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REASONED OPINION



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.

K E Y W O R D S

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

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CONTENTS

Abstract	
Summary	3
Summary Table	4
Background	5
Terms of Reference (as Provided by the Requestor)	5
Assessment	6
1. Regulatory Background Information on Dicofol	7
2. Residue Definitions and Existing Eu Mrls	8
2.1. Nature of residues and residue definitions	8
2.2. Analytical methods for MRLs enforcement	
2.3. Existing MRLs	11
3. Toxicological Reference Values	15
4. Consumer Risk Assessment	
Conclusions and Recommendations	
Abbreviations	19
Acknowledgements	19
Conflict of Interest	19
Requestor	19
Question Number	19
Copyright for non-EFSA Content	
References	
Appendix A	21
Appendix B	22
Appendix C	

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

		Existing	Outcome of the review	
Code ^a	Commodity	MRL ^b (mg/kg)	MRL proposal (mg/kg)	Comment
Residue de	finition for enforcem	ent (plants and a	nimal products): Dicofol (s	um 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	Теа	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. Fat soluble.

^aCommodity code number according to Annex I of Regulation (EC) No 396/2005.

^bMRL 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 2022⁴). 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:

- 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 justified⁵ and to identify MRLs that do not correspond to import tolerances or currently established CXLs (non-verified CXL/import tolerances);
- 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;
- 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;

¹Regulation (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.

²Standing 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).

³Standing 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).

⁴Standing 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).

⁵A 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 2009⁶ and all import tolerances established before and including 2007⁷F, 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 Regulation⁸ 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;
- 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).

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

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

⁸Regulation (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 I Background Infor	indion.	
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	<u>Codex MRL assessment (Art. 43)</u> : 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

TABLE 1 Background information.

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,⁹ 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.

^aIndicates 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).

^bCouncil 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.

^cCommission 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.

^dCommission 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.

^eAnnex 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. ^fCommission 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.

^ghttps://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:22006A0731(01)

^hCommission 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).

Primary	Crop				
crops	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	 ¹⁴C-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 Available metabolism studies.

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	 ¹⁴C-p,p'-dicofol and ¹⁴C-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, go	oat	1.5 mg a.s./kg and 15 mg a.s./kg in the diet	7	 ¹⁴C-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	
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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
The inclusion of metaboli	te DCBP in the EU re	sidue definition for plants was mainly driven by	e one proposed in the framework of JMPR assessments. 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.

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	-	-	-

TABLE	4	Analytical methods available.
	- T	Analytical methods available.

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.

^aSummed LOQ (individual LOQ of p,p'-dicofol and o,p'-dicofol as corresponding DCBP isomer are equal to $\frac{1}{2}$ of the summed LOQ).

^bSummed LOQ (individual LOQ of p,p'-dicofol and o,p'-dicofol are equal to ½ of the summed LOQ).

^cLOQ 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.

		vas nented °evoked	CXL was nented revoked	has PR, 2013; ns over, a MRL	revoked	CXL was nented in evoked	L was nented in revoked.
		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	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	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	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	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	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.
		ns. The pro CXL was lec eview.). n place and	in seeds. Th CXL was lec eview. , 2013). n place and	Existing EU MRL was legally implemented in Regulation (EC) 149/20 never been modified. The origin of this MRL is unknown. In 2012, JMPR proposed a CXL of 40 mg/kg. The proposed CXL was a CCPR 45/CAC in 2013 noting the reservations expressed ^a at EU le 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 res were expressed for the implementation of the in force CXL on te metabolism study on leafy crops is not available to support the	. The proposed CXL was led	ry meat. Th CXL was lec ew. t, 2013). n place and	ry fat. The p CXL was leç ew. 013). n place and
		In 1992, JMPR proposed a CXL of 0.2 mg/kg on melons. Th adopted by CCPR 26/CAC in 1995. The proposed CXL v 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	In 1992, JMPR proposed a CXL of 0.1 mg/kg on cotton seed adopted by CCPR 26/CAC in 1995. The proposed CXL wi 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	string EU MRL was legally implemented in Regulation (EC) never been modified. The origin of this MRL is unknown. 012, JMPR proposed a CXL of 40 mg/kg. The proposed C) CCPR 45/CAC in 2013 noting the reservations expressed ^a EFSA, 2013). FFSA, 2013). rsequently, the CXL proposal has not been legally implen sting EU MRL is not substantiated as no IT uses in place ar were expressed for the implementation of the in force C) metabolism study on leafy crops is not available to supp	992, JMPR proposed a CXL of 50 mg/kg on hops. The F adopted by CCPR 26/CAC in 1995. The proposed CXL v in Regulation (EU) No 899/2012 following MRL review. c CXL on hops was revoked in 2013 (CCPR, 2013). sting EU MRL is not substantiated as no IT use is in place	In 1994 JMPR proposed a CXL of 0.1 mg/kg on poultry meat adopted by CCPR 27/CAC in 1995. The proposed CXL wa 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	In 1994 JMPR proposed a CXL of 0.1 mg/kg on poultry fa adopted by CCPR 27/CAC in 1995. The proposed CXL 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 pla
		(L of 0.2 mg 2 in 1995. Th 9/2012 follo iked in 2013 antiated as	(L of 0.1 mg C in 1995. TH 9/2012 follo s revoked ir antiated as	implemente e origin of t cl. of 40 mg, ing the rese ing the root osal has not osal has not antiated as inplementai fy crops is r	In 1992, JMPR proposed a CXL of 50 mg/kg on hop: adopted by CCPR 26/CAC in 1995. The proposed in Regulation (EU) No 899/2012 following MRL r The CXL on hops was revoked in 2013 (CCPR, 2013). Existing EU MRL is not substantiated as no IT use is	L of 0.1 mg, 1 in 1995. Th 2012 followi s revoked in antiated as	L of 0.1 mg, 1 in 1995. Th 2012 followi evoked in 2 antiated as
משכיר הור בסילן מומ ירוווינמוטו אוויניוני הוכזר יממני מר זמו הניהויון זמאוימינים		pposed a CY CPR 26/CAG (EU) No 89 ns was revo is not substi	pposed a C) CPR 26/CA((EU) No 89 [,] in seeds wa is not subst	was legally hodified. Th pposed a CX in 2013 not e CXL prop is not substr tudy on lea	pposed a C> CPR 26/CA((EU) No 89 was revoke is not subst	posed a CX CPR 27/CAC U) No 899/2 rry meat wa is not subst	posed a CX CPR 27/CAC U) No 899/2 rry fat was r is not substi
	nent	2, JMPR pro lopted by C Regulation XL on melo XL on melo	2, JMPR prc lopted by C Regulation XL on cotto XE UMRL i ng EU MRL i	ting EU MRL v never been m 012, JMPR prc CCPR 45/CAC EFSA, 2013). isequently, th ting EU MRL i were express metabolism s	2, JMPR prc lopted by C Regulation XL on hops Pg EU MRL i	4 JMPR pro lopted by C gulation (E XL on poult ng EU MRL i	4 JMPR pro lopted by C gulation (E XL on poult XL on Poult
	Fall-back MRL (mg/kg) Comment	ln 199 ad in The C Existir	In 199 ad The C Existir	Existir no co CO CO CO Conse ER Existir we	In 199 ad in The C Existir	ln 199 ad Re The C Existir	In 199 ad Re The C Existir
	Fall-back MRL (mg/l	I	1	1	1	1	1
	Fall-back GAP	No fall-back GAP identified	No fall-back GAP identified	No fall-back GAP identified	No fall-back GAP identified	No fall-back GAP identified	No fall-back GAP identified
	_	No fall- ideı	No fall- ideı	No fall- ideı	No fall- ideı	No fall- ideı	No fall- ideı
	Existing MRL substantiated? (Y/N)						
	Existi subst (Y/N)	S./ N	Z	z	Z /:	Z Z	Z P
	MRL	USA: Foliar appl., 3×0.62 kg a.s./ ha, PHI 2 days	USA: Foliar appl., 2× 1.66 kg a.s./ ha, PHI 30d		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	Based on a residue of 0.1 mg of dicofol/ kg of feed (FAO and WHO, 1994)	Based on a residue of 0.1 mg of dicofol/ kg of feed (FAO and WHO, 1994)
	cGAP for existing MRL	A: Foliar appl., 3> ha, PHI 2 days	ır appl., 2> I 30d	nents	many: Foliar appl., a.s./ha, PHI 28 days A: Foliar appl., 2×1. ha, PHI 7 days	a residue (il/ kg of fe 1994)	a residue (il/ kg of fe 1994)
	cGAP for	USA: Folia ha, PH	USA: Foliar app ha, PHI 30d	See comments	Germany: a.s./ha USA: Folia ha, PH	Based on a resit dicofol/ kg c WHO, 1994)	Based on a resi dicofol/ kg c WHO, 1994)
	: of g MRL	CXL (CAC, 1995)	CXL (CAC, 1995)	See comments	CXL (CAC, 1995)	CXL (CAC, 1995)	CXL (CAC, 1995)
	Source of existing MRL	CXL (C	CXL (C)	See cor	CXL (C	CXL (C	CXL (C
D	Existing MRL (mg/kg)	0.2	0.1	20	20	0.1	0.1
	Commodity	Melons	Cotton seeds	٣	Hops	Poultry, muscle	Poultry, fat
	Ŭ	Σ	Ŭ	Теа	ĭ	Рс	Рс

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

(Continues)

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:	Existing MRL	Source of		Existing MRL substantiated?		Fall-back	
Poultry, liver	0.05	CXL (CAC, 1995)	Based on a residue of 0.1 mg of dicofol/ kg of feed (FAO and WHO, 1994)	Z	No fall-back GAP identified	- In 1992 JMI - CUL wa CXL wa implem The CXL or Existing FU	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 LT 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)	z	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)	z	No fall-back GAP identified	1	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)	z	No fall-back GAP identified	1	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)	z	No fall-back GAP identified	1	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. tolerance; MRL, r.	.s., active subs naximum resi	Abbreviations: a.s., active substance; CAC, Codex Alimentarius Cc tolerance; MRL, maximum residue limit; PHI, pre-harvest interval.	mentarius Commission; CCPR, Codex co vest interval.	mmittee on pesticide	eresidues; CXL, Codex	maximum residue	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; MRI, maximum residue limit; PAL, maximum residue limit; PAL, pre-harvest interval.

^aThere is evidence that dicofol is unstable under processing and is expected to produce degradation products which could also generate chloroform.

^bCommission 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.

^cIndicates 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, 2008⁹). 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.
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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

⁹Commission 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.

¹⁰See 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 identified¹²:

- 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

¹¹Commission 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.

¹²See 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.

INDEL 0	Summary table.							
			Outcome of the review					
Code ^a	Commodity	Existing MRL ^b (mg/kg)	MRL proposal (mg/kg)	Comment				
Residue d	efinition for enfor	cement (plan	ts and anima	l 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 $$				
0610000	Теа	20	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ				
0700000	Hops	50	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ $$				
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				

TABLE 8 Summary table.

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

^aCommodity code number according to Annex I of Regulation (EC) No 396/2005.

^bMRL currently set under Regulation (EU) No 899/2012.

ABBREVIATIONS

ABBREVIAT	IONS
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	Rappourter 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

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REFERENCES

- CAC (Codex Alimentarius Commission). (1995). Report on the Joint FAO/WHO food standards programme. Codex Alimentarius Commission, twenty-first session, Rome, 3–8 July 1995.
- CCPR (Codex committee on pesticide residues). (1994). Report of the 26th session of the Codex committee on pesticide residues, The Hague, The Netherlands, 11–18 April 1994.
- CCPR (Codex committee on pesticide residues). (1995). Report of the 27th session of the Codex committee on pesticide residues, The Hague, The Netherlands, 24 April-1 May 1995.
- CCPR (Codex committee on pesticide residues). (2013). Report of the 45th session of the Codex committee on pesticide residues, Beijing, China, 6–11 May 2013. ECHA and EFSA (European Chemicals Agency and European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson, N., Arena, M., Auteri, D., Barmaz, S., Grignard, E., Kienzler, A., Lepper, P., Lostia, A. M., Munn, S., Parra Morte, J. M., Pellizzato, F., Tarazona, J., Terron, A., & Van der Linden, S. (2018). Guidance for the identification of endocrine disruptors in the context of regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal, 16(6), 135. https://doi.org/10.2903/j.efsa.2018.5311
- EFSA (European Food Safety Authority). (2011). Reasoned opinion on the review of the existing maximum residue levels (MRLs) for dicofol according to article 12 of regulation (EC) No 396/2005. EFSA Journal, 9(8), 33. https://doi.org/10.2903/j.efsa.2011.2337
- EFSA (European Food Safety Authority). (2013). Scientific support for preparing an EU position in the 45th session of the codex committee on pesticide residues (CCPR). *EFSA Journal*, 11(7), 210. https://doi.org/10.2903/j.efsa.2013.3312
- EFSA (European Food Safety Authority). (2023a). Report on the pesticide peer review TC 100 dicolfol. April, 2023. www.efsa.europa.eu
- EFSA (European Food Safety Authority). (2023b). Member States consultation report on the targeted review of maximum residue levels (MRLs) for dicofol prepared by EFSA in the framework of Article 43 of Regulation (EC) No 396/2005, October 2023. www.efsa.europa.eu
- EFSA (European Food Safety Authority), Anastassiadou, M., Brancato, A., Carrasco Cabrera, L., Ferreira, L., Greco, L., Jarrah, S., Kazocina, A., Leuschner, R., Magrans, J. O., Miron, I., Pedersen, R., Raczyk, M., Reich, H., Ruocco, S., Sacchi, A., Santos, M., Stanek, A., Tarazona, J., ... Verani, A. (2019). Pesticide residue intake model- EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). *EFSA Supporting Publication*, 15. https://doi.org/10.2903/sp.efsa. 2019.EN-1605
- EFSA (European Food Safety Authority), Brancato, A., Brocca, D., Ferreira, L., Greco, L., Jarrah, S., Leuschner, R., Medina, P., Miron, I., Nougadere, A., Pedersen, R., Reich, H., Santos, M., Stanek, A., Tarazona, J., Theobald, A., & Villamar-Bouza, L. (2018). Guidance on use of EFSA pesticide residue intake model (EFSA PRIMo revision 3). *EFSA Journal*, *16*(1), 43. https://doi.org/10.2903/j.efsa.2018.5147
- EURLs (EU Reference Laboratories for Pesticide Residues). (2022). Evaluation Report prepared under Article 43 of Regulation (EC) No 396/2005. Analytical validations by the EURLs and capability of official laboratories to be considered for the targeted review of the MRLs for dicofol. December 2022. Updated on September 2023. www.efsa.europa.eu
- European Commission. (2008). Final Review report for the active substance dicofol finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 20 May 2008 in support of a decision concerning the non-inclusion of dicofol in Annex I of Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance. SANCO/1365/08 – rev. 0, 25 April 2008.
- FAO (Food and Agriculture Organization of the United Nations), & WHO (World Health Organization). (2012). Dicofol. In: Pesticide residues in food 2012. Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Rome, Italy, 11–20 September 2012. FAO Plant Production and Protection Paper 215.
- FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (1992). Dicofol. In: Pesticide residues in food – 1992. Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Rome, Italy, 21–30 September 1992. Evaluations, Part I, Residues. FAO Plant Production and Protection Paper 118.
- FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (1994). Dicofol. In: Pesticide residues in food – 1994. Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Rome, Italy, 19–28 September 1994. FAO Plant Production and Protection Paper 127.
- FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organization). (2011). Dicofol. In: Pesticide residues in food 2011. Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticides Residues, Part II, Toxicological. Geneva, Switzerland, 20–29 September 2011.
- Spain. (2006). Draft assessment report on the active substance dicofol prepared by the rapporteur Member State Spain in the framework of Council Directive 91/414/EEC, October 2005.

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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)

Image: contract of the	-	***				Dicefel (E)				Input	Input values		
	+	*				_							
Image: line of the state of the st		*			LOQs (mg/kg) range	rom: 0.02	to:	0.10	Details – chron	iic risk	Supplementary result	ts-	
Optimized Statistical Control Control Col Control Col Control Col Control Col Control Col Control Col Col <th< th=""><th></th><th>1</th><th></th><th></th><th></th><th></th><th>alues</th><th></th><th>assessmei</th><th></th><th>chronic risk assessme</th><th>ent</th><th></th></th<>		1					alues		assessmei		chronic risk assessme	ent	
Desire Fight Mutting Desire fight Mutting)	50		ADI (mg/kg bw per da		ARfD (mg/kg bw):	0.15					
Image: constrained of the co	ш	Uropean Food EFSA PRIMore	l Safety Authority vision 3.1: 2019/03/19		Source of ADI: Year of evaluation:	ES 2006	Source of ARfD: Year of evaluation:	ES 2006	Details – acuti assessment/ch	e rısk ildren	Details – acute risk assessment/adults	~ 6	
Nome Nome <th< th=""><th>Commen</th><th>nts:</th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th></th<>	Commen	nts:											
Control control Control control Control control Control control Control						Normal mod	힘						
Anticipation Control						Chronic risk assessment: JMPR	R methodology (II	EDVTMDI)					
International problem (1) Terms (1)					No of diets exceeding	the ADI :	1					Exposure rest	ulting from
10% W 600m 21 0.0 06. 06. 0.0 06. 06. 0		Calculated exposur (% of ADI)		Expsoure (µg/kg bw per dav)	Highest contributor to MS diet (in % of ADI)	Commodity/ recours of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ noun of commodities	3rd.	contributor to MS diet (in % of ADI)	modifies	MRLs set at 00 the LOQ unc (in % of ADI) (immodifies not der assessment (in % of ADI)
91 0.01d 0.11		124%	NL toddler	2.47	%09	Milk: Cattle	11%	Apples		7%	Maize/com	124%	
07.0 07.0 <th< td=""><td></td><td>65%</td><td>NL child</td><td>1.31</td><td>24%</td><td>Milk: Cattle</td><td>8%</td><td>Sugar beet roots</td><td></td><td>6%</td><td>Apples</td><td>65%</td><td></td></th<>		65%	NL child	1.31	24%	Milk: Cattle	8%	Sugar beet roots		6%	Apples	65%	
000 FORME 1 000		62%	DE child	1.24	20%		12%	Apples		4%	Wheat	62%	
6% FF edd 1 5 y ⁻¹ 10 2% 0 cm		55%	UN IIIIani FR toddler 2.3 vr	17.1	28% 28%		° %	- Otatioes Apples		3%	Wheat	55%	
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(1) Constraction (1) (2) Constraction (2) (2) <th< td=""><td>(1</td><td>45%</td><td>UK toddler</td><td>0.89</td><td>21%</td><td>Milk: Cattle</td><td>4%</td><td>Wheat</td><td></td><td>3%</td><td>Potatoes</td><td>45%</td><td></td></th<>	(1	45%	UK toddler	0.89	21%	Milk: Cattle	4%	Wheat		3%	Potatoes	45%	
360 GBX5rod (3) 7.5 VNut 64 Tomoto 25 Mix Cata 368 GBX5rod (3) 0.5 Y.6 Ottom 0.5 Mix Cata 0.5 Mix Cata 368 GBX5rod (3) 0.5 Y.6 Ottom 0.5 Mix Cata 0.5 Point 37.6 GBX5rod (3) 0.5 Y.6 Ottom 0.6 Point	noite	41% 41%	GEMS/Food G11 DK child	0.82	8% 13%	Milk: Cattle Milk: Cattle	4% %9	-otatoes Ryte		4% 4%	Soyabeans Wheat	41%	
383 GMS/Food (37) 0.3 5% Net Cutto 5% Net South 5% South 5% South South 5% South South 5% South South 5% South South South 5% South South South	dwn	38%	GEMS/Food G06	0.76	7%	Wheat	4%	Tomatoes		2%	Milk: Cattle	38%	
38. Editivation (1) 7. With cuttle 7. Cuttle 7. Cuttle 7. Cuttle 7. Cuttle 7. Cuttle 7. With cuttle 7. Solutions 7. Solutions 7. Solutions 7. Solutions Solutions <td>isuc</td> <td>38%</td> <td>GEMS/Food G07</td> <td>0.76</td> <td>6%</td> <td>Milk: Catfle</td> <td>4%</td> <td>Wheat</td> <td></td> <td>4%</td> <td>Potatoes</td> <td>38%</td> <td></td>	isuc	38%	GEMS/Food G07	0.76	6%	Milk: Catfle	4%	Wheat		4%	Potatoes	38%	
000 Current Cold 070 <t< td=""><td>o p</td><td>38%</td><td>GEMS/Food G15</td><td>0.75</td><td>%L</td><td>Milk: Cattle</td><td>5%</td><td>Wheat</td><td></td><td>4%</td><td>Potatoes</td><td>38%</td><td></td></t<>	o p	38%	GEMS/Food G15	0.75	%L	Milk: Cattle	5%	Wheat		4%	Potatoes	38%	
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37.8 Externant-LED/Y 0.7 17.9 Non-current 27.9	IVer	37%	GEMS/Food G10	0.73	5%	Milk: Cattle	4%	Wheat		3%	Soyabeans	37%	
96: Egeneral 071 7:3: 6:40 6:5 Signate fictorial 7:3: 6:40 6:40 7:3: 6:40 6:40 6:40 6:40 6:40 6:40 6:40 6:40 6:40 6:40 6:40 6:40 6:40 <td>e uo</td> <td>37%</td> <td>DE women 14-50 yr FS child</td> <td>0.73</td> <td>12%</td> <td>Milk: Catte Milk: Catte</td> <td>5% 76%</td> <td>Sugar beet roots Mheet</td> <td></td> <td>3%</td> <td>Apples Orannee</td> <td>37%</td> <td></td>	e uo	37%	DE women 14-50 yr FS child	0.73	12%	Milk: Catte Milk: Catte	5% 76%	Sugar beet roots Mheet		3%	Apples Orannee	37%	
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		8%	IE child	0.16	4%	Milk: Catfle	1%	Wheat		0.6%	Potatoes	8%	
		For 1 diet(s) the ADI is exceeded.	N is exceeded.										

Т

 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.
The calculation is based on the large portion of the most critical consumer group.

Results for childr No. of commodities	ren s for which ARfD/ADI is exceeded (IESTI):			Results for adults No. of commodities exceeded (IESTI):	for which ARfD/ADI is		
IESTI				IESTI			
		MRL/input				MRL/input	
Highest % of		for RA	Exposure	Highest % of		for RA	Expos
ARfD/ADI	Commodities	(mg/kg)	(µg/kg bw)	ARfD/ADI	Commodities	(mg/kg)	(µg/kg
2%	Potatoes	0.02/0.02	3.1	0.6%	Head cabbages	0.02/0.02	0.8
2%	Melons	0.02/0.02	3.0	0.5%	Watermelons	0.02/0.02	0.8
2%	Pears	0.02/0.02	2.8	0.5%	Melons	0.02/0.02	0.7
2%	Oranges	0.02/0.02	2.7	0.5%	Milk: Cattle	0.02/0.02	0.7
2%	Milk: Cattle	0.02/0.02	2.5	0.5%	Swedes/rutabagas	0.02/0.02	0.6
2%	Watermelons	0.02/0.02	2.4	0.5%	Table grapes	0.02/0.02	0.6
1%	Apples	0.02/0.02	2.2	0.4%	Oranges	0.02/0.02	0.6
1%	Pineapples	0.02/0.02	2.0	0.4%	Pears	0.02/0.02	0.6
1%	Bananas	0.02/0.02	1.9	0.4%	Potatoes	0.02/0.02	0.6
1%	Peaches	0.02/0.02	1.9	0.4%	Pineapples	0.02/0.02	0.5
1%	Mangoes	0.02/0.02	1.6	0.4%	Yams	0.02/0.02	0.5
1%	Grapefruits	0.02/0.02	1.6	0.4%	Apples	0.02/0.02	0.5
1.0%	Table grapes	0.02/0.02	1.5	0.4%	Cucumbers	0.02/0.02	0.5
	Cucumbers	0.02/0.02	1.3	0.4%	Aubergines/egg plants	0.02/0.02	0.5
0.9%							
0.8% Expand/collapse lis Total number of o diets (IESTI calculation	Carrots st commodities exceeding the ARfD/ADI in chi n)	0.02/0.02	1.3	0.3%	Mangoes	0.02/0.02	0.5
0.8% Expand/collapse lis Total number of o diets (IESTI calculation Results for childr	Carrots st commodities exceeding the ARfD/ADI in chi n)	0.02/0.02		0.3%			0.5
0.8% Expand/collapse lis Total number of o diets (IESTI calculation Results for childr	Carrots st commodities exceeding the ARfD/ADI in chi a)	0.02/0.02		0.3%	Mangoes		0.5
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0.8% Expand/collapse lis Total number of c diets (IESTI calculation Results for childr No of processed co (IESTI): IESTI	Carrots st commodities exceeding the ARfD/ADI in chi a)	0.02/0.02 Idren and adult		0.3% Results for adults No of processed oc is exceeded (IESTI IESTI	Mangoes	I MRL/input	
0.8% Expand/collapse lis Total number of c diets (IESTI calculation Results for childr No of processed cc (IESTI): IESTI Highest % of	Carots et commodities exceeding the ARTD/ADI in chi)) en en momodities for which ARTD/ADI is exceeded	0.02/0.02 Idren and adult MRL/input for RA	1.3 Exposure	0.3% Results for adults No of processed cc is exceeded (IESTI IESTI Highest % of	Mangoes mmodilies for which AR(D/AD	I MRL/input for RA	 Expos
0.8% Expand/collapse list Total number of c diets (IESTI calculation Results for childr No of processed cc (IESTI): IESTI Highest % of ARRD/ADI	Carrots commodities exceeding the ARID/ADI in chi b) ren commodities for which ARID/ADI is exceeded Processed commodities	0.02/0.02 Idren and adult MRL/input for RA (mg/kg)	1.3 Exposure (µg/kg bw)	0.3% Results for adults No of processed cc is exceeded (IESTI IESTI Highest % of ARID/ADI	Mangoes mmodilies for which ARID/AD	I MRL/input for RA (mg/kg)	0.5 Expor (µ9/g
0.8% Expand/collapse list Total number of c diets (IESTI calculation Results for child No of processed cc (IESTI): IESTI Highest % of ARfD/ADI 1%	Carots et commodities exceeding the ARTD/ADI in chi) en en modities for which ARTD/ADI is exceeded Processed commodities Sugar beets (root)/sugar	0.02/0.02 Idren and adult MRL/input for RA (mg/kg) 0.02/0.24	1.3 Exposure (µg/kg bw) 2.2	0.3% Results for adults No of processed cc is exceeded (IESTI IESTI Highest % of ARtD/ADI 0.7%	Mangoes mmodilies for which ARID/AD	MRL/input for RA (mg/kg) 0.02/0.02	Ехроз (µg/kg 1.*
0.8% Expand/collapse list Total number of c diets (IESTI calculation No of processed cc (IESTI): IESTI Highest % of AR(D/ADI 1% 1%	Carrots commodities exceeding the ARID/ADI in chi commodities for which ARID/ADI is exceeded mommodities for which ARID/ADI is exceeded Processed commodities Sugar beets (root)sugar Potatoes/rind	0.02/0.02 Idren and adult MRL/input for RA (mg/kg) 0.02/0.24 0.02/0.02	1.3 Exposure (µg/kg bw) 2.2 1.9	0.3% Results for adults No of processed cc is exceeded (IESTI IESTI Highest % of ARID/ADI 0.7% 0.6%	Mangoes mmodiles for which ARID/AD	MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.24	Ехроз (µg/kg 1.1 0.8
0.8% Expand/collapse list Total number of c diets (IESTI calculation No of processed or (IESTI) IESTI Highest % of ARR0/ADI 1% 1%	Carots at commodities exceeding the ARTD/ADI in chi commodities for which ARTD/ADI is exceeded Processed commodities Sugar beets (root)/sugar Potatoes/fried Pumpkins/boiled	0.02/0.02 Idren and adult MRL/input for RA (mg/kg) 0.02/0.24 0.02/0.02	1.3 (µg/kg bw) 2.2 1.9 1.8	0.3% Results for adults No of processed cc is exceeded (IEST) IESTI Highest % of ARTU/ADI 0.7% 0.6%	Mangoes mmodilies for which ARID/AD mmodilies for which ARID/AD mmodilies Processed commodiles Processed commodiles Coulting and the set of the	MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02	Ехроз (µg/kg 1. ⁻ 0.8 0.8
0.8% Expand/collapse lin Total number of c diets (IESTI calculation (IESTI): IESTI Highest % of ARIO/ADI 1% 1% 1%	Carots st commodities exceeding the ARID/ADI in chi o modifies for which ARID/ADI is exceeded Processed commodities Sugar beets (roct)sugar Putatos/rind Putatos/rind Putatos/rind	0.02/0.02 Idren and adult MRL/input for RA (mg/kg) 0.02/0.24 0.02/0.02 0.02/0.02	1.3 Exposure (µg/kg bw) 2.2 1.9 1.8 1.8	0.3% Results for adults No of processed oc is exceeded (IESTI Highest % of ARD/ADI 0.7% 0.6% 0.6% 0.5%	Mangoes mmodilies for which ARID/AD processed commodilies Processed commodilies Sugar best (col/sugar Caulifoxers/boiled Beetroot/solied	MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02	Expos (µg/kg 1. 0.8 0.8 0.7
0.8% Expand/collapse lit Total number of c diets (IEST1 calculation (IEST1) (I	Carots st commodities exceeding the ARTD/ADI in chi o ren Processed commodities Processed commodities Sugar beeks (root)/sugar Potatoes/fried Pumpkins/boiled Witkoofs/boiled Broccoli/boiled	0.02/0.02 Idren and adult MRL/input for RA (mg/kg) 0.02/0.24 0.02/0.02 0.02/0.02 0.02/0.02	1.3 Exposure (µg/kg bw) 2.2 1.9 1.8 1.8 1.6	0.3% Results for adults No of processed cy is exceeded (IESTI IESTI IESTI 0.7% 0.6% 0.5%	Mangoes mmodilies for which ARID/AD mmodilies for which ARID/AD mmodilies Processed commodilies Processed commodilies Col/Sugar Col/Suga	MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	Ехроз (µg/kg 1.* 0.8 0.7 0.6
0.8% Expand/collapse iii Total number of c diets (IESTI calculation (IESTI) IESTI Highest % of ARVI/ADI 1% 1% 1% 1% 1% 1%	Carots st commodities exceeding the ARID/ADI in chi o mmodities for which ARID/ADI is exceeded Processed commodities Sugar beets (roct)sugar Potatose/rind Putpos/boiled Broccol/boiled Caulifilowers/boiled	0.02/0.02 Idren and adult MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	1.3 Exposure (µg/kg bw) 2.2 1.9 1.8 1.8 1.6 1.4	0.3%	Mangoes mmodilies for which ARID/AD processed commodilies Processed commodilies Sugar best (col/sugar Caulifowers/boiled Bestroots/boiled Caleries/boiled Caleries/boiled	MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	Expos (µg/kg 0.8 0.8 0.7 0.6 0.6
0.8% Expand/collapse lit Total number of c diets (IEST1 calculation (IEST1) Highest % of ARD/ADI 1% 1% 1% 1% 0.9%	Carots st commodities exceeding the ARfD/ADI in chi on en on Processed commodities Sugar beds (rod/)sugar Potatos/fried Pumpkin5bolied Wittoor/sbolied Wittoor/sbolied Cauliflowers/bolied	0.02/0.02 Idren and adult MRL/input for RA (mg/kg) 0.02/0.24 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	1.3 Ехроѕиге (µg/kg bw) 2.2 1.9 1.8 1.8 1.8 1.6 1.4 1.3	0.3% Results for adults No of processed cy is exceeded (IESTI IESTI IESTI 0.7% 0.6% 0.5% 0.5% 0.4% 0.3%	Mangoes mmodilies for which ARID/AD modilies for which ARID/AD mmodilies Processed commolilies Pumpkins/boiled Sugar boets (rool/sugar Califlower/boiled Beetrools/boiled Appleg/juice Broccoli/boiled	MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	Ехроз (µg/kg 1.° 0.8 0.8 0.7 0.6 0.6 0.6 0.6
0.8% Expand/collapse iii Total number of c diets (IESTI calculation (IESTI) IESTI Highest % of ARVI/ADI 1% 1% 1% 1% 0.9% 0.8%	Carots st commodities exceeding the ARID/ADI in chi o modities for which ARID/ADI is exceeded Processed commodities Sugar beets (roct)sugar Potatose/rind Putatos/rind Broccoll/boiled Broccoll/boiled Escaroles/broad-leaved endives/boiled Potatose/rind(fakes)	0.02/0.02 Idren and adult MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	1.3 Exposure (μg/kg bw) 22 1.9 1.8 1.8 1.8 1.4 1.2	0.3% Results for adults No of processed or is exceeded (IEST) IESTI Highest % of ARIO/ADI 0.7% 0.6% 0.6% 0.5% 0.5% 0.5% 0.3%	Mangoes mmodilies for which ARID/AD processed commodilies Processed commodilies Sugar best (col/sugar Caulifowers/boiled Bestroots/boiled Celeries/boiled Broccoli/boiled Coffee beans/axtraction	MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	Ехрос (µg/kg 1.° 0.8 0.8 0.7 0.6 0.4 0.4
0.8% Expand/collapse ini Total number of c diets (IESTI calculation No of processed co (IESTI): Highest % of ARR/ADI 1% 1% 1% 1% 0.9% 0.8%	Carots st commodities exceeding the ARfD/ADI in chi o mmodities for which ARfD/ADI is exceeded Processed commodities Sugar beds (rod/)sugar Potatos/fried Pumpkin5boled Wittoors/boiled Escarote/sbroiled Cauliflowers/boiled Placabas/dried(flakes) Leeks/boiled	0.0200.02 Idren and aduit MRL/input for RA (mg/kg) 0.0270.02 0.0270.02 0.0270.02 0.0270.02 0.0270.02 0.0270.02 0.0270.02 0.0270.02 0.0270.02 0.0270.02 0.0270.02 0.0270.02	1.3 Exposure (µghg by) 2.2 1.8 1.8 1.8 1.8 1.6 1.4 1.3 1.2 1.1	0.3% Results for adults No of processed cc is exceeded (IEST) IESTI Highest % of A7% 0.6% 0.5% 0.4% 0.5% 0.3% 0.3% 0.3% 0.3% 0.3% 0.3% 0.3% 0.3	Mangoes mmodilies for which ARID/AD modilies for which ARID/AD modilies mmodilies mmodilies Processed commolilies Processed commolilies Calific beets (rool/sugar Calific beets/roolid Beetrools/boiled Califie beams/araction Courgetts/boiled	HRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	Expos (µg/kg 1. ⁻ 0.8 0.7 0.6 0.6 0.4 0.4 0.4
0.8% Expand/collapse iii Total number of c diets ICESTI calculation (ICESTI calculation (ICESTI) IEESTI Highest % of ARRO/ADI 1% 1% 1% 1% 0.9% 0.8% 0.8% 0.8%	Carots st commodities exceeding the ARID/ADI in chi o modifies for which ARID/ADI is exceeded Processed commodities Sugar beets (roct)sugar Potatose/rind Putatos/rind Broccoll/boiled Broccoll/boiled Broccoll/boiled Escaroles/broad-leaved endives/boiled Potatose/boiled Escaroles/boiled Escaroles/boiles/boiled Escaroles/boiled Escaroles/boiled Escaroles/boiled Escaroles/boiled Escaroles/boiled Escaroles/boiles/boiles/boiled Escaroles/boiles/bo	0.02/0.02 Idren and adult MRL/input for RA (mg/kg) 0.02/0.24 0.02/0.02	1.3 Exposure (µg/kg bw) 1.9 1.8 1.6 1.4 1.3 1.2 1.1	0.3% Results for adults No of processed co is exceeded (IEST) IESTI Highest % of ARD/ADI 0.7% 0.6% 0.6% 0.5% 0.5% 0.3	Mangoes mmodilies for which ARID/AD processed commodilies Processed commodilies Pumpkinsboiled Sugar besit (col/sugar Cauliflowers/boiled Bestroots/boiled Celeries/boiled Broccoli/boiled Coffee bean/sktraction Courgetss/boiled Parsinjab/boiled	MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	Expos (µg/kg 1.° 0.8 0.6 0.6 0.6 0.4 0.4 0.4 0.4
0.8% Expand/collapse iii Total number of c diets (IESTI calculation No of processed or (IESTI): IESTI Highest % of ARD/ADI 1% 1% 1% 0.9% 0.8% 0.8% 0.7% 0.7%	Carots st commodities exceeding the ARfD/ADI in chi on en on Processed commodilies Sugar beds (root/)sugar Pototos/fried Processed commodilies Sugar beds (root/)sugar Pototos/fried Pumpkins/boiled Witkods/boiled Escaroles/broiled Cauliflowers/boiled Pototos/fried(flakes) Leeks/boiled Apples/juice Oranges/juice	0.020.02 tdren and adult MRU/input for RA (mg/kg) 0.020.22 0.020.020 0.020.0200 0.020.020	1.3 —— Ехровите (µg/kg bw) 2.2 1.9 1.8 1.6 1.4 1.4 1.3 1.2 1.1 1.1	0.3% Results for adults No of processed oc is exceeded (IEST) IEST Highest % of ARID/ADI 0.7% 0.6% 0.5% 0.4% 0.5% 0.4% 0.3% 0.3% 0.3% 0.3% 0.3% 0.3% 0.3% 0.3	Mangoes mmodilies for which ARID/AD modilies for which ARID/AD Turnokinsholiad Purnokinsholiad Sugar beets (rool/sugar Califilowersholiad Beetroolsholida Celfersboliad Coffee beans/sutraction Corgettsbolied Parsnipsbolied Parsnipsbolied Parsnipsbolied	MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	Expos (µg/kg 1. 0.8 0.7 0.6 0.4 0.4 0.4 0.4 0.4
0.8% Expand/collapse iii Total number of c diets (IESTI calculation No of processed c (IESTI): IESTI Highest % of ARIO/ADI 1% 1% 1% 0.8% 0.8% 0.8% 0.8% 0.7% 0.7%	Carots et commodities exceeding the ARTD/ADI in chi	0.02/0.02 Idren and adult MRL/input for RA (mg/kg) 0.02/0.24 0.02/0.02/0.02 0.02/0.02/0.02 0.02/0.02/0.02/0.02/0.02/0.02/0.0	1.3 Exposure (µg/kg bw) 1.9 1.8 1.8 1.8 1.4 1.3 1.2 1.1 1.1 1.1 1.1	0.3% Results for adults No of processed co is exceeded (IESTI Highest % of ARTD/ADI 0.6% 0.6% 0.5% 0.3% 0.3% 0.3% 0.3% 0.3%	Mangoes mmodilies for which ARID/AD processed commodilies Processed commodilies Processed commodilies Cauliforwarbioled Bestrocolsboiled Bestrocolsboiled Bestrocolibolied Coffee beansixtraction Courgetesboiled Kohrbaitesboiled	I MRU/input for RA (mg/kg) 0.02/0.24 0.02/0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.0	Ехрот (µg/kg 1. ⁻ 0.8 0.7 0.6 0.4 0.4 0.4 0.4 0.4 0.4 0.4 0.4
0.8% Expand/collapse iii Total number of c diets (IESTI calculation No of processed or (IESTI): IESTI Highest % of ARID/ADI % 1% 1% 1% 0.9% 0.8% 0.8% 0.7% 0.7% 0.7%	Carots st commodities exceeding the ARfD/ADI in chi o mmodities for which ARfD/ADI is exceeded Processed commodities Sugar beds (rod/)sugar Potatose/fried Pumpkins/boiled Witkor/sholied Witkor/sholied Escaroles/broked/aevad end/ves/boiled Potatose/fried Apples/juice Oranges/juice Turnjes/boiled	0.02/0.02 tdren and adult MRU/input for RA (m/g/kg) 0.02/0.22 0.02/0.02/0.02/0.02 0.02/0.02/0.02/0.02/0.02/0.02/0.02/0.02	1.3 Exposure (μg/kg bw) 2.2 1.9 1.8 1.6 1.4 1.3 1.2 1.1 1.1 1.1 1.1 1.1 1.0	0.3% Results for adults No of processed or is exceeded (IEST) IEST Highest % of AFID/ADI 0.7% 0.6% 0.5% 0.5% 0.4% 0.3	Mangoes The ARID/AD Sector Arithmetic ARID/AD Sector Arithmetic ARID/AD Sector Arithmetic ARID/AD Sector Arithmetic Arith	MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	Export (µg/kg 1.* 0.8 0.6 0.6 0.6 0.6 0.4 0.4 0.4 0.4 0.4 0.4 0.4 0.4
0.8% Expand/collapse iii Total number of c diets (IESTI calculation No of processed or (IESTI): IESTI Highest % of ARIO/ADI 1% 1% 1% 1% 0.8% 0.8% 0.8% 0.8% 0.7% 0.7% 0.7%	Carots st commodities exceeding the ARTD/ADI in chi o ren Processed commodifies Sugar beds (root)/sugar Potatos/fried Pumpkinsboiled Wittoofs/boiled Broccoli/boiled Caulificwers/boiled Caulifice(fikes) Carots/fice(fikes)	0.02/0.02 Idren and adult MRL/input for RA (mg/kg) 0.02/0.24 0.02/0.02/0.02 0.02/	1.3 	0.3% Results for adults No of processed co is exceeded (IEST) IEST1 Highest % of ARID/ADI 0.6% 0.6% 0.5% 0.5% 0.3% 0.3% 0.3% 0.3% 0.3%	Mangoes mmodilies for which ARID/AD Processed commodilies Processed commodilies Processed commodilies Califitowersholed Beetrools/boiled Califitowersholed Beetrools/boiled Califitowersholed Parsing/broiled Kohrabies/boiled Kohrabies/boiled Forence fendels/boiled Escartes/broad-tesede	I MRU/input for RA (mg/kg) 0.02/0.24 0.02/0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.0	Expos (µg/kg 1.° 0.8 0.6 0.6 0.4 0.4 0.4 0.4 0.4 0.4 0.4 0.4 0.4
0.8% Expand/collapse iii Total number of c diets (IESTI calculation No of processed or (IESTI): IESTI Highest % of ARID/ADI % 1% 1% 1% 0.9% 0.8% 0.8% 0.7% 0.7% 0.7%	Carots st commodities exceeding the ARfD/ADI in chi o mmodities for which ARfD/ADI is exceeded Processed commodities Sugar beds (rod)/sugar Potatos/fried Pumpkins/boiled Witkods/boiled Broccoli/boiled Caulifowers/boiled Apples/juce Oranges/juce Turnips/boiled Sweet potatoss/boiled Sweet potatoss/boiled Sweet potatoss/boiled Sweet potatoss/boiled Sweet potatoss/boiled	0.02/0.02 tdren and adult MRU/input for RA (m/g/kg) 0.02/0.22 0.02/0.02/0.02/0.02 0.02/0.02/0.02/0.02/0.02/0.02/0.02/0.02	1.3 Exposure (μg/kg bw) 2.2 1.9 1.8 1.6 1.4 1.3 1.2 1.1 1.1 1.1 1.1 1.1 1.0	0.3% Results for adults No of processed or is exceeded (IEST) IEST Highest % of AFID/ADI 0.7% 0.6% 0.5% 0.5% 0.4% 0.3	Mangoes The ARID/AD Sector Arithmetic ARID/AD Sector Arithmetic ARID/AD Sector Arithmetic ARID/AD Sector Arithmetic Arith	MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	Expor (µg/kg 1. 0.8 0.6 0.6 0.6 0.4 0.4 0.4 0.4 0.4 0.4 0.4 0.4 0.4

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	**				Dicofol			IIIbar	values		
	(LOQs (mg/kg) range from:	from: 0.01	to:	0.10	Details– chronic risk	Supplementary results –	ts –	
					Toxicological reference values	lues		assessment	chronic risk assessment	ent	
				ADI (mg/kg bw per day):	y): 0.002	ARfD (mg/kg bw):	0.15			ſ	
ш	uropean Food	European Food Safety Authority		Source of ADI:	ES	Source of ARID:	ES	Details – acute risk	Details- acute risk		
	EFSA PRIMo re-	EFSA PRIMo revision 3.1; 2019/03/19		Year of evaluation:	2006	Year of evaluation:	2006	assessment/ children	assessment/ addits		
Comments:	nts:										
					Normal mode	de					
					Chronic risk assessment: JMPR methodology (IEDI/TMDI)	R methodology (IEDI/TMDI)				
				No of diets exceeding the ADI	the ADI :					Exposure resulting from	ulting from
			Expsoire	Hinhest contributor to		2nd contributor to		3rd contributor to MS		MRLs set at commodities not the LOQ under assessmen	commodities not under assessment
	Calculated exposure (% of ADI)	rre MS Diet	(µg/kg bw per day)			MS diet (in % of ADI)	Commodity/ aroup of commodities	diet (in % of ADI)			(in % of ADI)
	94%	NL toddler	1.87	30%	Milk: Cattle	11%	Apples	7%	Maize/corn	84%	
	53% 52%	NL child DE child	1.06	12% 12%	Milk: Cattle Apples	8% 10%	Sugar beet roots Milk: Cattle	6%	Apples Wheat	53% 52%	
	42%	FR child 3 15 yr	0.85	11%	Milk: Cattle	5%	Wheat	4%	Sugar beet roots	42%	
	41%	UK infant ED tooklar 03 m	0.83	19% 16%	Milk: Cattle Mily: Cotte	3%	Potatoes Amoloe	3%	Wheat	41%	
	38%	GEMS/Food G11	0.75	4%	min. caue Potatoes	4%	Milk: Cattle	4%	Soyabeans	38%	
(uoi	37%	GEMS/Food G06	0.73	7%	Wheat	4%	Tomatoes	2%	Potatoes	37%	
3du	35% 35%	FI adult GFMS/Food G08	0.70	28%	Coffee beans Wheat	4%	Potatoes Potatoes	%2:0 %2:0	Rye Milk: Cattle	35%	
insu	35%	GEMS/Food G07	0.69	4%	Wheat	4%	Potatoes	3%	Milk: Cattle	35%	
q co	35%	DK child	0.69	6%	Milk: Cattle	6%	Rye	4%	Wheat	35%	
oot	इ. इ. इ.	CN totaler GEMS/Food G15	0.68	5%	Wilk. Cattle Wheat	4%	Potatoes	5% 4%	Milk: Cattle	<i>१ ४</i> इ. इ.	
eger	¥\$%	GEMS/Food G10	0.68	4%	Wheat	3%	Soyabeans	3%	Potatoes	34%	
976	32%	RO general SE converal	0.64	89 88	Milk: Cattle Milk: Cattle	5% 4%	Wheat Brine: Miscle/meat	4%	Potatoes Potatoes	32%	
uo j	31%	IE adult	0.61	4%	Sweet potatoes	2%	Wheat	2%	Potatoes	31%	
DƏSE	30%	DE women 14-50 yr	0.61	6%	Milk: Cattle	5%	Sugar beet roots	360 200	Apples	30%	
iq) u	* * * *	ES Child DE general	0.59	%9 %9	Milk: Cattle Milk: Cattle	4%	wrnear Sudar beet roots	2%	Oranges Apoles	% PS	
oite	25%	NL general	0.51	4%	Milk: Cattle	3%	Sugar beet roots		Potatoes	25%	
Iusi	21%	PT general	0.42	5%	Potatoes	4%	Wheat		Wine grapes	21%	
l cal	21%	FR intent FR aduit	0.41	% % %	Milk: Cattle Wrine grannet	2% %Z	Potatoes Mille: Cattle		Apples	21%	
ICE	18%	ES adult	0.35	2%	Wilk: Cattle	2%	Wheat		Oranges	18%	
/103	17%	FI 3 yr	0.34	5%	Potatoes	1%	Bananas	1%	Wheat	17%	
IN/I	16%	IT toddler	0.33	7%	Wheat	2%	Other cereals	1%	Tomatoes	16%	
awı	14%	LT adult DK etiat	0.28	3%	Polatoes Milly Cattle	2%	Milk: Cattle	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Apples Wheat	14%	
	14%	FI6 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		Apples	12%	
	10%	UK adult PI cremeral	0.19	2%	vvneat Potatoes	8 ×	Milik: Cattle Annles	%L %L	Formatores	12%	
	%9	IE child	0.12	2%	Milk: Cattle	1%	Wheat		Potatoes	%9	
<u> </u>	Conclusion: The estimated long-	Conclusion: The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI	ADI.								
	The long-term intakt	The long-term intake of residues of Dicofol is unlikely to present a public health concern.	health concern.								

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	Deta <u>il</u> :	s - acute risk assessment /	dren [/] children			k assessment/adults/gene		s
		sment is based on the ARfD. sed on the large portion of the most critica	al consumer g	roup.				
			Shov	v results t	for all crops			
Results for No. of comm		or which ARfD/ADI is exceeded (IESTI):			Results for adults No. of commodities (IESTI):	for which ARfD/ADI is exceeded		
IESTI					IESTI			
			MRL/input				MRL/input	
Highest		0	for RA	Exposure	Highest % of	0	for RA	Exposur
ARfD/ 2%		Commodities Potatoes	(mg/kg) 0.02/0.02	(µg/kg bw) 3.1	ARfD/ADI 0.6%	Commodities Head cabbages	(mg/kg) 0.02/0.02	(µg/kg bv 0.84
2%		Potatoes Melons	0.02/0.02	3.1 3.0	0.6%	Head cabbages Watermelons	0.02/0.02	0.84
2%		Pears	0.02/0.02	2.8	0.5%	Melons	0.02/0.02	0.81
2%		Oranges	0.02/0.02	2.7	0.5%	Swedes/rutabagas	0.02/0.02	0.68
2%		Watermelons	0.02/0.02	2.4	0.5%	Table grapes	0.02/0.02	0.68
1%	6	Apples	0.02/0.02	2.2	0.4%	Oranges	0.02/0.02	0.61
1%		Pineapples	0.02/0.02	2.0	0.4%	Pears	0.02/0.02	0.61
1%		Bananas	0.02/0.02	1.9	0.4%	Potatoes	0.02/0.02	0.60
1%		Peaches	0.02/0.02	1.9	0.4%	Pineapples	0.02/0.02	0.59
1%		Mangoes	0.02/0.02	1.6	0.4%	Yams	0.02/0.02	0.57
1%		Grapefruits	0.02/0.02	1.6	0.4%	Apples	0.02/0.02	0.56
1.09		Table grapes Cucumbers	0.02/0.02	1.5 1.3	0.4%	Cucumbers	0.02/0.02	0.56
0.9		Cucumbers Carrots	0.02/0.02	1.3	0.4%	Aubergines/egg plants Mangoes	0.02/0.02	0.54
						Chinese cabhages/pe-tsai		
0.8 0.8 Expand/colla	%	Kiwi fruits (green, red, yellow)	0.02/0.02	1.2	0.3%	Chinese cabbages/pe-tsai	0.02/0.02	0.52
0.8 Expand/colla Total numb	% apse list		0.02/0.02			Chinese cabbages/pe-tsai		
0.8 Expand/colla	% apse list per of cor	Kiwi fruits (green, red, yellow)	0.02/0.02			Chinese cabbages/pe-tsai		
0.8 ⁴ Expand/colla Total numb adult diets (IESTI calcu Results for	% apse list per of cor ulation)	Kiwi fruits (green, red, yellow)	0.02/0.02		0.3%			
0.8 Expand/colla Total numb adult diets (IESTI calco Results for No of process	% apse list per of cor ulation) children ssed com	Kiwi fruits (green, red, yellow)	0.02/0.02		0.3% Results for adults No of processed cor	Chinese cabbages/pe-tsai		0.51
0.8 ⁶ Expand/colla Total numb adult diets (IESTI calcu Results for	% apse list per of cor ulation) children ssed com	Kiwi fruits (green, red, yellow)	0.02/0.02		0.3% Results for adults No of processed cor exceeded (IESTI):			
0.8 Expand/colla Total numb adult diets (IESTI calco Results for No of process	% apse list per of cor ulation) children ssed com	Kiwi fruits (green, red, yellow)	0.02/0.02		0.3% Results for adults No of processed cor		0.02/0.02	0.51
0.84 Expand/colla Total numb adult diets (IESTI calcu Results for No of proces exceeded (IE IESTI	% apse list oer of cor ulation) children ssed com ESTI):	Kiwi fruits (green, red, yellow)	0.02/0.02 children and MRL/input		0.3% Results for adults No of processed cor exceeded (IESTI): IESTI		0.02/0.02 MRL/input	
0.84 Expand/colla Total numb adult diets (IESTI calcu Results for No of proces exceeded (IE IESTI Highest	% apse list per of cor ulation) r children ssed com ESTI): t % of	Kiwi fruits (green, red, yellow) nmodilities exceeding the ARID/ADI in a modilities for which ARID/ADI is	0.02/0.02 children and MRL/input for RA	1.2 Exposure	0.3% Results for adults No of processed cost exceeded (IESTI): IESTI Highest % of	nmodities for which ARID/ADI is	0.02/0.02 MRL/input for RA	0.51
0.84 Expand/colla Total numb adult diets (IESTI calco Results for No of proces exceeded (IE IESTI Highest ARfD/	% apse list per of cor ulation) children ssed com ESTI): t % of /ADI	Kiwi fruits (green, red, yellow) mmodities exceeding the ARID/ADI in o modities for which ARID/ADI is Processed commodities	0.02/0.02 children and MRL/input for RA (mg/kg)	1.2 Exposure (µg/kg bw)	0.3% Results for adults No of processed cor exceeded (IESTI): IESTI Highest % of ARID/ADI	nmodilies for which ARID/ADI is Processed commodilies	0.02/0.02 MRL/input for RA (mg/kg)	0.51 Ехрози (µg/kg b
0.84 Expand/colla Total numb adult diets (IESTI calcu Results for No of proces exceeded (IE IESTI Highest	with apse list apse of cor- ulation) children ssed com ESTI): t % of (ADI	Kiwi fruits (green, red, yellow) nmodilities exceeding the ARID/ADI in a modilities for which ARID/ADI is	0.02/0.02 children and MRL/input for RA	1.2 Exposure	0.3% Results for adults No of processed cost exceeded (IESTI): IESTI Highest % of	nmodities for which ARID/ADI is	0.02/0.02 MRL/input for RA	0.51
0.84 Expand/colla Total numb adult diets (IESTI calcu Results for No of procest exceeded (IE IESTI Highest ARfD/ 1%	% apse list or of cor ulation) children ssed com ESTI): t % of (ADI %	Kivi fruits (green, red, yellow) mmodilities exceeding the ARID/ADI in a modilities for which ARID/ADI is Processed commodilies Sugar bests (root)/sugar	0.02/0.02 children and MRL/input for RA (mg/kg) 0.02/0.24	1.2 Exposure (µg/kg bw) 2.2	0.3% Results for adults No of processed cor exceeded (IESTI): IESTI Highest % of ARID/ADI 0.7%	nmodilies for which ARID/ADI is Processed commodilies Pumpkins/boiled	0.02/0.02 MRL/input for RA (mg/kg) 0.02/0.02	0.51 Exposu (µg/kg b 1.1
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0.8 Expand/collar Total numb adult diets (IEST) calco (IEST) calco Results for No of proces exceeded (IE IEST) Highest ARfD/ 1% 1% 1% 1% 1% 1% 1%	w apse list per of cor ulation)	Kiwi fruits (green, red, yellow) mmodities exceeding the ARTD/ADI in e mmodities for which ARTD/ADI is Processed commodities Sugar beets (root)/sugar Potatos/fried Protosided Witbodik-Doiled	0.02/0.02 children and MRL/input for RA (mg/kg) 0.02/0.24 0.02/0.02 0.02/0.02 0.02/0.02	1.2 Exposure (µg/kg bw) 2.2 1.9 1.8 1.8 1.6	0.3% Results for adults No of processed core exceeded (IEST): IESTI Highest % of ARD/ADI 0.7% 0.6% 0.5%	nmodilies for which ARID/ADI is Processed commodilies Pumpkins/boiled Sugar beats (root)/sugar Caufillowers/boiled Beetroots/boiled Celeries/boiled	0.02/0.02 MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	0.51 Exposu (µg/kg b 1.1 0.88 0.83 0.78 0.68
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0.85 Expand/colli Total numb adult diets (IESTI calcu No of process exceeded (IE IESTI Highest ARD/ 1% 1% 1% 1% 0.99 0.99 0.99	% apse list apr of cor ulation) children ssed com ESTI): t % of /ADI	Kiwi fruits (green, red, yellow) modities exceeding the ARID/ADI in o modities for which ARID/ADI is Processed commodities Sugar beets (root)/sugar Protatoss/ride Pumpkins/boiled Broccoli/boiled Escaroles/boiled Escaroles/boiled Pasaroles/boiled Potatoss/boiled Potatoss	0.02/0.02 children and MRL/input for RA (mg/kg) 0.02/0.24 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	1.2 Exposure (µg/kg bw) 2.2 1.9 1.8 1.8 1.8 1.4 1.4 1.2	0.3% Results for adults No of processed cor acceeded (IEST): IESTI Highest % of ARID/ADI 0.7% 0.6% 0.5% 0.5% 0.5% 0.3%	modifies for which ARID/ADI is Processed commodifies Pumpina/boiled Sugar beats (not)/sugar Caulifowers/boiled Celerics/boiled Calerics/boiled Apples/juice Broccoli/boiled Coffee bean/sktraction	0.02/0.02 MRL/input for RA (mg/kg) 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02 0.02/0.02	0.51 Exposu (µg/kg b 1.1 0.88 0.68 0.68 0.67 0.48 0.48
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0.8% Expand/colli Total numb aduit diets (IESTI calcular Results for No of proces exceeded (IESTI IESTI IESTI IESTI 1% 1% 1% 1% 0.9% 0.8% 0.8% 0.8% 0.8% 0.8% 0.8% 0.8% 0.8	% apse list per of cor ulation) children ssed com ESTI): t % of (ADI t % of (ADI 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	Kiwi fruits (green, red, yellow) mmodities exceeding the ARfD/ADI in o mmodities exceeding the ARfD/ADI in o mmodities for which ARfD/ADI is Processed commodilies Sugar beets (root)/sugar Potatose/fried Potatose/fri	0.02/0.02	1.2 Exposure (µg/kg bw) 2.2 1.9 1.8 1.6 1.4 1.4 1.1 1.1 1.1 1.1 1.1 1.0	0.3% Results for adults No of processed cor exceeded (IESTI): IESTI Highnet % of ARD/ADI 0.7% 0.6% 0.5% 0.5% 0.5% 0.5% 0.3% 0.3% 0.3% 0.3% 0.3% 0.3% 0.3% 0.3	nmodilies for which ARID/ADI is Processed commodilies Pumplina/boiled Sugar bests (root)/sugar Cauliflowers/boiled Bestroots/boiled Calerics/boiled Darghes/juce Bottonie/boiled Parsnips/boiled Wine graps/builed Wine graps/boiled	0.02/0.02	0.51 Exposu (µg/kg b 1.1 0.88 0.68 0.68 0.68 0.68 0.68 0.48 0.48 0.48 0.43 0.43 0.43 0.42 0.41
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APPENDIX C

		Chronic risk asses	sment	Acute risk assessm	ient
Commodity	Existing MRL (mg/kg)	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residu	e definition 1: sum	of o,p'-dicofol and p,p'	-dicofol, expressed as dico	ofol ^F	
Melons	0.2	0.02 ^b	LOQ	0.02 ^b	LOQ
Cotton seeds	0.1	0.02 ^b	LOQ	0.02 ^b	LOQ
Теа	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	<u>Scenario 1A</u> : 0.02 ^b	Scenario 1A: LOQ	<u>Scenario 1A:</u> 0.02 ^b	Scenario 1A: LOQ
		<u>Scenario 1B:</u> 0.01 ^b	<u>Scenario 1B:</u> Lowest EURLs LOQ	<u>Scenario 1B:</u> 0.01 ^b	<u>Scenario 1B:</u> 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			

Input values for the exposure calculations

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

^FThe active substance is fat soluble.

^aAn 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.

^bIndicates that the input value is proposed at the limit of quantification.



