0.80	15%	Milk: Cattle	3%	Apples	3%	Wheat	40%	
	38%	GEMS/Food G11	0.75	4%	Potatoes	4%	Milk: Cattle	4%	Soyabeans	38%	
	37%	GEMS/Food G06	0.73	7%	Wheat	4%	Tomatoes	2%	Potatoes	37%	
	35%	FI adult	0.70	28%	Coffee beans	1%	Potatoes	0.7%	Rye	35%	
	35%	GEMS/Food G08	0.70	4%	Wheat	4%	Potatoes	3%	Milk: Cattle	35%	
	35%	GEMS/Food G07	0.69	4%	Wheat	4%	Potatoes	3%	Milk: Cattle	35%	
	35%	DK child	0.69	6%	Milk: Cattle	6%	Rye	4%	Wheat	35%	
	34%	UK toddler	0.68	10%	Milk: Cattle	4%	Wheat	3%	Potatoes	34%	
	34%	GEMS/Food G15	0.68	5%	Wheat	4%	Potatoes	4%	Milk: Cattle	34%	
	34%	GEMS/Food G10	0.68	4%	Wheat	3%	Soyabeans	3%	Potatoes	34%	
	32%	RO general	0.64	6%	Milk: Cattle	5%	Wheat	4%	Potatoes	32%	
	31%	SE general	0.62	6%	Milk: Cattle	4%	Bovine: Muscle/meat	4%	Potatoes	31%	
	31%	IE adult	0.61	4%	Sweet potatoes	2%	Wheat	2%	Potatoes	31%	
	30%	DE women 14-50 yr	0.61	6%	Milk: Cattle	5%	Sugar beet roots	3%	Apples	30%	
	30%	ES child	0.59	6%	Milk: Cattle	4%	Wheat	2%	Oranges	30%	
	29%	DE general	0.59	6%	Milk: Cattle	4%	Sugar beet roots	2%	Apples	29%	
	25%	NL general	0.51	4%	Milk: Cattle	3%	Sugar beet roots	2%	Potatoes	25%	
	21%	PT general	0.42	5%	Potatoes	4%	Wheat	2%	Wine grapes	21%	
	21%	FR infant	0.41	8%	Milk: Cattle	2%	Potatoes	2%	Apples	21%	
	19%	FR adult	0.38	2%	Wine grapes	2%	Milk: Cattle	2%	Wheat	19%	
	18%	ES adult	0.35	2%	Milk: Cattle	2%	Wheat	1%	Oranges	18%	
	17%	FI 3 yr	0.34	5%	Potatoes	1%	Bananas	1%	Wheat	17%	
	16%	IT toddler	0.33	7%	Wheat	2%	Other cereals	1%	Tomatoes	16%	
	14%	LT adult	0.28	3%	Potatoes	2%	Milk: Cattle	2%	Apples	14%	
	14%	DK adult	0.28	3%	Milk: Cattle	1%	Potatoes	1%	Wheat	14%	
	14%	FI 6 yr	0.27	4%	Potatoes	1.0%	Wheat	0.8%	Bananas	14%	
	13%	UK vegetarian	0.26	2%	Wheat	2%	Milk: Cattle	1%	Potatoes	13%	
	12%	IT adult	0.24	4%	Wheat	1%	Tomatoes	0.8%	Apples	12%	
	12%	UK adult	0.24	2%	Wheat	1%	Milk: Cattle	1%	Potatoes	12%	
	10%	PL general	0.19	3%	Potatoes	2%	Apples	0.9%	Tomatoes	10%	
	6%	IE child	0.12	2%	Milk: Cattle	1%	Wheat	0.6%	Potatoes	6%	

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Dicofol is unlikely to present a public health concern.

Acute risk assessment /children	Acute risk assessment/adults/general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Potatoes	0.02/0.02	3.1
2%	Melons	0.02/0.02	3.0
2%	Pears	0.02/0.02	2.8
2%	Oranges	0.02/0.02	2.7
2%	Watermelons	0.02/0.02	2.4
1%	Apples	0.02/0.02	2.2
1%	Pineapples	0.02/0.02	2.0
1%	Bananas	0.02/0.02	1.9
1%	Peaches	0.02/0.02	1.9
1%	Mangoes	0.02/0.02	1.6
1%	Grapefruits	0.02/0.02	1.6
1.0%	Table grapes	0.02/0.02	1.5
0.9%	Cucumbers	0.02/0.02	1.3
0.8%	Carrots	0.02/0.02	1.3
0.8%	Kiwi fruits (green, red, yellow)	0.02/0.02	1.2

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.6%	Head cabbages	0.02/0.02	0.84
0.5%	Watermelons	0.02/0.02	0.81
0.5%	Melons	0.02/0.02	0.78
0.5%	Swedes/rutabagas	0.02/0.02	0.68
0.5%	Table grapes	0.02/0.02	0.68
0.4%	Oranges	0.02/0.02	0.61
0.4%	Pears	0.02/0.02	0.61
0.4%	Potatoes	0.02/0.02	0.60
0.4%	Pineapples	0.02/0.02	0.59
0.4%	Yams	0.02/0.02	0.57
0.4%	Apples	0.02/0.02	0.56
0.4%	Cucumbers	0.02/0.02	0.56
0.4%	Aubergines/egg plants	0.02/0.02	0.54
0.3%	Mangoes	0.02/0.02	0.52
0.3%	Chinese cabbages/pe-tsai	0.02/0.02	0.51

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Sugar beets (root)/sugar	0.02/0.24	2.2
1%	Potatoes/fried	0.02/0.02	1.9
1%	Pumpkins/boiled	0.02/0.02	1.8
1%	Witloofs/boiled	0.02/0.02	1.8
1%	Broccoli/boiled	0.02/0.02	1.6
0.9%	Cauliflowers/boiled	0.02/0.02	1.4
0.9%	Escaroles/broad-leaved endives/boiled	0.02/0.02	1.3
0.8%	Potatoes/dried (flakes)	0.02/0.09	1.2
0.8%	Leeks/boiled	0.02/0.02	1.1
0.7%	Apples/juice	0.02/0.02	1.1
0.7%	Oranges/juice	0.02/0.02	1.1
0.7%	Turnips/boiled	0.02/0.02	1.0
0.7%	Parsnips/boiled	0.02/0.02	1.0
0.7%	Sweet potatoes/boiled	0.02/0.02	1.0
0.6%	Florence fennels/boiled	0.02/0.02	0.91

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Pumpkins/boiled	0.02/0.02	1.1
0.6%	Sugar beets (root)/sugar	0.02/0.24	0.88
0.6%	Cauliflowers/boiled	0.02/0.02	0.83
0.5%	Beetroots/boiled	0.02/0.02	0.78
0.5%	Celeries/boiled	0.02/0.02	0.68
0.4%	Apples/juice	0.02/0.02	0.67
0.3%	Broccoli/boiled	0.02/0.02	0.48
0.3%	Coffee beans/extraction	0.1/0.02	0.48
0.3%	Courgettes/boiled	0.02/0.02	0.46
0.3%	Parsnips/boiled	0.02/0.02	0.43
0.3%	Kohlrabies/boiled	0.02/0.02	0.43
0.3%	Wine grapes/juice	0.02/0.02	0.42
0.3%	Escaroles/broad-leaved endives/	0.02/0.02	0.41
0.3%	Florence fennels/boiled	0.02/0.02	0.39
0.3%	Turnips/boiled	0.02/0.02	0.38

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Dicofol is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

APPENDIX C

Input values for the exposure calculations

Commodity	Existing MRL (mg/kg)	Chronic risk assessment		Acute risk assessment	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition 1: sum of o,p'-dicofol and p,p'-dicofol, expressed as dicofol[F]					
Melons	0.2	0.02[b]	LOQ	0.02[b]	LOQ
Cotton seeds	0.1	0.02[b]	LOQ	0.02[b]	LOQ
Tea	20	0.04[b]	LOQ	0.04[b]	LOQ
Hops	50	0.1[b]	LOQ	0.1[b]	LOQ
Poultry, muscle	0.1	0.02[b]	LOQ	0.02[b]	LOQ
Poultry, fat	0.1	0.02[b]	LOQ	0.02[b]	LOQ
Poultry, liver	0.05	0.02[b]	LOQ	0.02[b]	LOQ
Poultry, kidney	0.05	0.02[b]	LOQ	0.02[b]	LOQ
Poultry, edible offals (others)	0.05	0.02[b]	LOQ	0.02[b]	LOQ
Milk	0.1	Scenario 1A: 0.02[b] Scenario 1B: 0.01[b]	Scenario 1A: LOQ Scenario 1B: Lowest EURLs LOQ	Scenario 1A: 0.02[b] Scenario 1B: 0.01[b]	Scenario 1A: LOQ Scenario 1B: Lowest EURLs LOQ
Birds eggs	0.05	0.02[b]	LOQ	0.02[b]	LOQ
Other crops/ commodities	See Reg. (EU) 899/2012	LOQ[a]			

Abbreviations: EURLs, European reference laboratories for pesticide residues; LOQ, limit of quantification.

[F]The active substance is fat soluble.

[a]An LOQ of 0.04 mg/kg was applied to herbs, tea and cocoa beans, and of 0.1 mg/kg to coffee beans, herbal infusions, carobs and spices. A default LOQ of 0.02 mg/kg for all other commodities was applied.

[b]Indicates that the input value is proposed at the limit of quantification.