Approved: 27 October 2023

DOI: 10.2903/j.efsa.2023.8426

REASONED OPINION

efsa JOURNAL

Targeted review of maximum residue levels (MRLs) for diazinon

European Food Safety Authority (EFSA) | Giulia Bellisai | Giovanni Bernasconi | Marco Binaglia | Luis Carrasco Cabrera | Irene Castellan | Anna Federica Castoldi | Arianna Chiusolo | Katia Chukwubike | Federica Crivellente | Monica Del Aguila | Lucien Ferreira | German Giner Santonja | Luna Greco | Frederique Istace | Samira Jarrah | Anna Lanzoni | Renata Leuschner | Iris Mangas | Javier Martinez | Ileana Miron | Stefanie Nave | Martina Panzarea | Juan Manuel Parra Morte | Ragnor Pedersen | Hermine Reich | Silvia Ruocco | Miguel Santos | Alessia Pia Scarlato | Andrea Terron | Anne Theobald | Manuela Tiramani | Alessia Verani

Correspondence:
pesticides.mrl@efsa.europa.eu

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 diazinon in view of the possible lowering of the MRL. EFSA investigated the origin of the current EU MRLs. For existing EU MRLs that reflect previously authorised uses in the EU, or that are based on obsolete Codex MRLs, or import tolerances that are not required any longer, EFSA proposed the lowering to the limit of quantification. EFSA performed an indicative chronic and acute dietary risk assessment for the revised list of MRLs to allow risk managers to take the appropriate decisions. For some commodities, further risk management discussions are required to decide which of the risk management options proposed by EFSA should be implemented in the EU MRL legislation.

KEYWORDS

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

CONTENTS

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 diazinon.

In accordance with the terms of reference, EFSA investigated the origin of the current EU MRLs for diazinon, 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 MRL (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 diazinon 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 98) to discuss the toxicological profile and the TRVs for diazinon.

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 diazinon in plants and animals was previously investigated in the framework of the peer review, as well as by JMPR. According to the results of the metabolism studies assessed, the residue definition derived at European level for enforcement and risk assessment, both for plant and animal products, is diazinon. The residue is fat soluble. The same residue definitions were initially derived by the JMPR, however, in its latest assessment, the Meeting was not able to conclude on the metabolism, and only the residue definition for enforcement in plants was confirmed as diazinon.

Analytical methods are available for the enforcement of the proposed residue definition in high water content, high oil content and high acid content with an LOQ of 0.01 mg/kg; however, no validation data are available to monitor diazinon in spices and hops. Diazinon can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in muscle, fat, kidney, liver, milk and eggs. According to the EURLs, a QuEChERS (or QuOil) multi-residue analytical method with an LOQ of 0.01 mg/kg for the routine analysis of diazinon in high water content, high acid content, high oil content and dry commodities. In these commodities, even lower LOQs were successfully validated (down to 0.002 mg/kg for high water and high acid content commodities, down to 0.005 mg/kg for high oil content and dry commodities). A default LOQ of 0.01 mg/kg is also deemed achievable to monitor diazinon in all commodities of animal origin, and lower LOQs were also deemed achievable (down to 0.005 mg/kg for fat; down to 0.001 mg/kg for muscle, liver, kidney and fish; and down to 0.0005 mg/kg for milk and eggs).

The origin of all current MRLs set for diazinon (based on formerly approved uses or on CXLs) was investigated. None of the EU MRLs/CXLs established for plant commodities are substantiated, and no potential fall-back MRLs were identified. For what concerns livestock commodities, MRLs set for poultry muscle and edible offals and for swine and ruminant liver and kidney, are not substantiated. For swine and ruminant liver and kidney, the lower veterinary MRL set in Regulation (EU) 37/2010 could be considered by risk managers. All other livestock EU MRLs are based on external treatment and are identical to CXLs (recently revoked, hence not substantiated), and/or to veterinary MRLs set in Regulation (EU) 37/2010. For swine and ruminant muscle and fat and for milk, further considerations by risk managers are required to conclude whether the existing MRLs are substantiated.

The TRVs set at EU level and of those established by the JMPR were considered, and the set of toxicological studies used to derive these TRVs was assessed according to the current standards. As critical issues were identified, a Member States experts' consultation took place. The experts concluded that the data available are insufficient and that the TRVs cannot be confirmed for diazinon since its genotoxicity potential is inconclusive, in particular regarding its clastogenic and aneugenic potential. Accordingly, the EU ADI and acute reference dose (ARfD) derived in 2006 do not comply with the current scientific standards. Therefore, EFSA recommends that risk managers discuss whether these TRVs should be withdrawn. The following data would be required to finalise the toxicological assessment which is a prerequisite to derive robust TRVs:

- additional studies to conclude on the genotoxic potential of diazinon;
- up-to-date search for published literature;
- additional toxicological data to perform an ED assessment according to the 2018 ECHA/EFSA Guidance;
- interspecies comparative in vitro metabolism study on animal species used in pivotal studies and on human material;
- developmental neurotoxicity study;
- 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;
- assessment of the presence of toxicologically relevant impurities in the technical specification and in diazinon-treated commodities;
- full re-evaluation of the toxicological data package and reporting relevant details on the studies and the results in accordance with the current standards.

It is expected that the same limitations regarding the genotoxicity data package are applicable to JMPR values.

Chronic and acute exposure calculations were performed using revision 3.1 of PRIMo. A first scenario 1A considered only the veterinary MRLs set for livestock in Reg. (EU) 37/2010 that might be substantiated. Comparing to the EU TRVs, no acute risk was identified but exceedances of the ADI were observed up to 638% of the ADI (Dutch toddler). It was noted that these exceedances were mainly driven by swine fat and cattle milk. An additional calculation (scenario 1B) was therefore performed, considering the default LOQ of 0.01 mg/kg for swine fat and the lowest LOQ achievable (0.0005 mg/kg) for cattle milk. In this additional scenario, the highest chronic exposure decreased to 59% of the ADI (UK toddler), with the contribution of cattle milk decreasing to a maximum of 15% of the ADI. It is noted that, although the lowest achievable LOQ for cattle milk was considered in this scenario, an LOQ of 0.001 mg/kg would be already sufficiently protective.

In scenario 2A, a screening of the LOQs was performed. No acute risk was identified, but exceedances of the ADI up to 336% (Dutch toddler) were observed. Although the calculated chronic exposures are expected to be highly overestimated since based on the assumption that all commodities consumed contain residues at the LOQ, which is not expected to happen for a non-approved active substance, in order to support risk managers, an additional calculation (scenario 2B) was performed considering the lowest LOQs achievable according to the EURLs for each commodity group. In this additional scenario, the highest chronic exposure decreased to 103% of the EU ADI. Nevertheless, this slight exceedance of the ADI is not considered relevant, for the same reasons reported above.

EFSA emphasises that as the toxicological assessment revealed deficiencies regarding the toxicological studies available for diazinon and considering that EU TRVs do not meet the current scientific standards, the risk assessment cannot be finalised and results presented under the current review are indicative only. In addition, considering this indicative risk assessment, it is underlined that the veterinary MRLs for diazinon in cattle milk and swine fat lead to a potential chronic concern. Based on this outcome, EFSA recommends risk managers to reconsider the veterinary MRLs for these animal commodities.

Due to the deficiencies identified regarding the toxicological studies available for diazinon, none of the existing EU MRLs/CXLs listed in the summary table below are recommended for inclusion in Annex II to the Regulation. If a decision to withdraw the TRVs is taken, EFSA recommends that risk managers discuss whether all MRLs currently implemented in EU Regulation should be lowered to the respective LOQs.

Summary table:

			Outcome of the review	
Code[a]	**Commodity**	**Existing MRL**[b] **(mg/kg)**	**MRL proposal (mg/kg)**	**Comment**
Residue definition for enforcement: Diazinon[F]				
0120010	Almonds	0.05	LOQ	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0154020	Cranberries	0.2	LOQ	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0163080	Pineapples	0.3	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0213080	Radishes	0.1	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0220020	Onions	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0231020	Sweet peppers/bell peppers	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0234000	Sweet corn	0.02	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0243010	Chinese cabbage/ pe-tsai	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0244000	Kohlrabies	0.2	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0700000	Hops	0.5	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0810000	Seed spices	5	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0840000	Root and rhizome spices	0.5	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0900010	Sugar beet roots	0.1	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ

Code[a]	Commodity	Existing MRL[b] (mg/kg)	Outcome of the review: MRL proposal (mg/kg)	Outcome of the review: Comment
1011010 1012010 1013010 1014010 1015010	Muscle from Swine Bovine Sheep Goat	0.02	0.02 or LOQ	The existing MRL might still reflect the veterinary MRL currently in place Reg. (EU) 37/2010. However, risk managers should discuss whether the existing MRL needs to be lowered considering that, lacking robust TRVs for diazinon, the risk assessment is only indicative. Furthermore, in view of the very low EU TRVs, the default LOQ for bovine muscle will not be sufficiently protective for consumers
1012020 1013020 1014020	Fat from Bovine Sheep Goat	0.7	0.7 or LOQ	The existing MRL might still reflect the veterinary MRL currently in place Reg. (EU) 37/2010 However, risk managers should discuss whether the existing MRL needs to be lowered considering that, lacking robust TRVs for diazinon, the risk assessment is only indicative
1011020	Fat from swine	0.7	LOQ	The existing MRL might still reflect the veterinary MRL currently in place Reg. (EU) 37/2010 However, exceedances of the EU ADI were observed, with fat from swine being one of the main contributors to the chronic exposure (noting also that, lacking robust TRVs, the risk assessment is only indicative)
1011030 1012030 1013030 1014030	Liver from Swine Bovine Sheep Goat	0.03	0.02 or LOQ	The existing EU MRL is not substantiated. The veterinary MRL of 0.02 mg/kg currently set in Reg. (EU) 37/2010, might be considered as an alternative MRL However, risk managers should discuss whether the existing MRL needs to be lowered considering that, lacking robust TRVs for diazinon, the risk assessment is only indicative
1011040 1012040 1013040 1014040	Kidney from Swine Bovine Sheep Goat	0.03	0.02 or LOQ	Same comment as reported for liver (from swine, bovine, sheep, goat)
1016010	Poultry muscle	0.02	LOQ	The existing EU MRL is not substantiated. Hence, it should be lowered to the LOQ
1016050	Poultry edible offals (other than liver and kidney)	0.02	LOQ	Same comment as reported for poultry muscle
1020020 1020030 1020040 1020990	Milk from Sheep Goat Equine Other	0.02	0.02 or LOQ	The existing MRL might still reflect the veterinary MRL currently in place Reg. (EU) 37/2010 However, risk managers should discuss whether the existing MRL needs to be lowered considering that, lacking robust TRVs for diazinon, the risk assessment is only indicative
1010010	Milk from Bovine	0.02	LOQ	The existing MRL might still reflect the veterinary MRL currently in place Reg. (EU) 37/2010 However, exceedances of the EU ADI were observed, with cattle milk being the main contributor to the chronic exposure (noting that, lacking robust TRVs, the risk assessment is only indicative). Furthermore, in view of the very low EU TRVs, the default LOQ for milk from bovine will not be sufficiently protective for consumers

Abbreviations: ADI, acceptable daily intake; LOQ, limit of quantification; MRL, maximum residue limit; TRV, toxicological reference value.

[F] Fat soluble.

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

[b] MRL currently set under Regulation (EC) No 834/2013.

BACKGROUND

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

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

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

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

Based on these analyses, the European Commission conducted a prioritisation exercise to identify substances for which existing MRLs should be reviewed with high priority. The prioritisation was also discussed and agreed with Member States during several meetings of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), section Phytopharmaceuticals – Pesticides residues (September 2021,[2] November 2021[3] and February 2022[4]). The SCoPAFF agreed that 10 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 diazinon.

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 diazinon.

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 diazinon. In particular, the following tasks should be performed:

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

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

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

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

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

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

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

b. Scenario 2:

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

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

EFSA accepted the mandate and to deliver its assessment by finalising separate reasoned opinions for each of the substances included in this mandate, including diazinon, by 22 May 2023. Subsequently, an extension of this 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), 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 MRLs 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, an indicative screening of the chronic and acute consumer exposure is presented (ToR 5 and 6). The dietary exposure assessments are performed as requested in ToR 5 (a) and (b). 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

[6]The first EFSA scientific report in preparation of CCPR was prepared in 2010.
[7]The first evaluations of import tolerances under Regulation (EC) No 396/2005 which fully entered into force on 1.9.2008.
[8]Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006OJ L 353, 31.12.2008, p. 1.

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.
- 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 conclusion on the peer review of the pesticide risk assessment of the active substance diazinon (EFSA, 2006) and respective background documents: draft assessment report (DAR) (Portugal, 2004);
- the review report on diazinon (European Commission, 2006);
- the reports and evaluations of the JMPR (FAO and WHO, 1993a, 1993b, 1994a, 1994b, 1996a, 1996b, 2001, 2004, 2006a, 2006b, 2016, 2023);
- the reports of the Codex Committee on Pesticide residues (CCPR, 2005, 2007, 2023).

As requested by the terms of reference (ToR 2), Member States were invited to submit by 18 October 2022 the Good Agricultural Practices (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 7 Member States (CZ, DE, ES, FR, IT, NL and SE) and UK[9] provided feedback regarding diazinon 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 and, thus, made publicly available. In addition, an expert consultation in the area of mammalian toxicology was conducted in March 2023; the **peer review meeting report TC 98** (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 Joint Meeting on Pesticide residues (JMPR) Evaluation reports and taking into account the conclusions derived by EFSA in previous opinions and the screening of the available toxicological data with regard 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 in July and August 2023. Comments received by 9 August 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). The exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (**PRIMo**) are also key supporting documents made publicly available as background document to this reasoned opinion.

1 | REGULATORY BACKGROUND INFORMATION ON DIAZINON

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

TABLE 1 Background information.

Process	Status	Comments, references
Approval status	Not approved	Decision on non-inclusion of diazinon in Annex I of Council Directive 91/414/EEC by Decision 2007/393/EC[b]
EFSA conclusion available	Yes, see comments	EFSA (2006)
MRL review performed	No	–
EU MRL applications or other EU assessments	No	–
Classification under CLP Regulation	See comments	Acute Tox 4[a], H302 'harmful if swallowed' (CLP00[c]) Cut-off criteria are not met with regards to classification
Endocrine effects of a.s.	Not assessed	ED assessment according to ECHA and EFSA guidance (ECHA and EFSA et al., 2018) and scientific criteria (Commission Regulation (EC) No 2018/605[d]) have not been performed. Additional data would be needed to carry it out
Other relevant information	–	Diazinon is approved for veterinary uses: MRLs for diazinon are set in Regulation (EU) 37/2010[e]

[9]The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the United Kingdom from the EU, and in particular with the Protocol on IE/NI, the EU requirements on data reporting are also applicable to NI.

Abbreviations: a.s, active substance; CLP, classification, labelling and packaging; ECHA, European chemicals agency; ED, endocrine disruptor; MRL, maximum residue limit.

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

[b]Commission Decision of 6 June 2007 concerning the non-inclusion of diazinon in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance C(2009) 9196). OJ L 148, 9.6.2007, p. 9–10.

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

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

[e]Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 15, 20.1.2010, p. 1–72.

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 peer review and assessed previously by EFSA to derive the EU residue definitions, as well as additional studies that were submitted to JMPR in the framework of the setting of CXLs (studies not assessed at EU level).

TABLE 2 Available metabolism studies

Primary crops	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/Source
	Fruit crops	Apple	Only on one branch of one apple tree 1 foliar and soil appl. (1:9), 3360 g a.s./ha + 2 foliar appl. 10,080 g a.s./ha	14 DALT (mature apples and apple leaves)	[2-^{14}C-pyrimidinyl]-diazinon (FAO and WHO, 1993a, 1993b; Portugal, 2004)
	Root crops	Potato	1 soil appl. 4480 g a.s./ha + 2 foliar appl. 1400 g a.s./ha, 7 days intervals	After the 1st appl. (immature foliage and tubers), 15 DALT (mature foliage and tubers)	[2-^{14}C-pyrimidinyl]-diazinon (FAO and WHO, 1993a, 1993b; Portugal, 2004)
	Leafy crops	Lettuce	1 soil appl. 4480 g a.s./ha + 2 foliar appl., 1400 g a.s./ha, 14 days intervals	After the 1st appl. (immature leaves), 14 DALT (mature leaves)	[2-^{14}C-pyrimidinyl]-diazinon (FAO and WHO, 1993a, 1993b; Portugal, 2004)
	Cereals/grass	Sweet corn	1 soil appl. 4480 g a.s./ha + 2 foliar appl. 3500 g a.s./ha, 14 days intervals	After the 1st appl. (immature stalks, forage and ears) At maturity (forage, cobs and grain)	[2-^{14}C-pyrimidinyl]-diazinon (FAO and WHO, 1993a, 1993b; Portugal, 2004)
		Rice	1 or 2 appl. On paddy water. Dose applied unknown	5 and 9 DALT (whole plant)	[2-^{14}C-pyrimidinyl]-diazinon (FAO and WHO, 1993a, 1993b)
	Pulses/ oilseeds	Green bean	1 soil appl. 4480 g a.s./ha (planting) + 2 foliar appl. 1400 g a.s./ha, 15 days intervals	7 days after the 1st appl. (immature beans/vines), 14 DALT (mature beans and vines)	[2-^{14}C-pyrimidinyl]-diazinon (FAO and WHO, 1993a, 1993b; Portugal, 2004)
Livestock	**Animal**		**Dose (mg/kg feed)**	**Duration (day)**	**Comment/Source**
	Laying hen		25	7	[^{14}C]-diazinon (FAO and WHO, 1993a, 1993b; Portugal, 2004)
	Ruminant, goat		100	4	[2-^{14}C-pyrimidinyl]-diazinon (FAO and WHO, 1993a, 1993b; Portugal, 2004)
	Ruminant, sheep		40 mg/kg bw (dermal treatment)	3	[^{14}C]-diazinon applied to a shaved area of 10% of the back of the animal (FAO and WHO, 1993a, 1993b)
	Pigs		–	–	Study not required as metabolism in rat and ruminant was found to be similar (EFSA, 2006)

Abbreviations: a.s., active substance; bw, body weight; DAT, days after treatment; DALT, days after last treatment.

Metabolism studies on apple, potato, lettuce, sweet corn and green bean were assessed in the framework of the peer review (EFSA, 2006). In all three categories of crops (fruits, roots, leafy, cereals and pulses), the main metabolism pathways were qualitatively similar. Only in apple, diazinon was clearly the predominant component while in other crops, various

metabolites were present in similar or higher amounts than the parent compound. The residue definition for monitoring and risk assessment in plant commodities was proposed as diazinon. The residue definitions are applicable to all crop groups.

In addition to the metabolism studies assessed at EU level, the JMPR assessed a study on rice. This additional study showed similar metabolism pathway once the parent diazinon has been absorbed and translocated in rice plants (FAO and WHO, 1993a, 1993b).

The nature of diazinon residues in livestock was investigated and assessed in the framework of the peer review (EFSA, 2006). In the metabolism studies with goats and laying hens, diazinon was extensively degraded into various metabolites in all animal matrices except in fat where diazinon was the predominant component. A residue definition as diazinon was proposed for enforcement and risk assessment (EFSA, 2006), the residue being fat soluble. In the peer review, it was concluded that this residue definition would not apply to poultry as the exposure of poultry was below the trigger value justifying the establishment of a residue definition. This is in line with the conclusions reached by the JMPR following the assessment of the same metabolism studies. In addition to the metabolism studies assessed at EU level, the JMPR assessed a study on sheep with a dermal application. This additional study showed similar metabolism pathway except for the muscle, which was not analysed.

In a recent report, the JMPR concluded that, based on the metabolism studies reported in Table 2, the metabolite G-24576 (diazoxon) identified both in primary crops and animal, rapidly degrades in a range of plant commodities as well as in milk and animal tissues except fat. In the absence of data to support the storage interval in the metabolism studies, these studies could not be relied on for an assessment of the residue definitions for risk assessment. Considering the lack of suitable quantitative information on the individual levels of metabolites in plants and livestock, and the storage stability, the JMPR was unable to conclude on residue definitions for enforcement in plants, and for enforcement and risk assessment in livestock (FAO and WHO, 2023).

However, in its latest evaluation, the JMPR could not confirm these residue definitions (FAO and WHO, 2023).

Table 3 summarises the residue definitions derived at EU level and by the JMPR. The EU residue definitions for enforcement are the ones set in Regulation (EC) No 396/2005. EU residue definitions for risk assessment were proposed in the framework of the peer review (EFSA, 2006). The same residue definitions for enforcement and risk assessment were initially derived by the JMPR (FAO and WHO, 1993a, 1993b). However, in its latest evaluation, the JMPR could not confirm these residue definitions (FAO and WHO, 2023).

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

Type of residue definition (RD)	Commodity group	EU residue definition	JMPR residue definitions
RD for enforcement	Plant products	Diazinon	Diazinon (FAO and WHO, 1993a, 1993b)
	Animal products	Diazinon The residue is fat soluble	Diazinon. The residue is fat soluble (FAO and WHO, 1993a, 1993b). Residue definition not confirmed in the latest JMPR evaluation FAO and WHO, 2023)
RD for risk assessment	Plant products	Diazinon (EFSA, 2006)	Diazinon (FAO and WHO, 1993a, 1993b). Residue definition not confirmed in the latest JMPR evaluation (FAO and WHO, 2023)
	Animal products	Diazinon (EFSA, 2006)	Diazinon (FAO and WHO, 1993a, 1993b). Residue definition not confirmed in the latest JMPR evaluation (FAO and WHO, 2023)

Comments: The residue definitions for enforcement are identical in plant products. It should be highlighted that in its last assessment, JMPR could not conclude on a residue definition for risk assessment for plants, nor on residue definitions, both for enforcement and risk assessment, for animal commodities (FAO and WHO, 2023).

2.2 | Analytical methods for MRLs enforcement

Analytical methods for the determination of diazinon residues were assessed in the framework of the EU pesticides peer review (EFSA, 2006) and in the framework of the JMPR evaluation (FAO and WHO, 1993a, 1993b, 1996a, 1996b). Analytical methods are available to enforce residues of diazinon in high water, high acid and high oil content commodities with an LOQ of 0.01 mg/kg. No methods were reported to monitor diazinon in dry commodities and in specific matrices, i.e. spices, tea and hops.

Diazinon can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in muscle, fat, kidney, liver, milk and eggs (FAO and WHO, 1993a, 1993b, 1996a, 1996b; Portugal, 2004).

During the data collection, the EURLs provided information on a QuEChERS (or QuOil) multi-residue analytical method using GC–MS/MS and LC–MS/MS (only for dry commodities) techniques, with an LOQ of 0.01 mg/kg for the routine analysis of diazinon in high water content, high acid content, high oil content and dry commodities. In these commodities, even lower LOQs were successfully validated (down to 0.002 mg/kg for high water and high acid content commodities, and down to 0.005 mg/kg for high oil content and dry commodities). According to the EURLs, diazinon can be monitored in commodities of animal origin (egg, muscle, liver, kidney, milk and fish) with an LOQ of 0.01 mg/kg. In these commodities of animal origin, even lower LOQs were successfully validated (down to 0.001 mg/kg for muscle, liver and kidney, and down to

0.0005 mg/kg for milk and eggs). Based on the experience gained with these matrices, an LOQ of 0.005 mg/kg for animal fat is deemed achievable (EURLs, 2022). It is concluded that analytical methods are available for all commodities under assessment, except spices and hops (difficult matrices to analyse). The EURLs reported that the analytical standard for diazinon is commercially available (EURLs, 2022).

Table 4 provides an overview of the analytical methods available and their respective LOQs. It is concluded that analytical methods are available for all commodities under assessment, except spices and hops (difficult matrices to analyse). The EURLs reported that the analytical standard for diazinon is commercially available (EURLs, 2022).

TABLE 4 Analytical methods available.

Commodity group		Analytical method available	LOQ(mg/kg)	Source
Plant commodities	High water	Yes (LC-MS, GC-NPD/FPD, GC-MS)	0.01	Portugal (2004)
		Yes (GC-EC or NP)	0.01	FAO and WHO (1993a, 1993b)
		Yes (QuEChERS method with GC-MS/MS)	0.01 (lower LOQ achievable: 0.002)	EURLs (2022)
	High oil	Yes (GC-NPD/FPD)	0.01	Portugal (2004)
		Yes (GC-FPD)	0.01	FAO and WHO (1993a, 1993b)
		Yes (QuEChERS and QuOil method with GC-MS/MS)	0.01 (lower LOQ achievable: 0.005)	EURLs (2022)
	High acid content	Yes (GC-NPD/FPD)	0.01	Portugal (2004)
		Yes (QuEChERS method with GC-MS/MS)	0.01 (lower LOQ achievable: 0.002)	EURLs (2022)
	Dry	Yes (QuEChERS method with GC-MS/MS and LC-MS/MS)	0.01 (lower LOQ achievable: 0.005)	EURLs (2022)
	Other: hops, spices	No	–	–
Animal commodities	Muscle	Yes (GC-NPD/FPD/Thermionic)	0.01	Portugal (2004), FAO and WHO (1993a, 1993b)
		Yes (Q-EMR method with GC-MS/MS)	0.01 (lower LOQ achievable: 0.001)	EURLs (2022)
	Kidney	Yes (GC-NPD)	0.01	Portugal (2004)
		Yes (GC-NPD/FPD)	0.02	FAO and WHO (1993a, 1993b, 1996a, 1996b)
		Yes (QuEChERS method with LC-MS/MS)	0.01 (lower LOQ achievable: 0.001)	EURLs (2022)
	Liver	Yes (GC-NPD/FPD/Thermionic)	0.01	Portugal (2004), FAO and WHO (1996a, 1996b)
		Yes (Q-EMR method with GC-MS/MS)	0.01 (lower LOQ achievable: 0.001)	EURLs (2022)
	Fat	Yes (GC-NPD/FPD/Thermionic)	0.01	Portugal (2004), FAO and WHO (1996a, 1996b)
		–	0.005[a]	EURLs (2022)
	Milk	Yes (GC-NPD/FPD)	0.01	Portugal (2004)
		Yes (GC-NPD/Thermionic)	0.001–0.01	FAO and WHO (1996a, 1996b)
		Yes (QuEChERS method with LC-Q-TOF)	0.01 (lower LOQ achievable: 0.0005)	EURLs (2022)
	Eggs	Yes (GC-NPD/FPD)	0.01	Portugal (2004)
		Yes (Q-EMR method with GC-Orbitrap)	0.01 (lower LOQ achievable: 0.0005)	EURLs (2022)
	Fish	Yes (Q-EMR method with GC-MS/MS)	0.01	EURLs (2022)

Abbreviations: LOQ, limit of quantification; GC-MS, gas chromatography with mass spectrometry; GC-NPD, gas chromatography with Nitrogen-Phosphorus detector; GC-FPD, gas chromatography with flame-photometric detector; GC-Thermionic, gas chromatography with thermionic detector; GC-MS/MS, gas chromatography with tandem mass spectrometry; GC-Orbitrap, gas chromatography with quadrupole orbitrap; LC-MS/MS, liquid chromatography with tandem mass spectrometry; LC-Q-TOF, liquid chromatography with quadrupole time-of-flight; QuEChERS, Quick, Easy, Cheap, Effective, Rugged and Safe (analytical method); Q-EMR, QuEChERS with Enhanced Matrix Removal.

[a]Although no validation data are available for this specific commodity within the EURLs, it is assumed that the reported LOQ would be achievable based on the general behaviour of diazinon in other animal commodities (EURLs, 2022).

2.3 | Existing MRLs

The EU MRLs for diazinon are established in Annex II 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. However, it should be highlighted that in its latest evaluation, the JMPR could not conclude on the residue definition for risk assessment in plant commodities, nor on the residue definitions for enforcement and risk assessment in livestock (see Section 2.1). Hence, the JMPR proposed to withdraw all the CXLs for diazinon (FAO and WHO, 2023). Consequently, the CCPR decided to revoke all existing CXLs (CCPR, 2023). It should also be noted that the existing EU MRLs set for diazinon in livestock commodities (except poultry), are identical to CXLs based on external animal treatment and/or to the MRLs set for veterinary uses (antiparasitic agents/ agent against ectoparasites) in Regulation (EU) 37/2010. In the framework of the current targeted review, Member States did not notify import tolerances in place.

EFSA reported in Table 5, the existing EU MRLs for the respective crop/crop groups, 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 EU MRLs or CXLs are not sufficiently substantiated, information on potential fall-back GAPs and the associated calculated fall-back MRLs are included in Table 5. In the last column of this table, additional considerations relevant for taking risk management decisions are also reported.

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

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)	Fall-back GAP	Fall-back MRL (mg/kg)	Comment
Almonds	0.05	CXL (CAC, 1995)	USA: 4 × 0.06–0.17 kg a.s./ha (FAO and WHO, 1993a, 1993b)	N	No fall-back GAP identified	–	In 1993, JMPR derived a codex MRL proposal of 0.05 mg/kg for almonds This CXL is the same as the one in Reg. (EC) 149/2008 In 2023, all CXLs in place were revoked (CCPR, 2023) and no import tolerance was identified. Therefore, the MRL is not substantiated
Cranberries	0.2	CXL (CAC, 2007)	USA: soil application or via chemigation, 6 × 2.24 kg a.s./ha, PHI 7 days (FAO and WHO, 2006a, 2006b	N	No fall-back GAP identified	–	In 2006, JMPR derived a codex MRL proposal of 0.2 mg/kg for cranberries The EU did not express a reservation in the CCPR39/CAC in 2007. This CXL is the same as the one in Reg. (EC) 149/2008 In 2023, all CXLs in place were revoked (CCPR, 2023) and no import tolerance was identified. Therefore, the MRL is not substantiated
Pineapples	0.3	Reg. (EU) 834/2013	See comment	N	No fall-back GAP identified	–	The EU MRL in place was originally set based on an import tolerance (for which residue data could not be retrieved). In 1993, JMPR derived a codex MRL proposal of 0.1 mg/kg for pineapples. This CXL was implemented in Reg. (EC) 899/2012 However, the original import tolerance (IT) was overlooked, and Commission was informed that this IT as it stood before being amended would need to be maintained. Therefore, the EU MRL was raised again to 0.3 mg/kg in Reg. (EU) 834/2013 Since this IT is not supported anymore, the EU MRL is not substantiated. As all CXLs were recently revoked (CCPR, 2023), the CXL set for pineapple cannot be considered neither
Radishes	0.1	CXL (CAC, 1997)	Canada: soil application, 1 × 2.2 kg a.s./ha (FAO and WHO, 1993a, 1993b) USA: > 1 × 0.28–0.55 kg a.s./ha, PHI 10 days (FAO and WHO, 1993a, 1993b)	N	No fall-back GAP identified	–	In 1993, JMPR derived a codex MRL proposal of 0.1 mg/kg for radishes. This CXL is the same as the one in Reg. (EC) 149/2008 In 2023, all CXLs in place were revoked (CCPR, 2023) and no import tolerance was identified. Therefore, the MRL is not substantiated
Onions	0.05	CXL (CAC, 1995)	Australia: 2–4 × 0.56 kg a.s./ha, PHI 14 days (FAO and WHO, 1993a, 1993b) Mexico: > 1 × 0.25–0.6 kg a.s./ha, PHI 10 days (FAO and WHO, 1993a, 1993b) USA: 1 × 2.2–4.4 kg a.s./ha (FAO and WHO, 1993a, 1993b)	N	No fall-back GAP identified	–	In 1993, JMPR derived a codex MRL proposal of 0.05 mg/kg for onions This CXL is the same as the one in Reg. (EC) 149/2008 In 2023, all CXLs in place were revoked (CCPR, 2023) and no import tolerance was identified. Therefore, the MRL is not substantiated

(Continues)

TABLE 5 (Continued)

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)	Fall-back GAP	Fall-back MRL (mg/kg)	Comment
Sweet peppers/ bell peppers	0.05	CXL (CAC, 1995)	Australia: 2–4 × 0.56–1.12 kg a.s./ha, PHI 14 days (FAO and WHO, 1993a, 1993b) USA: 1 × 1.1–4.4 kg a.s./ha (FAO and WHO, 1993a, 1993b)	N	No fall-back GAP identified	–	In 1993, JMPR derived a codex MRL proposal of 0.05 mg/kg for sweet peppers/bell peppers. This CXL is the same as the one in Reg. (EC) 149/2008 In 2023, all CXLs in place were revoked (CCPR, 2023) and no import tolerance was identified. Therefore, the MRL is not substantiated
Sweet corn	0.02	CXL (CAC, 1995)	Australia: 0.52–1.12 kg a.s./ ha, PHI 14 days (FAO and WHO, 1993a, 1993b) USA: 1 × 2.2–4.4 kg a.s./ha 2–3 × 1.1–1.4 kg a.s./ha (FAO and WHO, 1993a, 1993b)	N	No fall-back GAP identified	–	In 1993, JMPR derived a codex MRL proposal of 0.02 mg/kg for sweet corn. This CXL is the same as the one in Reg. (EC) 149/2008 In 2023, all CXLs in place were revoked (CCPR, 2023) and no import tolerance was identified. Therefore, the MRL is not substantiated
Chinese cabbages/ pe-tsai	0.05	CXL (CAC, 1997)	Australia: > 1 × 0.56–1.12 kg a.s./ha, PHI 14 days (FAO and WHO, 1993a, 1993b)	N	No fall-back GAP identified	–	In 1993, JMPR derived a codex MRL proposal of 0.05 mg/kg for Chinese cabbages/petsai. This CXL is the same as the one in Reg. (EC) 149/2008 In 2023, all CXLs in place were revoked (CCPR, 2023) and no import tolerance was identified. Therefore, the MRL is not substantiated
Kohlrabies	0.2	CXL (CAC, 1997)	Australia: > 1 × 0.56–1.12 kg a.s./ha, PHI 14 days (FAO and WHO, 1993a, 1993b)	N	No fall-back GAP identified	–	In 1993, JMPR derived a codex MRL proposal of 0.2 mg/kg for kohlrabies This CXL is the same as the one in Reg. (EC) 149/2008 In 2023, all CXLs in place were revoked (CCPR, 2023) and no import tolerance was identified. Therefore, the MRL is not substantiated
Hops	0.5	CXL (CAC, 1997)	Canada: 0.25–1.12 kg a.s./ ha, PHI 14 days (FAO and WHO, 1994a, 1994b)	N	No fall-back GAP identified	–	In 1994, JMPR derived a codex MRL proposal of 0.5 mg/kg for hops. This CXL is the same as the one in Reg. (EC) 149/2008 In 2023, all CXLs in place were revoked (CCPR, 2023) and no import tolerance was identified. Therefore, the MRL is not substantiated
Seed spices	5	CXL (CAC, 2005)	Codex MRL based on monitoring data (FAO and WHO, 2004)	N	No fall-back GAP identified	–	In 2004, JMPR derived a codex MRL proposal of 5 mg/kg for seed spices. The EU did not express a reservation in the CCPR37/CAC in 2005. This CXL is the same as the one in Reg. (EC) 839/2008 In 2023, all CXLs in place were revoked (CCPR, 2023) and no import tolerance was identified. Therefore, the MRL is not substantiated
Root and rhizome spices	0.5	CXL (CAC, 2005)	Codex MRL based on monitoring data (FAO and WHO, 2004)	N	No fall-back GAP identified	–	In 2004, JMPR derived a codex MRL proposal of 0.5 mg/kg for root and rhizome spices. The EU did not express a reservation in the CCPR37/CAC in 2005. This CXL is the same as the one in Reg. (EC) 839/2008 In 2023, all CXLs in place were revoked (CCPR, 2023) and no import tolerance was identified. Therefore, the MRL is not substantiated

TABLE 5 (Continued)

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)	Fall-back GAP	Fall-back MRL (mg/kg)	Comment
Sugar beet roots	0.1	CXL (CAC, 1995)	Chile: 1–2 × 0.4–0.6 kg a.s./ha, PHI 14 days (FAO and WHO, 1993a, 1993b) USA: 1 × 1.1–4.4 kg a.s./ha (FAO and WHO, 1993a, 1993b)	N	No fall-back GAP identified	–	In 1993, JMPR derived a codex MRL proposal of 0.1 mg/kg for sugar beet root. This CXL is the same as the one in Reg. (EC) 149/2008 In 2023, all CXLs in place were revoked (CCPR, 2023) and no import tolerance was identified. Therefore, the MRL is not substantiated
Muscle from swine, bovine, sheep, goat	0.02	See comments	MRL accommodates external animal treatment	tbd	n.r.	–	The origin of the existing MRL is unclear In 1996, JMPR derived a codex MRL proposal of 0.02 mg/kg for muscle (fat) from swine, bovine, sheep, goat and equine that accommodates external animal treatment. The EU did not express a reservation in the CCPR37/CAC in 2005. However, this CXL was not implemented in Reg. (EC) 149/2008 Reg. (EU) 899/2012 replaced the MRL of 0.05[a] mg/kg with the MRL of 0.02 mg/kg. This MRL is the same as the one set for veterinary uses in Reg. (EU) 37/2010 Since the CCPR proposed to revoke all existing CXLs (CCPR, 2023), the CXL is not substantiated, while the veterinary MRL set in Reg. (EU) 37/2010 could be considered Nevertheless, noting that the MRL set in Reg. (EU) 37/2010 is identical to the CXL that was withdrawn, risk managers should discuss whether it is substantiated
Fat from swine, bovine, sheep, goat	0.7	Reg. (EU) 37/2010	MRL accommodates external animal treatment (antiparasitic agents/agent against ectoparasites)	tbd	n.r.	–	In 1996, JMPR derived a codex MRL proposal of 2 mg/kg for fat from swine, bovine, sheep, goat and equine that accommodates external animal treatment. The EU did not express a reservation in the CCPR37/CAC in 2005. However, this CXL was not implemented in Reg. (EC) 149/2008. Reg. (EU) 899/2012 replaced the MRL of 0.05[a] mg/kg with the MRL of 0.7 mg/kg. This MRL is the same as the one set for veterinary uses in Reg. (EU) 37/2010. Noting that this veterinary MRL of 0.7 mg/kg is also equal to an old CXL, that has been withdrawn, risk managers should discuss whether it is substantiated

(Continues)

TABLE 5 (Continued)

Commodity	Existing MRL (mg/kg)	Source of existing MRL	cGAP for existing MRL	Existing MRL substantiated? (Y/N)	Fall-back GAP	Fall-back MRL (mg/kg)	Comment
Liver and kidney from swine, bovine, sheep, goat	0.03	See comments.	MRL accommodating external animal treatment	N	Reg. (EU) 37/2010 MRL accommodating external animal treatment (antiparasitic agents/ agent against ectoparasites)	0.02	The origin of the existing MRL is unclear. In 1996, JMPR derived a codex MRL proposal of 0.03 mg/kg for liver and kidney from swine, bovine, sheep, goat and equine that accommodates external animal treatment. The EU did not express a reservation in the CCPR37/CAC in 2005. However, this CXL was not implemented in Reg. (EC) 149/2008. Reg. (EU) 899/2012 replaced the MRL of 0.05[a] mg/kg with the MRL of 0.03 mg/kg. However, this MRL is different from the MRL of 0.02 mg/kg set for veterinary uses in Reg. (EU) 37/2010. Since the CCPR proposed to revoke all existing CXLs (CCPR, 2023), the CXL is not substantiated, while the veterinary MRL set in Reg. (EU) 37/2010 could be considered. Nevertheless, risk managers should discuss whether this veterinary MRL is substantiated.
Muscle and edible offals (other than liver and kidney) from poultry	0.02	CXL (CAC, 1999)	No information on the dietary burden could be retrieved (FAO and WHO, 1996b)	N	No fall-back use identified	–	In 1996, JMPR derived a codex MRL proposal of 0.02[a] mg/kg for muscle and edible offals of poultry. The EU did not express a reservation in the CCPR37/CAC in 2005. However, this CXL was not implemented in Reg. (EC) 149/2008. Reg. (EU) 899/2012 replaced the MRL of 0.05[a] mg/kg with the MRL of 0.02 mg/kg. Since the CCPR proposed to revoke all existing CXLs (CCPR, 2023), this MRL is not substantiated.
Milk from bovine, sheep, goat, equine, other	0.02	See comments	MRL accommodates external animal treatment	tbd	n.r.	–	The origin of the existing MRL is unclear. In 1996, JMPR derived a codex MRL proposal of 0.02 mg/kg for milk from swine, bovine, sheep, goat and other that accommodates external animal treatment. The EU did not express a reservation in the CCPR37/CAC in 2005. However, this CXL was not implemented in Reg. (EC) 149/2008. Reg. (EU) 899/2012 replaced the default MRL of 0.01[a] mg/kg with the MRL of 0.02 mg/kg. This MRL is the same as the one set for veterinary uses in Reg. (EU) 37/2010. Since the CCPR proposed to revoke all existing CXLs (CCPR, 2023), the CXL is not substantiated, while the veterinary MRL set in Reg. (EU) 37/2010 could be considered. Nevertheless, noting that the MRL set in Reg. (EU) 37/2010 is identical to the CXL that was withdrawn, risk managers should discuss whether it is substantiated.

Abbreviations: a.s., active substance; CAC, Codex Alimentarius Commission; CCPR, Codex committee on pesticide residues: CXL, Codex maximum residue limit; cGAP, critical good agricultural practice; GAP, good agricultural practice; IT, import tolerance; MRL, maximum residue limit; PHI, preharvest interval; n.r., not relevant; tbd, to be discussed.

[a]Indicates that the MRL 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 toxicological reference values (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 diazinon reported in Table 6 were derived by EFSA in 2006; the TRVs were not formally adopted by the European Commission as the authorisation for diazinon use in plant protection products was withdrawn in June 2007;[10] nevertheless, they are currently reported in the EU pesticides database.[11] In 2016, JMPR derived an ADI and an ARfD which can be found in Table 7.

The difference between the ADI value derived by EFSA and JMPR relates to a different interpretation of the overall database as the NOAELs established are mainly similar. There is no difference in the interpretation of the data to derive the ARfD, except that the human data could not be used by EFSA, as they were not more critical than the animal data.

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

TRV	Value	Reference	Comments
ADI	0.0002 mg/kg bw per day	EFSA (2006)	Based on a NOAEL 0.02 mg/kg bw per day for inhibition of RBC and brain AChE in 90-day and 1-year studies in dogs and applying an UF of 100
ARfD	0.025 mg/kg bw	EFSA (2006)	Based on a NOAEL 2.5 mg/kg bw for RBC and brain AChE inhibition in acute neurotoxicity studies in rats; UF of 100 applied

Abbreviations: AChE, acetylcholinesterase (activity); ADI, acceptable daily intake; ARfD, acute reference dose; bw, body weight; NOAEL, no observed adverse effect level; RBC, red blood cells; UF, uncertainty factor.

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

TRV	Value	Reference	Comments
ADI	0.003 mg/kg bw per day	FAO and WHO (2016)	Based on the overall NOAEL of 0.3 mg/kg bw per day from all repeated-dose toxicity studies for inhibition of AChE and applying an UF of 100
ARfD	0.03 mg/kg bw	FAO and WHO (2001, 2006a, 2016)	Based on a NOAEL of 2.5 mg/kg bw in an acute neurotoxicity study in rats and applying an UF of 100. The ARfD is supported by the NOAEL of 0.31 mg/kg bw, the highest dose tested in a single dose human volunteers' study and applying an UF of 10

Abbreviations: AChE, acetylcholinesterase (activity); 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 the EU and the JMPR TRVs, focusing 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 in the DAR (Portugal, 2004) and following peer review (EFSA, 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 98 in March 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 diazinon contains studies assessing the three endpoints, i.e. gene mutation in bacterial and mammalian cells (in vitro), clastogenicity (in vitro and in vivo) and aneugenicity (in vivo).[12] The studies were conducted according to the good laboratory practice and OECD test guidelines in place at the time of their conduct and were considered acceptable by the RMS. One of the test guidelines was deleted in the meantime (in vitro unscheduled DNA synthesis assay – TG 482 [OECD, 1986]) used in one study but not impacting the overall genotoxicity assessment. Three additional in vivo tests (mouse dominant lethal and chromosome studies in male germinal epithelium showing negative outcome) were not considered acceptable by the RMS and not considered further (Portugal, 2004).

The studies for gene mutation gave negative results. The chromosome aberration test in vitro gave equivocal response and the in vivo micronucleus (MN) study addressing clastogenicity and aneugenicity, as well as follow-up to the equivocal result obtained in vitro was inconclusive since evidence of bone marrow exposure was not demonstrated. Regarding the

[10]Commission Decision of 6 June 2007 concerning the non-inclusion of diazinon in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. OJ L 148, 9.6.2007, p. 9–10.

[11]https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/612

[12]See experts' consultation point 2.1 at the Pesticide Peer Review Teleconference 98 (EFSA, 2023a).

in vitro chromosome aberration test in human lymphocytes (2002), the experts noted that applying the criteria of the updated TG 473 (OECD, 2016a), the study should rather be considered supplementary and a clastogenic potential cannot be discarded as, at least in one of the experiments (with metabolic activation), a dose-related increase in chromosome aberrations is observed, reaching statistical significance in one of the test concentrations when compared with the concurrent negative control. Since the reporting is limited in the DAR, a comparison with available historical control data is not possible. The in vivo MN study from 1988 should also be considered supplementary due to strong deviations from the current test guidelines such as scoring only 1000 immature erythrocytes per animal for the incidence of micronucleated immature erythrocytes instead of the minimal 4000 currently recommended in TG 474 (OECD, 2016b). Tabulated results are mostly not reported in the DAR, and more importantly, no information is available on the bone marrow exposure to the test material in the MN study. Other limitations were noted in the data set, such as low purity of the test material in the Ames test and in vivo MN test that reduce the reliability of these studies, implying overall that all genotoxicity studies should be considered, at best, as supplementary. It was noted that published literature was not retrieved that may have captured sensitive effects not reported in the available studies.

Considering the limitations and uncertainties identified in the studies, all experts agreed that a genotoxic potential cannot be fully ruled out for diazinon when considering current standards, in particular regarding its clastogenic and aneugenic potential.

With regard to the toxicological data package needed to derive an ADI and ARfD for diazinon according to the current data requirements,[13] the experts identified major limitations and missing data as listed below[14]:

- 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 consequently in diazinon-treated commodities, in particular the impurities known to present high toxicity such as diazoxon, TEPP,[15] O,S-TEPP[16] and S,S-TEPP[17] is unknown;
- 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;
- an up-to-date search for published literature is missing;
- the assessment of the endocrine disruptive potential of diazinon was not conducted since insufficient investigations of the ED parameters are available according to the current ECHA/EFSA Guidance (ECHA and EFSA et al., 2018);
- a developmental neurotoxicity (DNT) study was not available to the peer review, while diazinon belongs to the chemical class of organophosphates pesticides, presenting a neurotoxic mode of action; inhibition of acetylcholinesterase activity having been identified as the most sensitive endpoint in all species tested, after single or repeated administrations. A DNT study was submitted to the US EPA but only a short summary of the outcome was retrieved. EFSA noted that diazinon was found positive in several endpoint for the microelectrode array (neuronal network formation) and in additional assays for DNT (synaptogenesis) in the US EPA battery and included in Tox Cast, which is an alert of DNT concern;
- concerning the assessment of the individual studies, the summary of the toxicological studies reported in the DAR is not detailed and reported as would be expected in current standards and an independent review of the findings could not be fully undertaken.

The experts expressed concern regarding the lack of substance specific information on neurological effects on the developing organisms, and more susceptible populations since the available neurotoxicity studies were all performed on adult animals (while infants and children are still undergoing critical period of neurodevelopment). In the absence of these data, it would be appropriate to use an additional UF of 10 as a precautionary approach to establish the TRVs (as done for other active substance belonging to the same chemical class). It was also suggested that the different assessments of the no observed adverse effect levels/lowest observable adverse effect level (NOAEL/LOAEL) between the JMPR and EU assessments to derive the ADI could possibly be solved using a benchmark dose analysis for the critical endpoint (AChE inhibition) (EFSA et al., 2022). Overall, considering the missing DNT study that is critical to the risk assessment of organophosphate pesticides, it would not be appropriate to keep the formerly established TRVs for diazinon, and an additional UF of at least 10 should be considered to address this issue.

Other data gaps need also to be considered when choosing an additional UF. Taking into account that the genotoxicity potential of diazinon is inconclusive, and that genotoxicity is considered a non-threshold mode of action, all experts agreed that an additional UF would not be appropriate for diazinon.

[13]Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market OJ L 93, 3.4.2013, p. 1–84.

[14]See experts' consultation point 2.2 at the Pesticide Peer Review Teleconference 98 (EFSA, 2023a).

[15]TEPP: tetraethyl pyrophosphate.

[16]O,S-TEPP: O,O,O,O-tetraethyl-thiopyrophosphate.

[17]S,S-TEPP: O,O,O,O-tetraethyl-dithiopyrophosphate.

It was concluded that the existing TRVs derived at EU level in the past cannot be confirmed for diazinon since its genotoxicity potential is inconclusive, in particular regarding its clastogenic and aneugenic potential. Accordingly, the ADI and ARfD derived in 2006 in the EU do not comply with the current scientific standards.

The JMPR values suffer from the same limitations considering that, although the genotoxicity data package available to the JMPR is not reported in detail, it is expected to include the same data set (FAO and WHO, 2016).

4 | CONSUMER RISK ASSESSMENT

In order to address ToR 5, ToR 6 and ToR 11, EFSA calculated the chronic and acute dietary exposure, based on the current residue definition for risk assessment, i.e. diazinon. 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., 2019, 2018). Screenshots of the report sheet of these PRIMo calculations for are presented in Appendix B. All input values included in the exposure calculations are summarised in Appendix C.

The following scenarios were calculated:

- **Scenario 1A**:
  - All livestock commodities for which the MRL might be substantiated are considered in this first scenario, using the veterinary MRLs from Reg. (EU) 37/2010 as input values both for chronic and acute exposure assessment.
  - All other commodities for which the CXLs/MRLs were revoked or are no longer substantiated, and for which no GAP was reported in the framework of the MRL review, were not included in the calculation. It is noted that this is deviating from the terms of reference, but in this specific case, this deviation is considered relevant to identify and clearly present the contribution of the existing/proposed EU MRLs to the toxicological burden.
- **Scenario 1B**:
  - Considering the results from scenario 1A, an additional calculation was performed to identify a safe scenario. This scenario is identical to scenario 1A, except for swine fat and cattle milk, for which the input values are lowered, respectively, to the default LOQ and to the lowest achievable LOQ.
- **Scenario 2A:**
  - All MRLs that were evaluated by EFSA before and including 2009 and all import tolerances established before and including 2007, respectively, are lowered to the appropriate LOQ.
  - 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 where no GAP was reported in the framework of the MRL review were included in the calculation with the appropriate LOQ.
- **Scenario 2B:**
  - This additional scenario is calculated to screen the lowest achievable LOQs. It is identical to scenario 2A but lowering all the default LOQs to the lowest LOQs achievable according to the EURLs, for each commodity group.

The acute and chronic exposure calculations were compared to current EU TRVs (EFSA, 2006), noting that during the experts' meeting on mammalian toxicology held in March 2023, the experts concluded that these TRVs do not comply with the current scientific standards (see Section 3). To give a comprehensive overview, the exposure calculations were also compared to the less conservative TRVs derived by the JMPR (FAO and WHO, 2016), however, considering that the experts also noted deficiencies in the toxicological database used by JMPR (see Section 3).

In scenario 1A, the highest acute exposure is calculated for milk (cattle), representing 10% of the EU ARfD. The EU ADI is exceeded for 21 diets, with the highest chronic exposure calculated for Dutch toddler representing 638% of the ADI derived at EU level. The highest contributors to these 21 diets for which exceedances were identified, are cattle milk (up to 597% ADI) and swine fat (up to 78% ADI). An additional calculation (scenario 1B) was therefore performed considering the default LOQ of 0.01 mg/kg for swine fat and the lowest LOQ achievable (0.0005 mg/kg, EURLs, 2022) for cattle milk. In this additional scenario, the highest chronic exposure decreases to 59% ADI (UK toddler), with the contribution of cattle milk decreasing to a maximum of 15% of the ADI. The highest acute exposure is calculated for bovine fat representing 6% ARfD. It is noted that, although the lowest achievable LOQ for cattle milk was considered in this scenario, an LOQ of 0.001 mg/kg would be already sufficiently protective.

In scenario 2A, which aims at screening the LOQs, the EU ADI is exceeded for 23 diets, with the highest chronic exposure calculated for Dutch toddler representing 336% of the ADI derived at EU level. The highest acute exposure is calculated for potatoes, representing 6% of the EU ARfD. Although the calculated chronic exposures are expected to be highly overestimated since based on the assumption that all commodities consumed contain residues at the LOQ, which is not expected

to happen for a non-approved active substance, in order to support risk managers an additional calculation (scenario 2B) was performed considering the lowest achievable LOQs.

In scenario 2B, the highest chronic exposure is calculated for Dutch toddler, representing 103% of the ADI derived at EU level. Nevertheless, this slight exceedance of the ADI is not considered relevant, for the same reasons reported above. The highest acute exposure is calculated for potatoes, representing 1% of the EU ARfD.

In the JMPR scenarios, the highest chronic exposure is calculated for Dutch toddler, representing in scenario 1A and scenario 2A, 43% and 22% of the ADI, respectively. The highest acute exposure is calculated for milk representing 8% of the ARfD in scenario 1A, and in potatoes representing 5% of the ARfD in scenario 2A. Scenarios 1B and 2B are not necessary since no exceedances were identified in scenario 1A and 2A when considering the JMPR TRVs.

EFSA highlights that the toxicological assessment revealed deficiencies regarding the toxicological studies available for diazinon (EFSA, 2023a). Therefore, considering the high level of uncertainty affecting the EU TRVs and the TRVs derived by JMPR, the risk assessment requested in ToR 5 cannot be finalised and the results presented in this review are indicative only.

5 | CONCLUSIONS AND RECOMMENDATIONS

The metabolism of diazinon in plants and animals was previously investigated in the framework of the peer review, as well as by JMPR. According to the results of the metabolism studies assessed, the residue definition derived at European level for enforcement and risk assessment, both for plant and animal products, is diazinon. The residue is fat soluble. The same residue definitions were initially derived by the JMPR, however, in its latest assessment, the Meeting was not able to conclude on the metabolism, and only the residue definition for enforcement in plants was confirmed as diazinon.

Analytical methods are available for the enforcement of the proposed residue definition in high water content, high oil content and high acid content with an LOQ of 0.01 mg/kg; however, no validation data are available to monitor diazinon in spices and hops. Diazinon can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in muscle, fat, kidney, liver, milk and eggs. According to the EURLs, a QuEChERS (or QuOil) multi-residue analytical method with an LOQ of 0.01 mg/kg for the routine analysis of diazinon in high water content, high acid content, high oil content and dry commodities. In these commodities, even lower LOQs were successfully validated (down to 0.002 mg/kg for high water and high acid content commodities, down to 0.005 mg/kg for high oil content and dry commodities). A default LOQ of 0.01 mg/kg is also deemed achievable to monitor diazinon in all commodities of animal origin, and lower LOQs were also deemed achievable (down to 0.005 mg/kg for fat, down to 0.001 mg/kg for muscle, liver, kidney and fish, and down to 0.0005 mg/kg for milk and eggs).

The origin of all current MRLs set for diazinon (based on formerly approved uses or on CXLs) was investigated. None of the EU MRLs/CXLs established for plant commodities are substantiated, and no potential fall-back MRLs were identified. For what concerns livestock commodities, MRLs set for poultry muscle and edible offals and for swine and ruminant liver and kidney, are not substantiated. For swine and ruminant liver and kidney, the lower veterinary MRL set in Regulation (EU) 37/2010 could be considered by risk managers. All other livestock EU MRLs are based on external treatment and are identical to CXLs (recently revoked, hence not substantiated), and/or to veterinary MRLs set in Regulation (EU) 37/2010. For swine and ruminant muscle and fat and for milk, further considerations by risk managers are required to conclude whether the existing MRLs are substantiated.

The TRVs set at EU level and of those established by the JMPR were considered, and the set of toxicological studies used to derive these TRVs was assessed according to the current standards. As critical issues were identified, a Member States experts' consultation took place. The experts concluded that the data available are insufficient and that the TRVs cannot be confirmed for diazinon since its genotoxicity potential is inconclusive, in particular regarding its clastogenic and aneugenic potential. Accordingly, the EU ADI and ARfD derived in 2006 do not comply with the current scientific standards. Therefore, EFSA recommends that risk managers discuss whether these TRVs should be withdrawn. The following data would be required to finalise the toxicological assessment which is a prerequisite to derive robust TRVs:

- additional studies to conclude on the genotoxic potential of diazinon;
- up-to-date search for published literature;
- additional toxicological data to perform an ED assessment according to the 2018 ECHA/EFSA Guidance;
- interspecies comparative in vitro metabolism study on animal species used in pivotal studies and on human material;
- DNT study;
- 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;
- assessment of the presence of toxicologically relevant impurities in the technical specification and in diazinon-treated commodities;
- full re-evaluation of the toxicological data package and reporting relevant details on the studies and the results in accordance with the current standards.

It is expected that the same limitations regarding the genotoxicity data package are applicable to JMPR values.

Chronic and acute exposure calculations were performed using revision 3.1 of PRIMo. A first scenario 1A considered only the veterinary MRLs set for livestock in Reg. (EU) 37/2010 that might be substantiated. Comparing to the EU TRVs, no acute risk was identified but exceedances of the ADI were observed up to 638% of the ADI (Dutch toddler). It was noted that these exceedances were mainly driven by swine fat and cattle milk. An additional calculation (scenario 1B) was therefore

performed, considering the default LOQ of 0.01 mg/kg for swine fat and the lowest LOQ achievable (0.0005 mg/kg) for cattle milk. In this additional scenario, the highest chronic exposure decreased to 59% ADI (UK toddler), with the contribution of cattle milk decreasing to a maximum of 15% of the ADI. It is noted that, although the lowest achievable LOQ for cattle milk was considered in this scenario, an LOQ of 0.001 mg/kg would be already sufficiently protective.

In scenario 2A, a screening of the LOQs was performed. No acute risk was identified but exceedances of the ADI up to 336% (Dutch toddler) were observed. Although the calculated chronic exposures are expected to be highly overestimated since based on the assumption that all commodities consumed contain residues at the LOQ, which is not expected to happen for a non-approved active substance, in order to support risk managers, an additional calculation (scenario 2B) was performed considering the lowest LOQs achievable according to the EURLs for each commodity group. In this additional scenario, the highest chronic exposure decreased to 103% of the EU ADI. Nevertheless, this slight exceedance of the ADI is not considered relevant, for the same reasons reported above.

EFSA emphasises that as the toxicological assessment revealed deficiencies regarding the toxicological studies available for diazinon and considering that EU TRVs do not meet the current scientific standards, the risk assessment cannot be finalised, and results presented under the current review are indicative only. In addition, considering this indicative risk assessment, it is underlined that the veterinary MRLs for diazinon in cattle milk and swine fat, lead to a potential chronic concern. Based on this outcome, EFSA recommends risk managers to reconsider the veterinary MRLs for these animal commodities.

Due to the deficiencies identified regarding the toxicological studies available for diazinon, none of the existing EU MRLs/CXLs listed in Table 8 below are recommended for inclusion in Annex II to the Regulation. If a decision to withdraw the TRVs is taken, EFSA recommends that risk managers discuss whether all MRLs currently implemented in EU Regulation should be lowered to the respective LOQs.

TABLE 8 Summary table.

			Outcome of the review	
Code[a]	**Commodity**	**Existing MRL[b] (mg/kg)**	**MRL proposal (mg/kg)**	**Comment**
Residue definition for enforcement: Diazinon[F]				
0120010	Almonds	0.05	LOQ	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0154020	Cranberries	0.2	LOQ	The existing MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0163080	Pineapples	0.3	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0213080	Radishes	0.1	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0220020	Onions	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0231020	Sweet peppers/ bell peppers	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0234000	Sweet corn	0.02	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0243010	Chinese cabbage/ pe-tsai	0.05	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0244000	Kohlrabies	0.2	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0700000	Hops	0.5	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0810000	Seed spices	5	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0840000	Root and rhizome spices	0.5	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
0900010	Sugar beet roots	0.1	LOQ	The existing EU MRL is not substantiated. Hence, the MRL should be lowered to the LOQ
1011010 1012010 1013010 1014010 1015010	Muscle from Swine Bovine Sheep Goat	0.02	0.02 or LOQ	The existing MRL might still reflect the veterinary MRL currently in place Reg. (EU) 37/2010 However, risk managers should discuss whether the existing MRL needs to be lowered considering that, lacking robust TRVs for diazinon, the risk assessment is only indicative Furthermore, in view of the very low EU TRVs, the default LOQ for bovine muscle will not be sufficiently protective for consumers

(Continues)

TABLE 8 (Continued)

			Outcome of the review	
Code[a]	Commodity	Existing MRL[b] (mg/kg)	MRL proposal (mg/kg)	Comment
1012020 1013020 1014020	Fat from Bovine Sheep Goat	0.7	0.7 or LOQ	The existing MRL might still reflect the veterinary MRL currently in place Reg. (EU) 37/2010 However, risk managers should discuss whether the existing MRL needs to be lowered considering that, lacking robust TRVs for diazinon, the risk assessment is only indicative
1011020	Fat from swine	0.7	LOQ	The existing MRL might still reflect the veterinary MRL currently in place Reg. (EU) 37/2010 However, exceedances of the EU ADI were observed, with fat from swine being one of the main contributors to the chronic exposure (noting also that, lacking robust TRVs, the risk assessment is only indicative)
1011030 1012030 1013030 1014030	Liver from Swine Bovine Sheep Goat	0.03	0.02 or LOQ	The existing EU MRL is not substantiated. The veterinary MRL of 0.02 mg/kg currently set in Reg. (EU) 37/2010, might be considered as an alternative MRL However, risk managers should discuss whether the existing MRL needs to be lowered considering that, lacking robust TRVs for diazinon, the risk assessment is only indicative
1011040 1012040 1013040 1014040	Kidney from Swine Bovine Sheep Goat	0.03	0.02 or LOQ	Same comment as reported for liver (from swine, bovine, sheep, goat)
1016010	Poultry muscle	0.02	LOQ	The existing EU MRL is not substantiated. Hence, it should be lowered to the LOQ
1016050	Poultry edible offals (other than liver and kidney)	0.02	LOQ	Same comment as reported for poultry muscle
1020020 1020030 1020040 1020990	Milk from Sheep Goat Equine Other	0.02	0.02 or LOQ	The existing MRL might still reflect the veterinary MRL currently in place Reg. (EU) 37/2010 However, risk managers should discuss whether the existing MRL needs to be lowered considering that, lacking robust TRVs for diazinon, the risk assessment is only indicative
1010010	Milk from Bovine	0.02	LOQ	The existing MRL might still reflect the veterinary MRL currently in place Reg. (EU) 37/2010 However, exceedances of the EU ADI were observed, with cattle milk being the main contributor to the chronic exposure (noting that, lacking robust TRVs, the risk assessment is only indicative). Furthermore, in view of the very low EU TRVs, the default LOQ for milk from bovine will not be sufficiently protective for consumers

Abbreviations: ADI, acceptable daily intake; LOQ, limit of quantification; MRL, maximum residue limit; TRV, toxicological reference value.

[F]Fat soluble.

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

[b]MRL currently set under Regulation (EC) No 834/2013.

ABBREVIATIONS

a.s.	active substance
AChE	acetylcholinesterase
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
cGAP	critical good agricultural practice
CXL	Codex maximum residue limit
DALT	days after last treatment
DAR	draft assessment report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DNT	developmental neurotoxicity study

EC	European Commission
ECHA	European Chemicals Agency
ED	endocrine disruptor
EPA	(US) Environmental Protection Agency
EURLs	European Reference Laboratories
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC–MS	gas chromatography with mass spectrometry
GC–MS/MS	gas chromatography with tandem mass spectrometry
ha	hectare
hL	hectolitre
HR	highest residue
IT	import tolerance
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC–MS/MS	liquid chromatography - mass spectrometry
LOAEL	lowest observable adverse effect level
LOQ	limit of quantification (determination)
MN	Micronucleus (test)
MRL	maximum residue limit
MS	Member States
n.r.	not relevant
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
OJ	Official Journal of the European Union
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
RAC	(ECHA) Risk Assessment Committee
RBC	red blood cells
RD	residue definition
SCoPAFF	Standing Committee on Plants, Animals, Food and Feed
STMR	supervised trials median residue
tbd	to be discussed
TG	test guideline
ToR	terms of reference
TRV	toxicological reference value WHO
UF	World Health Organization uncertainty factor
USA	United States of America

ACKNOWLEDGEMENTS

EFSA wishes to thank the following experts from ANSES (French Agency for Food, Environmental and Occupational Health & Safety) for the support provided to this reasoned opinion: Nicolas Breysse, Pierre L'Yvonnet, Tomin-Gwenn Robin and Xavier Sarda.

CONFLICT OF INTEREST

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

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2022-00446

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*.

CAC (Codex Alimentarius Commission). (1997). *Report on the joint FAO/WHO food standards programme. Codex Alimentarius Commission, Twenty-Second Session, Geneva, 23–28 June 1997*.

CAC (Codex Alimentarius Commission). (1999). *Report on the joint FAO/WHO food standards programme. Codex Alimentarius Commission, Twenty-Third Session, Roe, 28 June-3 July 1999*.

CAC (Codex Alimentarius Commission). (2005). *Report on the joint FAO/WHO food standards programme. Codex Alimentarius Commission, Twenty-Eighth Session, Rome, 4–9 July 2005*.

CAC (Codex Alimentarius Commission). (2007). *Report on the joint FAO/WHO food standards programme. Codex Alimentarius Commission, Thirtieth Session, Rome, 2–7 July 2007*.

CCPR (Codex committee on pesticide residues). (2005). *Report of the 37th session of the codex committee on pesticide residues, The Hague, the Netherlands, 18–23 April 2005*.

CCPR (Codex committee on pesticide residues). (2007). *Report of the 39th session of the codex committee on pesticide residues, Beijing, China, 7–12 May 2007*.

CCPR (Codex committee on pesticide residues). (2023). *Report of the 53rd session of the Codex committee on pesticide residues, Beijing, China, 26 June – 1 July 2023*.

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). (2006). Conclusion on pesticide peer review. Conclusion regarding the peer review of the pesticide risk assessment of the active substance diazinon. *EFSA Scientific Report*, *85*, 73 Issued on 23 June 2006.

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

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*, *16*(3), 15. https://doi.org/10.2903/sp.efsa.2019.EN-1605

EFSA (European Food Safety Authority), More, S. J., Bampidis, V., Benford, D., Bragard, C., Halldorsson, T. I., Hernandez-Jerez, A. F., Bennekou, S. H., Koutsoumanis, K., Lambré C., Machera, K., Mennes, W., Mullins, E., Nielsen, S. S., Schrenk, D., Turck, D., Younes, M., Aerts, M., Edler, L., … Schlatter, J. (2022). Guidance on the use of the benchmark dose approach in risk assessment. *EFSA Journal*, *20*(10), 67. https://doi.org/10.2903/j.efsa.2022.7584

EFSA (European Food Safety Authority). (2023a). *Report on the pesticide peer review TC 98 – diazinon. 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 diazinon prepared by EFSA in the framework of Article 43 of Regulation (EC) No 396/2005. October 2023*. www.efsa.europa.eu

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 diazinon. October 2022*. www.efsa.europa.eu

European Commission. (2006). *Review report for the active substance diazinon finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 29 September 2006 in support of a decision concerning the non-inclusion of diazinon in Annex I of Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance. SANCO/10052/06-rev.0, 12 September 2006*.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organisation). (1993a). *Diazinon. Report of the 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, Geneva, Switzerland, 20–29 September 1993. FAO Plant Production and Protection Paper 122*.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organisation). (1993b). *Diazinon. In: Pesticides residues in food – 1993. Joint Meeting of the FAP Panel of Experts in Pesticides Residues in Food and the Environment and WHO Toxicological and Environmental Core Assessment Groups. Geneva, Switzerland, 20–29 September 1993. Evaluations, Part I, Residues. FAO Plant Production and Protection Paper 124*.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organisation). (1994a). *Diazinon. Report of the 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 Organisation). (1994b). *Diazinon. In: Pesticides residues in food – 1994. Joint Meeting of the FAP Panel of Experts in Pesticides Residues in Food and the Environment and WHO Toxicological and Environmental Core Assessment Groups. Rome, Italy, 19–28 September 1994. Evaluations, Part I, Residues. FAO Plant Production and Protection Paper 131/1*.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organisation). (1996a). *Diazinon. Report of the 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, 16–25 September 1996. FAO Plant Production and Protection Paper 140*.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organisation). (1996b). *Diazinon. In: Pesticides residues in food – 1996. Joint Meeting of the FAP Panel of Experts in Pesticides Residues in Food and the Environment and WHO Toxicological and Environmental Core Assessment Groups. Rome, Italy, 16–25 September 1996. Evaluations, Part I, Residues. FAO Plant Production and Protection Paper 142*.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organisation). (2001). *Pesticides residues in food–2001. Joint FAO/WHO Meeting on Pesticides Residues. FAO Plant Production and Protection Paper 167*.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organisation). (2004). *Pesticides residues in food–2004. Joint FAO/WHO Meeting on Pesticides Residues. Report of the 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, 20–29 September 2004. FAO Plant Production and Protection Paper 178*.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organisation). (2006a). *Diazinon. Report of the 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, 3–12 October 2006. FAO Plant Production and Protection Paper 187*.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organisation). (2006b). *Diazinon. In: Pesticides residues in food – 2006. Joint meeting of the FAP panel of experts in pesticides residues in food and the environment and WHO toxicological and environmental Core assessment groups. Rome, Italy, 3–12 October 2006. Evaluations, Part I, Residues. FAO Plant Production and Protection Paper 189/2*.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organisation). (2016). *Diazinon. Report of the 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, 13–22 September 2016. FAO Plant Production and Protection Paper 229*.

FAO and WHO (Food and Agriculture Organization of the United Nations and World Health Organisation). (2023). *Pesticides residues in food–2022. Joint FAO/WHO Meeting on Pesticides Residues. Report of the 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, 13–22 September 2022*.

OECD (Organisation for Economic Co-operation and Development) (1986), *Test No. 482: Genetic toxicology: DNA damage and repair, unscheduled DNA synthesis in mammalian cells in vitro, OECD guidelines for the testing of chemicals, Section 4*, OECD Publishing. https://doi.org/10.1787/9789264071445-en

OECD (Organisation for Economic Co-operation and Development) (2016a), *Test No. 473: In Vitro mammalian chromosomal aberration test, OECD guidelines for the testing of chemicals, section 4*, OECD Publishing. https://doi.org/10.1787/9789264264649-en

OECD (Organisation for Economic Co-operation and Development). (2016b). *Test No. 474: Mammalian erythrocyte micronucleus test, OECD guidelines for the testing of chemicals, Section 4, OECD Publishing, Paris*. https://doi.org/10.1787/9789264264762-en

Portugal. (2004). *Draft assessment report on the active substance diazinon prepared by the rapporteur Member State Portugal in the framework of Council Directive 91/414/EEC, August 2004*.

How to cite this article: EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Binaglia, M., Carrasco Cabrera, L., Castellan, I., Castoldi, A. F., Chiusolo, A., Chukwubike, K., Crivellente, F., Del Aguila, M., Ferreira, L., Giner Santonja, G., Greco, L., Istace, F., Jarrah, S., Lanzoni, A., Leuschner, R., Mangas, I., … Verani, A. (2023). Targeted review of maximum residue levels (MRLs) for diazinon. *EFSA Journal*, *21*(11), e8426. https://doi.org/10.2903/j.efsa.2023.8426

APPENDIX A

Summary of the fall-back GAPs collected from Member States

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

APPENDIX B

Pesticide Residue Intake Model (PRIMo)

- PRIMo_EU_(Sc.1A)

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Diazinon (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.0002	ARfD (mg/kg bw):	0.025
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2006	Year of evaluation:	2006

Input values: Details - chronic risk assessment; Supplementary results - chronic risk assessment; Details - acute risk assessment/children; Details - acute risk assessment/adults

Comments: **Scenario 1A**

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

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

No of diets exceeding the ADI : 21

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
638%	NL toddler	1.28	597%	Milk: Cattle	10%	Bovine: Muscle/meat	9%	Swine: Fat tissue		638%
409%	UK infant	0.82	387%	Milk: Cattle	12%	Bovine: Muscle/meat	8%	Bovine: Fat tissue		409%
335%	FR toddler 2 3 yr	0.67	293%	Milk: Cattle	14%	Swine: Fat tissue	12%	Bovine: Muscle/meat		335%
297%	NL child	0.59	244%	Milk: Cattle	16%	Swine: Fat tissue	15%	Bovine: Fat tissue		297%
297%	FR child 3 15 yr	0.59	229%	Milk: Cattle	35%	Swine: Fat tissue	15%	Bovine: Muscle/meat		297%
260%	UK toddler	0.52	207%	Milk: Cattle	41%	Bovine: Fat tissue	13%	Bovine: Muscle/meat		260%
207%	DE child	0.41	198%	Milk: Cattle	6%	Swine: Muscle/meat	3%	Bovine: Muscle/meat		207%
206%	GEMS/Food G11	0.41	78%	Swine: Fat tissue	78%	Milk: Cattle	29%	Bovine: Fat tissue		206%
204%	GEMS/Food G15	0.41	95%	Swine: Fat tissue	70%	Milk: Cattle	14%	Bovine: Fat tissue		204%
183%	ES child	0.37	125%	Milk: Cattle	29%	Swine: Fat tissue	14%	Bovine: Muscle/meat		183%
182%	FR infant	0.36	168%	Milk: Cattle	6%	Swine: Fat tissue	4%	Swine: Muscle/meat		182%
177%	DE general	0.35	123%	Milk: Cattle	32%	Swine: Fat tissue	11%	Swine: Muscle/meat		177%
172%	GEMS/Food G08	0.34	80%	Swine: Fat tissue	56%	Milk: Cattle	20%	Swine: Muscle/meat		172%
168%	DE women 14-50 yr	0.34	124%	Milk: Cattle	25%	Swine: Fat tissue	9%	Swine: Muscle/meat		168%
168%	SE general	0.34	124%	Milk: Cattle	44%	Bovine: Muscle/meat				168%
164%	DK child	0.33	126%	Milk: Cattle	22%	Swine: Muscle/meat	13%	Bovine: Muscle/meat		164%
161%	DK adult	0.32	70%	Swine: Fat tissue	53%	Milk: Cattle	23%	Bovine: Fat tissue		161%
137%	RO general	0.27	116%	Milk: Cattle	12%	Swine: Muscle/meat	6%	Swine: Fat tissue		137%
129%	GEMS/Food G07	0.26	64%	Milk: Cattle	23%	Swine: Fat tissue	14%	Bovine: Fat tissue		129%
124%	GEMS/Food G10	0.25	55%	Milk: Cattle	25%	Bovine: Fat tissue	23%	Swine: Fat tissue		124%
117%	NL general	0.23	85%	Milk: Cattle	10%	Swine: Muscle/meat	7%	Swine: Fat tissue		117%
98%	LT adult	0.20	46%	Swine: Fat tissue	40%	Milk: Cattle	10%	Swine: Muscle/meat		98%
88%	IE child	0.18	47%	Swine: Fat tissue	36%	Milk: Cattle	3%	Sheep: Fat tissue		88%
86%	ES adult	0.17	49%	Milk: Cattle	19%	Swine: Fat tissue	7%	Bovine: Muscle/meat		86%
72%	FR adult	0.14	45%	Milk: Cattle	12%	Swine: Fat tissue	7%	Swine: Muscle/meat		72%
58%	IE adult	0.12	44%	Milk: Cattle	4%	Bovine: Muscle/meat	4%	Swine: Muscle/meat		58%
47%	UK adult	0.09	30%	Milk: Cattle	10%	Bovine: Fat tissue	7%	Bovine: Muscle/meat		47%
41%	GEMS/Food G06	0.08	25%	Milk: Cattle	5%	Bovine: Fat tissue	3%	Bovine: Muscle/meat		41%
39%	UK vegetarian	0.08	33%	Milk: Cattle	7%	Bovine: Fat tissue	0.1%	Bovine: Muscle/meat		39%
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 638.5 % of the ADI.
For 21 diet(s), the ADI is exceeded.

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Milk: Cattle	0.02/0.02	2.5
6%	Bovine: Fat tissue	0.7/0.7	1.5
5%	Swine: Fat tissue	0.7/0.7	1.2
2%	Milk: Goat	0.02/0.02	0.48
1.0%	Swine: Muscle/meat	0.02/0.02	0.24
0.6%	Bovine: Liver	0.02/0.02	0.16
0.6%	Bovine: Muscle/meat	0.02/0.02	0.14
0.4%	Sheep: Muscle/meat	0.02/0.02	0.11
0.3%	Bovine: Kidney	0.02/0.02	0.08
0.3%	Milk: Sheep	0.02/0.02	0.07
0.1%	Swine: Kidney	0.02/0.02	0.03
0.10%	Swine: Liver	0.02/0.02	0.02

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Swine: Fat tissue	0.7/0.7	1.4
3%	Milk: Cattle	0.02/0.02	0.77
3%	Bovine: Fat tissue	0.7/0.7	0.68
1%	Milk: Goat	0.02/0.02	0.37
1%	Milk: Sheep	0.02/0.02	0.30
0.5%	Bovine: Muscle	0.02/0.02	0.11
0.4%	Swine: Muscle/meat	0.02/0.02	0.10
0.4%	Sheep: Muscle/meat	0.02/0.02	0.09
0.3%	Bovine: Liver	0.02/0.02	0.08
0.2%	Sheep: Liver	0.02/0.02	0.06
0.2%	Swine: Kidney	0.02/0.02	0.04
0.2%	Bovine: Kidney	0.02/0.02	0.04
0.1%	Goat: Muscle	0.02/0.02	0.03
0.1%	Swine: Liver	0.02/0.02	0.03
0.01%	Sheep: Kidney	0.02/0.02	0.00

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)

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

- PRIMo_EU (Sc.1B)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Diazinon (F)

LOQs (mg/kg) range from:	0.01	to:	0.01
Toxicological reference values			
ADI (mg/kg bw per day):	0.0002	ARfD (mg/kg bw):	0.025
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2006	Year of evaluation:	2006

Input values | Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments: **Scenario 1B:** **Identical to scenario 1A, except for cattle milk and swine fat (highest contributors), input values are set at the lowest LOQ and default LOQ, respectively.**

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
59%	UK toddler	0.12	41%	Bovine: Fat tissue	13%	Bovine: Muscle/meat	5%	Milk: Cattle		59%
53%	GEMS/Food G11	0.11	29%	Bovine: Fat tissue	12%	Swine: Muscle/meat	7%	Bovine: Muscle/meat	1%	53%
47%	GEMS/Food G10	0.09	25%	Bovine: Fat tissue	9%	Bovine: Muscle/meat	9%	Swine: Muscle/meat	0.3%	47%
47%	SE general	0.09	44%	Bovine: Muscle/meat	3%	Milk: Cattle				47%
47%	NL toddler	0.09	15%	Milk: Cattle	10%	Bovine: Muscle/meat	9%	Bovine: Fat tissue	0.1%	47%
44%	NL child	0.09	15%	Bovine: Fat tissue	11%	Swine: Muscle/meat	9%	Bovine: Muscle/meat	0.2%	44%
43%	GEMS/Food G07	0.09	14%	Bovine: Fat tissue	12%	Swine: Muscle/meat	9%	Bovine: Muscle/meat	0.3%	43%
42%	GEMS/Food G15	0.08	14%	Bovine: Fat tissue	14%	Swine: Muscle/meat	5%	Bovine: Muscle/meat	1%	42%
41%	DK adult	0.08	23%	Bovine: Fat tissue	9%	Swine: Muscle/meat	5%	Bovine: Muscle/meat	1.0%	41%
41%	DK child	0.08	22%	Swine: Muscle/meat	13%	Bovine: Muscle/meat	3%	Milk: Cattle		41%
39%	FR child 3 15 yr	0.08	15%	Bovine: Muscle/meat	15%	Swine: Muscle/meat	6%	Milk: Cattle	0.5%	39%
38%	GEMS/Food G08	0.08	20%	Swine: Muscle/meat	10%	Bovine: Fat tissue	4%	Bovine: Muscle/meat	1%	38%
36%	FR toddler 2 3 yr	0.07	12%	Bovine: Muscle/meat	12%	Swine: Muscle/meat	7%	Milk: Cattle	0.2%	36%
33%	ES child	0.07	14%	Bovine: Muscle/meat	12%	Swine: Muscle/meat	3%	Milk: Cattle	0.4%	33%
31%	UK infant	0.06	12%	Bovine: Muscle/meat	10%	Milk: Cattle	8%	Bovine: Fat tissue		31%
27%	NL general	0.05	10%	Swine: Muscle/meat	7%	Bovine: Muscle/meat	7%	Bovine: Fat tissue	0.1%	27%
25%	DE general	0.05	11%	Swine: Muscle/meat	4%	Bovine: Fat tissue	4%	Bovine: Muscle/meat	0.5%	25%
22%	DE women 14-50 yr	0.04	9%	Swine: Muscle/meat	5%	Bovine: Fat tissue	3%	Bovine: Muscle/meat	0.4%	22%
18%	RO general	0.04	12%	Swine: Muscle/meat	3%	Bovine: Muscle/meat	3%	Milk: Cattle	0.1%	18%
18%	ES adult	0.04	7%	Bovine: Muscle/meat	7%	Swine: Muscle/meat	2%	Sheep: Muscle/meat	0.3%	18%
18%	UK adult	0.04	10%	Bovine: Fat tissue	7%	Bovine: Muscle/meat	0.7%	Milk: Cattle		18%
16%	FR adult	0.03	7%	Swine: Muscle/meat	6%	Bovine: Muscle/meat	1%	Milk: Cattle	0.2%	16%
16%	GEMS/Food G06	0.03	5%	Bovine: Fat tissue	3%	Bovine: Muscle/meat	2%	Milk: Sheep	0.0%	16%
15%	IE adult	0.03	4%	Bovine: Muscle/meat	4%	Swine: Muscle/meat	4%	Sheep: Muscle/meat		15%
14%	DE child	0.03	6%	Swine: Muscle/meat	5%	Milk: Cattle	3%	Bovine: Muscle/meat		14%
14%	LT adult	0.03	10%	Swine: Muscle/meat	3%	Bovine: Muscle/meat	1.0%	Milk: Cattle	0.7%	14%
12%	FR infant	0.02	4%	Milk: Cattle	4%	Swine: Muscle/meat	4%	Bovine: Muscle/meat	0.1%	12%
8%	UK vegetarian	0.02	7%	Bovine: Fat tissue	0.8%	Milk: Cattle	0.1%	Bovine: Muscle/meat		8%
7%	IE child	0.01	3%	Sheep: Fat tissue	2%	Swine: Muscle/meat	0.9%	Milk: Cattle	0.7%	7%
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Diazinon (F) is unlikely to present a public health concern.

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Bovine: Fat tissue	0.7/0.7	1.5
2%	Milk: Goat	0.02/0.02	0.48
1.0%	Swine: Muscle/meat	0.02/0.02	0.24
0.6%	Bovine: Liver	0.02/0.02	0.16
0.6%	Bovine: Muscle/meat	0.02/0.02	0.14
0.4%	Sheep: Muscle/meat	0.02/0.02	0.11
0.3%	Bovine: Kidney	0.02/0.02	0.08
0.3%	Milk: Sheep	0.02/0.02	0.07
0.2%	Milk: Cattle	0/0	0.06
0.1%	Swine: Kidney	0.02/0.02	0.03
0.10%	Swine: Liver	0.02/0.02	0.02
0.07%	Swine: Fat tissue	0.01/0.01	0.02

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Bovine: Fat tissue	0.7/0.7	0.68
1%	Milk: Goat	0.02/0.02	0.37
1%	Milk: Sheep	0.02/0.02	0.30
0.5%	Bovine: Muscle	0.02/0.02	0.11
0.4%	Swine: Muscle/meat	0.02/0.02	0.10
0.4%	Sheep: Muscle/meat	0.02/0.02	0.09
0.3%	Bovine: Liver	0.02/0.02	0.08
0.2%	Sheep: Liver	0.02/0.02	0.06
0.2%	Swine: Kidney	0.02/0.02	0.04
0.2%	Bovine: Kidney	0.02/0.02	0.04
0.1%	Goat: Muscle	0.02/0.02	0.03
0.1%	Swine: Liver	0.02/0.02	0.03
0.08%	Swine: Fat tissue	0.01/0.01	0.02
0.08%	Milk: Cattle	0/0	0.02
0.01%	Sheep: Kidney	0.02/0.02	0.00

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

- PRIMo_EU_(Sc.2A)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Diazinon (F)

LOQs (mg/kg) range from:	0.001	to:	0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.0002	ARfD (mg/kg bw):	0.025
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2006	Year of evaluation:	2006

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

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

Comments: Scenario 2A: screening of the default LOQs (except bovine milk: lowest LOQ achievable)

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 23

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	336%	NL toddler	0.67	54%	Apples	35%	Maize/corn	27%	Bananas	324%	
	223%	DE child	0.45	62%	Apples	21%	Wheat	20%	Oranges	215%	
	215%	NL child	0.43	42%	Sugar beet roots	29%	Apples	21%	Wheat	202%	
	179%	GEMS/Food G06	0.36	36%	Wheat	18%	Tomatoes	10%	Potatoes	173%	
	176%	FI adult	0.35	139%	Coffee beans	6%	Potatoes	4%	Rye	176%	
	171%	GEMS/Food G11	0.34	20%	Potatoes	19%	Soyabeans	18%	Wheat	157%	
	167%	FR child 3 15 yr	0.33	23%	Wheat	18%	Sugar beet roots	17%	Oranges	148%	
	163%	GEMS/Food G08	0.33	20%	Wheat	20%	Potatoes	10%	Soyabeans	146%	
	161%	GEMS/Food G07	0.32	21%	Wheat	19%	Potatoes	9%	Soyabeans	143%	
	158%	GEMS/Food G10	0.32	20%	Wheat	16%	Soyabeans	15%	Potatoes	142%	
	157%	GEMS/Food G15	0.31	23%	Wheat	18%	Potatoes	9%	Soyabeans	142%	
	145%	IE adult	0.29	18%	Sweet potatoes	11%	Wheat	11%	Potatoes	137%	
	144%	DK child	0.29	28%	Rye	22%	Wheat	12%	Potatoes	124%	
	141%	FR toddler 2 3 yr	0.28	16%	Apples	15%	Wheat	14%	Sugar beet roots	126%	
	134%	RO general	0.27	25%	Wheat	19%	Potatoes	10%	Tomatoes	122%	
	129%	ES child	0.26	22%	Wheat	13%	Cocoa beans	11%	Oranges	108%	
	129%	SE general	0.26	22%	Bovine: Muscle/meat	21%	Potatoes	16%	Wheat	107%	
	127%	DE women 14-50 yr	0.25	23%	Sugar beet roots	13%	Apples	11%	Coffee beans	120%	
	126%	UK toddler	0.25	20%	Wheat	17%	Potatoes	16%	Sugar beet roots	117%	
	123%	DE general	0.25	21%	Sugar beet roots	12%	Apples	12%	Coffee beans	114%	
	121%	UK infant	0.24	16%	Potatoes	13%	Wheat	10%	Milk: Cattle	113%	
	110%	NL general	0.22	14%	Sugar beet roots	12%	Potatoes	10%	Wheat	99%	
	104%	PT general	0.21	27%	Potatoes	20%	Wheat	12%	Wine grapes	104%	
	89%	FI 3 yr	0.18	24%	Potatoes	7%	Bananas	6%	Wheat	89%	
	88%	FR adult	0.18	12%	Wine grapes	11%	Wheat	10%	Coffee beans	80%	
	82%	IT toddler	0.16	33%	Wheat	8%	Other cereals	7%	Tomatoes	82%	
	80%	ES adult	0.16	12%	Wheat	6%	Oranges	5%	Potatoes	68%	
	72%	FI 6 yr	0.14	19%	Potatoes	6%	Cocoa beans	5%	Wheat	72%	
	66%	FR infant	0.13	10%	Potatoes	8%	Apples	7%	Sugar beet roots	62%	
	62%	LT adult	0.12	16%	Potatoes	9%	Apples	5%	Rye	54%	
	61%	IT adult	0.12	21%	Wheat	6%	Tomatoes	4%	Apples	61%	
	58%	UK vegetarian	0.12	10%	Wheat	7%	Potatoes	4%	Oranges	58%	
	57%	DK adult	0.11	6%	Potatoes	6%	Wheat	5%	Apples	48%	
	54%	UK adult	0.11	8%	Wheat	7%	Potatoes	5%	Wine grapes	49%	
	49%	PL general	0.10	17%	Potatoes	10%	Apples	4%	Tomatoes	49%	
	23%	IE child	0.05	6%	Wheat	3%	Potatoes	2%	Apples	21%	

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 336.4 % of the ADI.
For 23 diet(s) the ADI is exceeded.

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Potatoes	0.01/0.01	1.5
6%	Melons	0.01/0.01	1.5
6%	Pears	0.01/0.01	1.4
5%	Oranges	0.01/0.01	1.3
5%	Watermelons	0.01/0.01	1.2
4%	Apples	0.01/0.01	1.1
4%	Pineapples	0.01/0.01	1.0
4%	Bananas	0.01/0.01	0.97
4%	Peaches	0.01/0.01	0.95
3%	Mangoes	0.01/0.01	0.79
3%	Grapefruits	0.01/0.01	0.79
3%	Table grapes	0.01/0.01	0.73
3%	Cucumbers	0.01/0.01	0.66
3%	Carrots	0.01/0.01	0.63
2%	Kiwi fruits (green, red, yellow)	0.01/0.01	0.62

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Head cabbages	0.01/0.01	0.42
2%	Watermelons	0.01/0.01	0.41
2%	Melons	0.01/0.01	0.39
1%	Swedes/rutabagas	0.01/0.01	0.34
1%	Table grapes	0.01/0.01	0.34
1%	Oranges	0.01/0.01	0.31
1%	Pears	0.01/0.01	0.31
1%	Potatoes	0.01/0.01	0.30
1%	Pineapples	0.01/0.01	0.30
1%	Yams	0.01/0.01	0.28
1%	Apples	0.01/0.01	0.28
1%	Cucumbers	0.01/0.01	0.28
1%	Aubergines/egg plants	0.01/0.01	0.27
1%	Mangoes	0.01/0.01	0.26
1%	Chinese cabbages/pe-tsai	0.01/0.01	0.25

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Sugar beets (root)/sugar	0.01/0.12	1.1
4%	Potatoes/fried	0.01/0.01	0.93
4%	Pumpkins/boiled	0.01/0.01	0.89
4%	Witloofs/boiled	0.01/0.01	0.89
3%	Broccoli/boiled	0.01/0.01	0.79
3%	Cauliflowers/boiled	0.01/0.01	0.70
3%	Escaroles/broad-leaved endives/boiled	0.01/0.01	0.66
2%	Potatoes/dried (flakes)	0.01/0.05	0.59
2%	Leeks/boiled	0.01/0.01	0.57
2%	Apples/juice	0.01/0.01	0.54
2%	Oranges/juice	0.01/0.01	0.53
2%	Turnips/boiled	0.01/0.01	0.51
2%	Parsnips/boiled	0.01/0.01	0.51
2%	Sweet potatoes/boiled	0.01/0.01	0.50
2%	Florence fennels/boiled	0.01/0.01	0.45

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Pumpkins / boiled	0.01/0.01	0.55
2%	Sugar beets (root) / sugar	0.01/0.12	0.44
2%	Cauliflowers / boiled	0.01/0.01	0.42
2%	Beetroots / boiled	0.01/0.01	0.39
1%	Celeries / boiled	0.01/0.01	0.34
1%	Apples / juice	0.01/0.01	0.33
1.0%	Broccoli / boiled	0.01/0.01	0.24
1.0%	Coffee beans / extraction	0.05/0.01	0.24
0.9%	Courgettes / boiled	0.01/0.01	0.23
0.9%	Parsnips / boiled	0.01/0.01	0.21
0.9%	Kohlrabies / boiled	0.01/0.01	0.21
0.8%	Wine grapes / juice	0.01/0.01	0.21
0.8%	Escaroles/broad-leaved	0.01/0.01	0.20
0.8%	Florence fennels / boiled	0.01/0.01	0.19
0.8%	Turnips / boiled	0.01/0.01	0.19

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

- PRIMo_EU_(Sc.2B)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Diazinon (F)

LOQs (mg/kg) range from:	0.001	to:	0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.0002	ARfD (mg/kg bw):	0.025
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2006	Year of evaluation:	2006

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

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

Comments: **Scenario 2B: identification of safe LOQs for the consumers (considering the lowest LOQs achievable according to the EURLs)**

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
103%	NL toddler	0.21	18%	Maize/corn	15%	Milk: Cattle	11%	Apples	103%	
59%	NL child	0.12	10%	Wheat	8%	Sugar beet roots	6%	Milk: Cattle	59%	
59%	DE child	0.12	12%	Apples	11%	Wheat	5%	Milk: Cattle	59%	
56%	GEMS/Food G06	0.11	18%	Wheat	4%	Rice	4%	Tomatoes	56%	
51%	GEMS/Food G11	0.10	9%	Soyabeans	9%	Wheat	4%	Potatoes	51%	
50%	GEMS/Food G10	0.10	10%	Wheat	8%	Soyabeans	3%	Rice	50%	
49%	GEMS/Food G08	0.10	10%	Wheat	5%	Soyabeans	4%	Potatoes	49%	
48%	FR child 3 15 yr	0.10	11%	Wheat	6%	Milk: Cattle	4%	Sugar beet roots	48%	
47%	GEMS/Food G07	0.09	11%	Wheat	4%	Soyabeans	4%	Potatoes	47%	
47%	GEMS/Food G15	0.09	11%	Wheat	4%	Soyabeans	4%	Potatoes	47%	
46%	DK child	0.09	14%	Rye	11%	Wheat	3%	Milk: Cattle	46%	
41%	FR toddler 2 3 yr	0.08	8%	Wheat	7%	Milk: Cattle	3%	Apples	41%	
39%	UK infant	0.08	10%	Milk: Cattle	7%	Wheat	3%	Potatoes	39%	
39%	RO general	0.08	13%	Wheat	4%	Potatoes	3%	Milk: Cattle	39%	
37%	ES child	0.07	11%	Wheat	3%	Milk: Cattle	3%	Cocoa beans	37%	
37%	FI adult	0.07	28%	Coffee beans	2%	Rye	1%	Potatoes	37%	
37%	UK toddler	0.07	10%	Wheat	5%	Milk: Cattle	3%	Potatoes	37%	
37%	IE adult	0.07	6%	Wheat	4%	Sweet potatoes	2%	Potatoes	37%	
34%	SE general	0.07	8%	Wheat	4%	Potatoes	4%	Bovine: Muscle/meat	34%	
33%	DE women 14-50 yr	0.07	5%	Wheat	5%	Sugar beet roots	3%	Milk: Cattle	33%	
33%	DE general	0.07	5%	Wheat	4%	Sugar beet roots	3%	Milk: Cattle	33%	
31%	PT general	0.06	10%	Wheat	5%	Potatoes	2%	Wine grapes	31%	
30%	NL general	0.06	5%	Wheat	3%	Sugar beet roots	2%	Potatoes	30%	
29%	IT toddler	0.06	17%	Wheat	4%	Other cereals	1%	Tomatoes	29%	
23%	FI 3 yr	0.05	5%	Potatoes	3%	Wheat	2%	Rye	23%	
23%	FR adult	0.05	6%	Wheat	2%	Wine grapes	2%	Coffee beans	23%	
23%	ES adult	0.05	6%	Wheat	1%	Oranges	1%	Milk: Cattle	23%	
20%	IT adult	0.04	10%	Wheat	2%	Other cereals	1%	Tomatoes	20%	
19%	FI 6 yr	0.04	4%	Potatoes	2%	Wheat	2%	Rye	19%	
18%	FR infant	0.04	4%	Milk: Cattle	2%	Wheat	2%	Potatoes	18%	
17%	LT adult	0.03	3%	Potatoes	3%	Rye	3%	Wheat	17%	
17%	UK vegetarian	0.03	5%	Wheat	1%	Potatoes	1.0%	Rice	17%	
15%	DK adult	0.03	3%	Wheat	1%	Milk: Cattle	1%	Rye	15%	
15%	UK adult	0.03	4%	Wheat	1%	Potatoes	1%	Wine grapes	15%	
10%	PL general	0.02	3%	Potatoes	2%	Apples	0.9%	Tomatoes	10%	
8%	IE child	0.02	3%	Wheat	0.9%	Milk: Cattle	0.7%	Rice	8%	

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 103.4 % of the ADI.
For 1 diet(s) the ADI is exceeded.

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Potatoes	0/0	0.31
1%	Melons	0/0	0.30
1%	Pears	0/0	0.28
1%	Oranges	0/0	0.27
1%	Avocados	0.01/0.01	0.25
1.0%	Watermelons	0/0	0.24
0.9%	Apples	0/0	0.22
0.8%	Pineapples	0/0	0.20
0.8%	Bananas	0/0	0.19
0.8%	Peaches	0/0	0.19
0.7%	Honey and other apiculture products	0.05/0.05	0.18
0.6%	Mangoes	0/0	0.16
0.6%	Grapefruits	0/0	0.16
0.6%	Table grapes	0/0	0.15
0.5%	Cucumbers	0/0	0.13

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Head cabbages	0/0	0.08
0.3%	Watermelons	0/0	0.08
0.3%	Melons	0 / 0	0.08
0.3%	Avocados	0.01/0.01	0.08
0.3%	Honey and other apiculture	0.05/0.05	0.07
0.3%	Swedes/rutabagas	0/0	0.07
0.3%	Table grapes	0/0	0.07
0.2%	Oranges	0/0	0.06
0.2%	Pears	0/0	0.06
0.2%	Potatoes	0/0	0.06
0.2%	Pineapples	0/0	0.06
0.2%	Yams	0/0	0.06
0.2%	Apples	0/0	0.06
0.2%	Cucumbers	0/0	0.06
0.2%	Aubergines/egg plants	0/0	0.05

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.9%	Sugar beets (root)/sugar	0/0.02	0.22
0.7%	Potatoes/fried	0/0	0.19
0.7%	Pumpkins/boiled	0/0	0.18
0.7%	Witloofs/boiled	0/0	0.18
0.6%	Broccoli/boiled	0/0	0.16
0.6%	Cauliflowers/boiled	0/0	0.14
0.5%	Escaroles/broad-leaved endives/boiled	0/0	0.13
0.5%	Potatoes/dried (flakes)	0/0.01	0.12
0.5%	Maize/oil	0.01/0.13	0.12
0.5%	Leeks/boiled	0/0	0.11
0.4%	Apples/juice	0/0	0.11
0.4%	Oranges/juice	0/0	0.11
0.4%	Turnips/boiled	0/0	0.10
0.4%	Parsnips/boiled	0/0	0.10
0.4%	Sweet potatoes/boiled	0/0	0.10

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Pumpkins/boiled	0 / 0	0.11
0.4%	Sugar beets (root)/sugar	0 / 0.02	0.09
0.3%	Cauliflowers/boiled	0 / 0	0.08
0.3%	Beetroots/boiled	0 / 0	0.08
0.3%	Celeries/boiled	0 / 0	0.07
0.3%	Apples/juice	0 / 0	0.07
0.3%	Maize/oil	0.01 / 0.13	0.06
0.2%	Broccoli/boiled	0 / 0	0.05
0.2%	Coffee beans/extraction	0.01 / 0	0.05
0.2%	Courgettes/boiled	0 / 0	0.05
0.2%	Parsnips/boiled	0 / 0	0.04
0.2%	Kohlrabies/boiled	0 / 0	0.04
0.2%	Wine grapes/juice	0 / 0	0.04
0.2%	Escaroles/broad-leaved	0 / 0	0.04
0.2%	Florence fennels/boiled	0 / 0	0.04

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

- PRIMo_JMPR_(Sc.1A)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Diazinon (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw per day):	0.003	ARfD (mg/kg bw):	0.03
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2016	Year of evaluation:	2016

Input values | Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments: **Scenario 1A**

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
43%	NL toddler	1.28	40%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.6%	Swine: Fat tissue		43%
27%	UK infant	0.82	26%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.5%	Bovine: Fat tissue		27%
22%	FR toddler 2 3 yr	0.67	20%	Milk: Cattle	0.9%	Swine: Fat tissue	0.8%	Bovine: Muscle/meat		22%
20%	NL child	0.59	16%	Milk: Cattle	1%	Swine: Fat tissue	1%	Bovine: Fat tissue		20%
20%	FR child 3 15 yr	0.59	15%	Milk: Cattle	2%	Swine: Fat tissue	1.0%	Bovine: Muscle/meat		20%
17%	UK toddler	0.52	14%	Milk: Cattle	3%	Bovine: Fat tissue	0.9%	Bovine: Muscle/meat		17%
14%	DE child	0.41	13%	Milk: Cattle	0.4%	Swine: Muscle/meat	0.2%	Bovine: Muscle/meat		14%
14%	GEMS/Food G11	0.41	5%	Swine: Fat tissue	5%	Milk: Cattle	2%	Bovine: Fat tissue		14%
14%	GEMS/Food G15	0.41	6%	Swine: Fat tissue	5%	Milk: Cattle	0.9%	Bovine: Fat tissue		14%
12%	ES child	0.37	8%	Milk: Cattle	2%	Swine: Fat tissue	0.9%	Bovine: Muscle/meat		12%
12%	FR infant	0.36	11%	Milk: Cattle	0.4%	Swine: Fat tissue	0.2%	Swine: Muscle/meat		12%
12%	DE general	0.35	8%	Milk: Cattle	2%	Swine: Fat tissue	0.7%	Swine: Muscle/meat		12%
11%	GEMS/Food G08	0.34	5%	Swine: Fat tissue	4%	Milk: Cattle	1%	Swine: Muscle/meat		11%
11%	DE women 14-50 yr	0.34	8%	Milk: Cattle	2%	Swine: Fat tissue	0.6%	Swine: Muscle/meat		11%
11%	SE general	0.34	8%	Milk: Cattle	3%	Bovine: Muscle/meat				11%
11%	DK child	0.33	8%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	Bovine: Muscle/meat		11%
11%	DK adult	0.32	5%	Swine: Fat tissue	4%	Milk: Cattle	2%	Bovine: Fat tissue		11%
9%	RO general	0.27	8%	Milk: Cattle	0.8%	Swine: Muscle/meat	0.4%	Swine: Fat tissue		9%
9%	GEMS/Food G07	0.26	4%	Milk: Cattle	2%	Swine: Fat tissue	0.9%	Bovine: Fat tissue		9%
8%	GEMS/Food G10	0.25	4%	Milk: Cattle	2%	Bovine: Fat tissue	2%	Swine: Fat tissue		8%
8%	NL general	0.23	6%	Milk: Cattle	0.6%	Swine: Muscle/meat	0.5%	Swine: Fat tissue		8%
7%	LT adult	0.20	3%	Swine: Fat tissue	3%	Milk: Cattle	0.6%	Swine: Muscle/meat		7%
6%	IE child	0.18	3%	Swine: Fat tissue	2%	Milk: Cattle	0.2%	Sheep: Fat tissue		6%
6%	ES adult	0.17	3%	Milk: Cattle	1%	Swine: Fat tissue	0.5%	Bovine: Muscle/meat		6%
5%	FR adult	0.14	3%	Milk: Cattle	0.8%	Swine: Fat tissue	0.4%	Swine: Muscle/meat		5%
4%	IE adult	0.12	3%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.3%	Swine: Muscle/meat		4%
3%	UK adult	0.09	2%	Milk: Cattle	0.7%	Bovine: Fat tissue	0.4%	Bovine: Muscle/meat		3%
3%	GEMS/Food G06	0.08	2%	Milk: Cattle	0.3%	Bovine: Fat tissue	0.2%	Bovine: Muscle/meat		3%
3%	UK vegetarian	0.08	2%	Milk: Cattle	0.5%	Bovine: Fat tissue	0.0%	Bovine: Muscle/meat		3%
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
	IT toddler			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:

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

The long-term intake of residues of Diazinon (F) is unlikely to present a public health concern.

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Milk: Cattle	0.02/0.02	2.5
5%	Bovine: Fat tissue	0.7/0.7	1.5
4%	Swine: Fat tissue	0.7/0.7	1.2
2%	Milk: Goat	0.02/0.02	0.48
0.8%	Swine: Muscle/meat	0.02/0.02	0.24
0.5%	Bovine: Liver	0.02/0.02	0.16
0.5%	Bovine: Muscle/meat	0.02/0.02	0.14
0.4%	Sheep: Muscle/meat	0.02/0.02	0.11
0.3%	Bovine: Kidney	0.02/0.02	0.08
0.2%	Milk: Sheep	0.02/0.02	0.07
0.08%	Swine: Kidney	0.02/0.02	0.03
0.08%	Swine: Liver	0.02/0.02	0.02

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Swine: Fat tissue	0.7/0.7	1.4
3%	Milk: Cattle	0.02/0.02	0.77
2%	Bovine: Fat tissue	0.7/0.7	0.68
1%	Milk: Goat	0.02/0.02	0.37
1%	Milk: Sheep	0.02/0.02	0.30
0.4%	Bovine: Muscle	0.02/0.02	0.11
0.3%	Swine: Muscle/meat	0.02/0.02	0.10
0.3%	Sheep: Muscle/meat	0.02/0.02	0.09
0.3%	Bovine: Liver	0.02/0.02	0.08
0.2%	Sheep: Liver	0.02/0.02	0.06
0.1%	Swine: Kidney	0.02/0.02	0.04
0.1%	Bovine: Kidney	0.02/0.02	0.04
0.1%	Goat: Muscle	0.02/0.02	0.03
0.09%	Swine: Liver	0.02/0.02	0.03
0.01%	Sheep: Kidney	0.02/0.02	0.00

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

- PRIMo_JMPR_(Sc.2A)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Diazinon (F)

LOQs (mg/kg) range from:	0.001	to:	0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.003	ARfD (mg/kg bw):	0.03
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2016	Year of evaluation:	2016

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

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

Comments: **Scenario 2A: screening of the default LOQs (except bovine milk: lowest LOQ achievable)**

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
22%	NL toddler	0.67	4%	Apples	2%	Maize/corn	2%	Bananas	22%	
15%	DE child	0.45	4%	Apples	1%	Wheat	1%	Oranges	14%	
14%	NL child	0.43	3%	Sugar beet roots	2%	Apples	1%	Wheat	13%	
12%	GEMS/Food G06	0.36	2%	Wheat	1%	Tomatoes	0.7%	Potatoes	12%	
12%	FI adult	0.35	9%	Coffee beans	0.4%	Potatoes	0.2%	Rye	12%	
11%	GEMS/Food G11	0.34	1%	Potatoes	1%	Soyabeans	1%	Wheat	10%	
11%	FR child 3 15 yr	0.33	2%	Wheat	1%	Sugar beet roots	1%	Oranges	10%	
11%	GEMS/Food G08	0.33	1%	Wheat	1%	Potatoes	0.7%	Soyabeans	10%	
11%	GEMS/Food G07	0.32	1%	Wheat	1%	Potatoes	0.6%	Soyabeans	10%	
11%	GEMS/Food G10	0.32	1%	Wheat	1%	Soyabeans	1.0%	Potatoes	9%	
10%	GEMS/Food G15	0.31	2%	Wheat	1%	Potatoes	0.6%	Soyabeans	9%	
10%	IE adult	0.29	1%	Sweet potatoes	0.8%	Wheat	0.8%	Potatoes	9%	
10%	DK child	0.29	2%	Rye	1%	Wheat	0.8%	Potatoes	8%	
9%	FR toddler 2 3 yr	0.28	1%	Apples	1%	Wheat	0.9%	Sugar beet roots	8%	
9%	RO general	0.27	2%	Wheat	1%	Potatoes	0.6%	Tomatoes	8%	
9%	ES child	0.26	1%	Wheat	0.9%	Cocoa beans	0.7%	Oranges	7%	
9%	SE general	0.26	1%	Bovine: Muscle/meat	1%	Potatoes	1%	Wheat	7%	
8%	DE women 14-50 yr	0.25	2%	Sugar beet roots	0.9%	Apples	0.8%	Coffee beans	8%	
8%	UK toddler	0.25	1%	Wheat	1%	Potatoes	1%	Sugar beet roots	8%	
8%	DE general	0.25	1%	Sugar beet roots	0.8%	Apples	0.8%	Coffee beans	8%	
8%	UK infant	0.24	1%	Potatoes	0.9%	Wheat	0.6%	Milk: Cattle	8%	
7%	NL general	0.22	1.0%	Sugar beet roots	0.8%	Potatoes	0.6%	Wheat	7%	
7%	PT general	0.21	2%	Potatoes	1%	Wheat	0.8%	Wine grapes	7%	
6%	FI 3 yr	0.18	2%	Potatoes	0.4%	Bananas	0.4%	Wheat	6%	
6%	FR adult	0.18	0.8%	Wine grapes	0.7%	Wheat	0.7%	Coffee beans	5%	
5%	IT toddler	0.16	2%	Wheat	0.5%	Other cereals	0.5%	Tomatoes	5%	
5%	ES adult	0.16	0.8%	Wheat	0.4%	Oranges	0.3%	Potatoes	5%	
5%	FI 6 yr	0.14	1%	Potatoes	0.4%	Cocoa beans	0.3%	Wheat	5%	
4%	FR infant	0.13	0.6%	Potatoes	0.6%	Apples	0.5%	Sugar beet roots	4%	
4%	LT adult	0.12	1%	Potatoes	0.6%	Apples	0.4%	Rye	4%	
4%	IT adult	0.12	1%	Wheat	0.4%	Tomatoes	0.3%	Apples	4%	
4%	UK vegetarian	0.12	0.7%	Wheat	0.5%	Potatoes	0.3%	Oranges	4%	
4%	DK adult	0.11	0.4%	Potatoes	0.4%	Wheat	0.3%	Apples	3%	
4%	UK adult	0.11	0.6%	Wheat	0.5%	Potatoes	0.4%	Wine grapes	3%	
3%	PL general	0.10	1%	Potatoes	0.7%	Apples	0.3%	Tomatoes	3%	
2%	IE child	0.05	0.4%	Wheat	0.2%	Potatoes	0.1%	Apples	1%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Diazinon (F) is unlikely to present a public health concern.

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Potatoes	0.01/0.01	1.5
5%	Melons	0.01/0.01	1.5
5%	Pears	0.01/0.01	1.4
4%	Oranges	0.01/0.01	1.3
4%	Watermelons	0.01/0.01	1.2
4%	Apples	0.01/0.01	1.1
3%	Pineapples	0.01/0.01	1.0
3%	Bananas	0.01/0.01	0.97
3%	Peaches	0.01/0.01	0.95
3%	Mangoes	0.01/0.01	0.79
3%	Grapefruits	0.01/0.01	0.79
2%	Table grapes	0.01/0.01	0.73
2%	Cucumbers	0.01/0.01	0.66
2%	Carrots	0.01/0.01	0.63
2%	Kiwi fruits (green, red, yellow)	0.01/0.01	0.62

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Head cabbages	0.01/0.01	0.42
1%	Watermelons	0.01/0.01	0.41
1%	Melons	0.01/0.01	0.39
1%	Swedes/rutabagas	0.01/0.01	0.34
1%	Table grapes	0.01/0.01	0.34
1%	Oranges	0.01/0.01	0.31
1%	Pears	0.01/0.01	0.31
1.0%	Potatoes	0.01/0.01	0.30
1.0%	Pineapples	0.01/0.01	0.30
0.9%	Yams	0.01/0.01	0.28
0.9%	Apples	0.01/0.01	0.28
0.9%	Cucumbers	0.01/0.01	0.28
0.9%	Aubergines/egg plants	0.01/0.01	0.27
0.9%	Mangoes	0.01/0.01	0.26
0.8%	Chinese cabbages/pe-tsai	0.01/0.01	0.25

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Sugar beets (root)/sugar	0.01/0.12	1.1
3%	Potatoes/fried	0.01/0.01	0.93
3%	Pumpkins/boiled	0.01/0.01	0.89
3%	Witloofs/boiled	0.01/0.01	0.89
3%	Broccoli/boiled	0.01/0.01	0.79
2%	Cauliflowers/boiled	0.01/0.01	0.70
2%	Escaroles/broad-leaved endives/boiled	0.01/0.01	0.66
2%	Potatoes/dried (flakes)	0.01/0.05	0.59
2%	Leeks/boiled	0.01/0.01	0.57
2%	Apples/juice	0.01/0.01	0.54
2%	Oranges/juice	0.01/0.01	0.53
2%	Turnips/boiled	0.01/0.01	0.51
2%	Parsnips/boiled	0.01/0.01	0.51
2%	Sweet potatoes/boiled	0.01/0.01	0.50
2%	Florence fennels/boiled	0.01/0.01	0.45

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Pumpkins/boiled	0.01/0.01	0.55
1%	Sugar beets (root)/sugar	0.01/0.12	0.44
1%	Cauliflowers/boiled	0.01/0.01	0.42
1%	Beetroots/boiled	0.01/0.01	0.39
1%	Celeries/boiled	0.01/0.01	0.34
1%	Apples/juice	0.01/0.01	0.33
0.8%	Broccoli/boiled	0.01/0.01	0.24
0.8%	Coffee beans/extraction	0.05/0.01	0.24
0.8%	Courgettes/boiled	0.01/0.01	0.23
0.7%	Parsnips/boiled	0.01/0.01	0.21
0.7%	Kohlrabies/boiled	0.01/0.01	0.21
0.7%	Wine grapes/juice	0.01/0.01	0.21
0.7%	Escaroles/broad-leaved	0.01/0.01	0.20
0.6%	Florence fennels/boiled	0.01/0.01	0.19
0.6%	Turnips/boiled	0.01/0.01	0.19

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

APPENDIX C

Input values for the exposure calculations

Commodity	Existing MRL (mg/kg)	Chronic risk assessment		Acute risk assessment	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Diazinon[F]					
Almonds	0.05	Scenario 2A: 0.01 Scenario 2B: 0.005	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.01 Scenario 2B: 0.005	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Cranberries	0.2	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Pineapples	0.2	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Radishes	0.1	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Onions	0.05	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Sweet peppers/bell peppers	0.05	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Sweet corn	0.02	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Chinese cabbages/pe-tsai	0.05	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Kohlrabies	0.2	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]

(Continues)

APPENDIX C (Continued)

Commodity	Existing MRL (mg/kg)	Chronic risk assessment		Acute risk assessment	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Hops	0.5	Scenario 2A: 0.05 Scenario 2B: 0.01	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.05 Scenario 2B: 0.01	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Seed spices	5	Scenario 2A: 0.05 Scenario 2B: 0.01	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.05 Scenario 2B: 0.01	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Root and rhizome spices	0.5	Scenario 2A: 0.05 Scenario 2B: 0.01	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.05 Scenario 2B: 0.01	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Sugar beet roots	0.1	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.01 Scenario 2B: 0.002	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Muscle from swine, bovine, sheep, goat	0.02	Scenario 1A and 1B: 0.02 Scenario 2A: 0.01 Scenario 2B: 0.001	Scenario 1A and 1B: MRL (Reg (EU) 37/2010) Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 1A and 1B: 0.02 Scenario 2A: 0.01 Scenario 2B: 0.001	Scenario 1A and 1B: MRL (Reg (EU) 37/2010) Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Fat from bovine, sheep, goat	0.7	Scenario 1A and 1B: 0.7 Scenario 2A: 0.01 Scenario 2B: 0.005	Scenario 1A and 1B: MRL (Reg (EU) 37/2010) Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 1A and 1B: 0.7 Scenario 2A: 0.01 Scenario 2B: 0.005	Scenario 1A and 1B: MRL (Reg (EU) 37/2010) Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Fat from swine	0.7	Scenario 1A: 0.7 Scenario 1B and 2A: 0.01 Scenario 2B: 0.005	Scenario 1A: MRL (Reg (EU) 37/2010) Scenario 1B and 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 1A: 0.7 Scenario 1B and 2A: 0.01 Scenario 2B: 0.005	Scenario 1A: MRL (Reg (EU) 37/2010) Scenario 1B and 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Liver and kidney from swine, bovine, sheep, goat	0.03	Scenario 1A and 1B: 0.02 Scenario 2A: 0.01 Scenario 2B: 0.001	Scenario 1A and 1B: MRL (Reg (EU) 37/2010) Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 1A and 1B: 0.02 Scenario 2A: 0.01 Scenario 2B: 0.001	Scenario 1A and 1B: MRL (Reg (EU) 37/2010) Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]

Commodity	Existing MRL (mg/kg)	Chronic risk assessment		Acute risk assessment	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Muscle and edible offals (other than liver and kidney) from poultry	0.02	Scenario 2A: 0.01 Scenario 2B: 0.001	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 2A: 0.01 Scenario 2B: 0.001	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Milk from sheep, goat, equine, other	0.02	Scenario 1A and 1B: 0.02 Scenario 2A: 0.01 Scenario 2B: 0.0005	Scenario 1A and 1B: MRL (Reg (EU) 37/2010) Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]	Scenario 1A and 1B: 0.02 Scenario 2A: 0.01 Scenario 2B: 0.0005	Scenario 1A and 1B: MRL (Reg (EU) 37/2010) Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]
Milk from bovine	0.02	Scenario 1A: 0.02 Scenario 1B, 2A and 2B: 0.0005	Scenario 1A: MRL (Reg (EU) 37/2010) Scenario 1B, 2A and 2B: Lowest EURLs LOQ[b]	Scenario 1A: 0.02 Scenario 1B, 2A and 2B: 0.0005	Scenario 1A: MRL (Reg (EU) 37/2010) Scenario 1B, 2A and 2B: Lowest EURLs LOQ[b]
Other crops/commodities	See Reg (EU) 834/2013	Scenario 2A: LOQ[a] Scenario 2B: Lowest EURLs LOQ[b]			

Abbreviations: LOQ, limit of quantification; MRL, maximum residue limit.

[F]The active substance is fat soluble.

[a]An LOQ 0.05 mg/kg was applied to tea, coffee beans, herbal infusions, cocoa beans, carobs, hops and spices. According to the available analytical methods for diazinon, an LOQ of 0.01 mg/kg was applied for all other commodities.

[b]Following EURLs report (EURLs, 2022), a lower achievable LOQ of 0.001 mg/kg was applied to muscle, liver and kidney (from swine, ruminant and poultry); of 0.002 mg/kg to high water and high acid content commodities, of 0.005 mg/kg to fat of swine and ruminant, high oil content and dry commodities, and of 0.0005 mg/kg to milk and eggs. An LOQ of 0.01 mg/kg was applied to other commodities.

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union