Approved: 30 September 2024

DOI: 10.2903/j.efsa.2024.9056

CONCLUSION ON PESTICIDES PEER REVIEW

efsa JOURNAL

Peer review of the pesticide risk assessment of the active substance elemental iron

European Food Safety Authority (EFSA) | Fernando Álvarez | Maria Arena | Domenica Auteri | Sofia Batista Leite | Marco Binaglia | Anna Federica Castoldi | Arianna Chiusolo | Angelo Colagiorgi | Mathilde Colas | Federica Crivellente | Chloe De Lentdecker | Isabella De Magistris | Mark Egsmose | Gabriella Fait | Franco Ferilli | German Giner Santonja | Varvara Gouliarmou | Katrin Halling | Laia Herrero Nogareda | Alessio Ippolito | Frederique Istace | Samira Jarrah | Dimitra Kardassi | Aude Kienzler | Anna Lanzoni | Roberto Lava | Renata Leuschner | Alberto Linguadoca | Jochem Louisse | Christopher Lythgo | Oriol Magrans | Iris Mangas | Andrea Mioč | Ileana Miron | Tunde Molnar | Laura Padovani | Vincenzo Padricello | Martina Panzarea | Juan Manuel Parra Morte | Simone Rizzuto | Anamarija Romac | Agnès Rortais | Miguel Santos | Rositsa Serafimova | Rachel Sharp | Csaba Szentes | Andrea Terron | Anne Theobald | Manuela Tiramani | Giorgia Vianello | Laura Villamar-Bouza

Correspondence:
pesticides.peerreview@efsa.europa.eu

Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State Austria for the pesticide active substance elemental iron and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative uses of elemental iron in field and greenhouses (permanent and non-permanent structures) via granule application by spreading on all edible and non-edible crops, ornamental plants and amenity grassland to control molluscs. The reliable endpoints, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed.

KEYWORDS

elemental iron, molluscicide, peer review, pesticide, risk assessment

CONTENTS

SUMMARY

Elemental iron was requested as a new active substance for which, in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council, the rapporteur Member State (RMS), Austria, received an application from ADAMA Agriculture B.V. on 28 June 2018 for approval. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 9 August 2018.

An initial evaluation of the dossier on elemental iron was provided by the RMS in the draft assessment report (DAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 12 of Regulation (EC) No 1107/2009. The following conclusions are derived.

The uses of elemental iron according to the representative uses in field and greenhouse (permanent and non-permanent structures) via granule application by spreading on all edible and non-edible crops, ornamental plants and amenity grassland to control molluscs, as proposed at EU level, results in a sufficient molluscicidal efficacy against the target pests.

The assessment of the data package revealed no issues that could not be finalised or that need to be included as critical areas of concern with respect to **identity, physical and chemical properties and analytical methods**.

In the area of **mammalian toxicology**, no issues that could not be finalised or that need to be included as critical areas of concern were identified.

In the **residues** section, considering the proposed Good Agricultural Practices (GAPs), significant iron residues in plant and animal commodities compared to the background levels of iron are not expected. With regard to the five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 (European Commission, 2015) for potential inclusion in Annex IV of Regulation (EC) No 396/2005, one criterion (IV) is considered to be met for iron.

Iron is considered a natural occurring component of both terrestrial and aquatic ecosystems and the data available on environmental **fate and behaviour** were sufficient to carry out the required environmental exposure assessments at EU level for the representative uses assessed.

No data gaps, critical areas of concern or issues that could not be finalised were identified in the area of **ecotoxicology**.

Based on the available information, it can be concluded that it is unlikely that elemental iron meets the criteria for endocrine disruption for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

BACKGROUND

Regulation (EC) No 1107/2009 of the European Parliament and of the Council[1] (hereinafter referred to as 'the Regulation') lays down, inter alia, the detailed rules as regards the procedure and conditions for approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant(s) for comments on the initial evaluation in the draft assessment report (DAR), provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 12 of the Regulation, EFSA is required to adopt a conclusion on whether an active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation (also taking into consideration recital (10) of the Regulation) within 120 days from the end of the period provided for the submission of written comments, subject to an extension of 30 days where an expert consultation is necessary, and a further extension of up to 150 days where additional information is required to be submitted by the applicant(s) in accordance with Article 12(3).

Elemental iron is a new active substance for which, in accordance with Article 7 of the Regulation, the RMS, Austria (hereinafter referred to as the 'RMS'), received an application from ADAMA Agriculture B.V. on 28 June 2018 for approval of the active substance elemental iron. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 9 August 2018.

The RMS provided its initial evaluation of the dossier on elemental iron in the DAR, which was received by EFSA on 2 July 2021 (Austria, 2021). The peer review was initiated on 18 November 2021 by dispatching the DAR to the Member States and the applicant, ADAMA Agriculture B.V., for consultation and comments. EFSA also provided comments. In addition, EFSA conducted a public consultation on the DAR. The comments received were collated by EFSA and forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 12(3) of the Regulation were considered in a teleconference between EFSA and the RMS on 9 September 2022. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology and ecotoxicology.

The outcome of the teleconference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an experts' consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether elemental iron can be expected to meet the approval criteria provided for in Article 4 of the Regulation, taking into consideration recital (10) of the Regulation.

A final consultation on the conclusions arising from the peer review of the risk assessment and on the proposal for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 took place with Member States via a written procedure in June – July 2024.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the formulation for representative uses evaluated on the basis of the representative uses of elemental iron in field and greenhouse (permanent and non-permanent structures) via granule application by spreading on all edible and non-edible crops, ornamental plants and amenity grassland to control molluscs, as proposed by the applicant. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the DAR and considered during the peer review, if any, are presented in the conclusion.

Furthermore, this conclusion also addresses the requirement for an assessment by EFSA under Article 12 of Regulation (EC) No 396/2005, provided that the active substance will be approved under Regulation (EC) No 1107/2009 without restrictions affecting the residue assessment. In the event of a non-approval of the active substance or an approval with restrictions that have an impact on the residue assessment, the Annex IV considerations from this conclusion might no longer be relevant and a new assessment under Article 12 of Regulation (EC) No 396/2005 will be required.

A list of the relevant end points for the active substance and the formulation is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for elemental iron according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2024), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

[1]Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

- the comments received on the DAR;
- the reporting table (09 September 2022);
- the evaluation table (27 September 2024);
- the report(s) of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR, including its revisions (Austria, 2024), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

THE ACTIVE SUBSTANCE AND THE FORMULATION(S) FOR REPRESENTATIVE USES

This substance was notified as elemental iron, its IUPAC name is iron. It should be noted that based on the data provided, the presence of other oxidation states of iron cannot be excluded (see Section 1). The formulation for representative uses evaluated was 'Final Bite®', a bait (ready to use) (RB) containing 10 g/kg of total iron.

The information on the active substance and the formulation for representative uses, including the co-formulants in these formulations, was considered in the overall assessment during the peer review. None of the co-formulants is an unacceptable co-formulant listed in Annex III of Regulation (EC) No 1107/2009,[2] however one co-formulant is an approved active substance, one co-formulant is a non-approved active substance and two co-formulants are approved basic substances under Regulation (EC) 1107/2009.[3] Details on the composition of the formulations cannot be reported in conclusions because of the provisions in Article 63(2)(d) of Regulation (EC) No 1107/2009, however this information was fully available and evaluated during the peer review. A proposal for classification of the formulation(s) according to Regulation (EC) 1272/2008 was provided by the applicant and assessed by the RMS (please see Volumes 3 CP of the RAR).

The representative uses evaluated were field and greenhouse (permanent and non-permanent structures) granule application by spreading on all edible and non-edible crops, ornamental plants and amenity grassland to control molluscs. Full details of the GAPs can be found in the list of end points in Appendix B.

Data were submitted to conclude that the use of elemental iron according to the representative uses proposed at EU level result in a sufficient molluscicide efficacy, following the guidance document SANCO/10054/2013-rev. 3 (European Commission, 2013).

CONCLUSIONS OF THE EVALUATION

General aspects

With regard to the mammalian toxicological information available for the formulation for representative uses 'Final Bite', studies were performed on acute (oral, dermal and inhalation) toxicity, skin and eye irritation and skin sensitisation. With regard to the co-formulants contained in 'Final Bite', sufficient toxicological data were available for all components. The experts considered that the available toxicological information did sufficiently address the genotoxicity and repeated dose toxicity of 'Final Bite' over short- and long-term and no concern was identified.[4]

The availability of ecotoxicity data with the formulation for representative uses was discussed at the experts' meeting.[5] Furthermore, the experts also discussed the data retrieval search and the available data for the individual components. Considering the reasoning agreed by the experts, no concerns were identified.

1 | IDENTITY, PHYSICAL/CHEMICAL/TECHNICAL PROPERTIES AND METHODS OF ANALYSIS

The following guidance documents were followed in the production of this conclusion: European Commission (2000a, 2000b).

[2]Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and Council listing co-formulants which are not accepted for inclusion in plant protection products. OJ L 74, 4.3.2021, p. 7–26.

[3]See Regulation (EC) No 1107/2009 for acceptability criteria for co-formulants and Section 2.13.6 of the Technical report on the outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods. EFSA Supporting Publication, EN-1623. 10.2903/sp.efsa.2019.EN-1623.

[4]See Expert's consultation point 2.7 at the Pesticide Peer Review Experts' TC 114 (September 2023) (EFSA, 2024).

[5]See Expert's consultation point 5.7 at the Pesticide Peer Review Experts' TC 114 – TC 117 (September 2023) (EFSA, 2024).

The proposed reference specification for elemental iron was based on batch data from industrial scale production. A minimum purity of 989 g of elemental iron/kg was proposed. EFSA considers that since a non-specific analytical method for elemental iron was used for the analysis of the technical material batches, the minimum purity of 989 g/kg corresponds to the total iron. A **data gap** was set for data on the content of elemental iron in at least five batches of the technical active substance measured using a specific analytical method for elemental iron (see Section 10). Arsenic, mercury and lead were considered as relevant impurities with maximum contents of 0.003 g/kg, 0.001 g/kg and 0.01 g/kg respectively (see Section 2). Additional relevant impurities can be present in the technical material however batch data on their content were not provided[6] (**data gap**, see Section 10). An assessment of the compliance of the material tested in (eco)toxicological with the specifications was not required (see Section 2 and 5). A FAO specification does not exist for elemental iron.

The main data regarding the identity of elemental iron and its physical and chemical properties are given in Appendix B. A non-specific analytical method was used in the formulation storage stability studies, thus a **data gap** was set for the content of the elemental iron in the formulation before and after accelerated storage conditions and before and after 2 years storage at ambient temperature (see Section 10). Sufficient information on the identity of a co-formulant in the formulation was not provided (see Section 10).

Adequate methods are available for the generation of data required for the risk assessment. Specific methods of analysis were not available for the determination of elemental iron in the technical material and in the formulation (**data gap**, see Section 10). Methods of analysis are available for the determination of the relevant impurities (arsenic, mercury and lead) in the technical material and in the representative formulation. Analytical methods for the determination of residues in plant materials, foodstuff of animal origin, environmental matrixes, body fluids and body tissues are not required due to the fact that residue definitions for monitoring are not proposed.

2 | MAMMALIAN TOXICITY

The toxicological profile of the active substance elemental iron was discussed at the Pesticide Peer Review Experts' Meeting TC 114 in September 2023. The assessment is based on the following guidance documents: EFSA (2014a, 2022).

Regarding the proposed **reference specification** (RS), toxicological relevant impurities i.e. arsenic, lead and mercury were identified (see Section 1), with maximum levels at 0.003 g/kg (0.03 w/w%), 0.01 g/kg (0.1 w/w%) and 0.001 g/kg (0.01 w/w%), respectively. EFSA notes that for inorganic arsenic and lead, according to EFSA CONTAM Panel (EFSA CONTAM Panel, 2010, 2024, respectively) there are no recommended tolerable intake levels. For inorganic arsenic, EFSA derived a $BMDL_{05}$[7] of 0.06 μg/kg bw per day based on increased incidence of skin cancer. For lead, EFSA derived a $BMDL_{01}$[8] of 0.5 μg/kg bw per day for neurodevelopmental effects in children (close to the $BMDL_{10}$[9] for nephrotoxic effects in adults). In both cases EFSA CONTAM Panel recommended a margin of exposure (MOE) approach.[10] For mercury, the lowest health-based guidance value (HBGV) derived by EFSA CONTAM Panel (2012) is the tolerable weekly intake (TWI) of 1.3 μg/kg bw (corresponding to 0.19 μg/kg bw per day), based on neurodevelopmental effects of methylmercury. Based on the proposed reference specifications and the representative uses of the active substance, the non-dietary exposure estimates to arsenic, lead and mercury do not exceed the BMDLs or TWI (minimum MOE = 50, for arsenic for operators when workwear is used[11]). Pending on the data gap set in Section 1 regarding the content of additional relevant impurities in at least five batches of the technical material, further assessment of the toxicological relevance may be needed.

Reliable toxicity data with the active substance are limited to acute inhalation toxicity study, and therefore an assessment of the compliance of the material tested with the specifications was not required (see Section 1).

Because of the limited data package, the risk assessment mainly relied on publicly available scientific literature, epidemiological studies in humans (use of iron as food supplement in humans) and on data from related iron compounds (ferric phosphate, ferric pyrophosphate and ferrous sulfate). Previous EFSA evaluations of ferrous, ferric and phosphate salts used as food additives and nutrient sources and as plant protection products did not identify any toxicological concern (e.g. EFSA ANS Panel, 2009, 2010; EFSA NDA Panel, 2015, 2024[12]; EFSA, 2012, 2014a, 2014b, 2015, 2020). Therefore, although data were not available to assess the toxicological profile of elemental iron, this did not appear to be scientifically necessary considering the lack of concerns in the available publications (from literature and previous EFSA evaluations) and that iron is an essential nutrient. Thus, it is not expected that the additional exposure to elemental iron deriving from its use as a plant protection product will increase the risk to human health from its intake as a food supplement and/or food additive.

[6]See confidential evaluation table, data requirement 0.2.

[7]Dose where the change in response is likely to be smaller than 5%.

[8]Dose where the change in response is likely to be smaller than 1%.

[9]Dose where the change in response is likely to be smaller than 10%.

[10]Arsenic: 'An MOE of 1 would correspond to an exposure level that is associated with a 5% increase relative to the background incidence for skin cancer, based on the available data' (EFSA CONTAM Panel, 2024).

[11]See Appendix B, Section 'Impact on human and animal health' under 'Other toxicological studies (Regulation (EU) No 283/2013, Annex Part A, point 5.8)' for details.

[12]A safe level of supplemental iron intake of 40 mg iron/day has been established for adults. This value differs from the one used for the semi-quantitative risk assessment conducted by the RMS and agreed as part of the peer review process (TC 114 in September 2023). However, it is considered that there is no impact in the overall evaluation for the substance under assessment.

Nevertheless, a semi-quantitative exposure assessment was proposed by the RMS and accepted by the peer review.[13] For long-term consumer risk assessment 0.8 mg/kg body weight (bw) per day was proposed as reference value, based on the permitted tolerable daily intake (PMTDI) set by JEFCA[14] (FAO/WHO, 1983). On the same basis, for non-dietary risk assessment the proposed reference value was 0.4 mg/kg bw per day considering a correction factor of 50% for oral bioavailability. No reference points for acute dietary and non-dietary risk assessment were deemed necessary. In April 2024, the EFSA NDA Panel (EFSA NDA Panel, 2024) established new safe levels for iron intake in the range of 5 to 40 mg iron/day for the different age groups. Considering mean body weights for the various age groups, these values correspond to 0.6–0.8 mg/kg bw per day and 0.3–0.4 mg/kg bw per day for dietary and non-dietary risk assessment, respectively. Therefore, the lower bound of the ranges was used as reference value for dietary and non-dietary risk assessment, i.e. 0.6 mg/kg bw per day and 0.3 mg/kg bw per day, respectively.

In line with previous EFSA conclusions (EFSA, 2012, 2015, 2020), a default **dermal absorption** value of 10% was used as a worst-case scenario.

The **non-dietary exposure** estimates for the operators are below the reference value with the use of standard workwear during mixing/loading and application, based on the EFSA calculators (2014, 2022), only in case of tractor-mounted applications (see Section 8). For the workers, exposure estimates are below the reference value even without workwear during the indoor activities (searching, reaching, picking) according to the EFSA calculator (2022). For residents (covering also bystanders in the absence of AAOEL), risk mitigation measures are not needed.

3 | RESIDUES

For residues no studies were submitted and the open literature data was provided regarding the role of iron in plants and its background levels. However, a proper and detailed literature search according to the EFSA guidance on submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011) was not provided (data gap).

The five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 (European Commission, 2015) for potential inclusion in Annex IV of Regulation (EC) No 396/2005, i.e. approval as basic substance (criterion I), listed in Annex I of Regulation (EC) No 396/2005 (criterion II), having no identified hazardous properties (criterion III), natural exposure is higher than the one linked to the use as plant protection product (criterion IV) and consumer exposure is not expected considering the representative uses (criterion V) were assessed. Four criteria (I, II, III and V) are not met as the substance is not approved as a basic substance, not listed in Annex I of Regulation (EC) 396/2005, and reference values were established as reported in the tox section (see Section 2). For criterion V, the possibility of increased exposure to iron residues due to the application method cannot be excluded. Apart from the potential soil uptake of iron released after the use, granule baits spread on the soil surface may directly come into the contact with plants.

The criterion IV was considered to be met for the following reasons:

- For the natural exposure in relation to the one linked to the representative use (criterion IV), background iron levels were compared with the potentially occurring ones after the use. The main route of plant exposure to elemental iron is via soil. Predicted accumulating concentrations of iron present in the soil even after several years of the use as a pesticide are only 0.038% of the median (FOREGS, 2005) of the background concentration present in soil (see Section 4). Therefore, the driver of iron plant uptake is not expected to be the representative use as the use relevant concentrations are substantially lower compared with the background concentrations to which plants are already exposed. It should also be noted that the elemental iron has to become bioavailable (formed as an ion) before it is taken up by plants. The applied amount of iron as a pesticide is unlikely to be fully available for plant uptake as the elemental iron undergoes reactions to form more complex compounds that are less readily absorbed by plants.
  In addition to soil uptake, plants may come into direct contact with bait granules containing iron. A potential concentration arising from this scenario was calculated for lettuce as a crop which is the one most likely having granules lodged in its leaves at a later BBCH growth stage. The calculated amount in case several granules adhere to lettuce leaves corresponded to 13.8% of the naturally present iron content in lettuce (0.64 mg/100 g). Being water insoluble, granules will most probably remain for several days on a crop and manual removal or washing them off is expected, resulting in incomplete absorption by plants. It is therefore considered the conditions of the use would not significantly increase the background levels of iron in food and feed items. Consequently, animal food commodities are also not expected to contain increased iron levels resulting from the representative use.
  The representative use of elemental iron on all edible and non-edible crops and amenity vegetation applied as granule baits on the soil surface is unlikely to lead to significant increase of iron concentrations in food when compared to the background iron levels.

Based on calculations estimating iron concentrations in lettuce (0.88 mg/kg lettuce) and the ratio of iron to arsenic, mercury and lead in the technical material (see Section 1), potential concentrations of these impurities when some granules

[13]See Expert's consultation point 2.5 at the Pesticide Peer Review Experts' TC 114 (September 2023) (EFSA, 2024).

[14]https://apps.who.int/food-additives-contaminants-jecfa-database/Home/Chemical/2859.

are lodged among the lettuce leaves were estimated as well. These estimates were then extrapolated to all crops where such bait lodging could be expected (e.g. leafy, head brassica, spinach & similar) and were used for chronic dietary exposure calculations with PRIMo 3.1 for the respective crops. With this screening approach, a MoE of approx. 10,000 for arsenic (BMDL05 of 0.06 µg/kg bw per day), an MoE of approx. 20,000 for lead (BMDL01 of 0.5 µg/kg bw per day) and exposure to mercury corresponding to approx. 0.001% of the TWI (1.3 µg/kg bw) was estimated.

A risk to consumers from the representative uses with regard to the impurities arsenic, mercury and lead in the technical material elemental iron is considered unlikely.

4 | ENVIRONMENTAL FATE AND BEHAVIOUR

Iron, in its elemental state (Fe^0) or when available as ions (Fe^{2+} or Fe^{3+}), is the fourth most abundant element and the second most common metal observed in the Earth's crust. Elemental iron is rarely found in nature, while its ions are considered natural occurring components of both terrestrial and aquatic ecosystems. Based on a comprehensive European geological mapping project (FOREGS, 2005), the median levels of total iron in European topsoil, stream sediments and floodplain sediments are 35,100 mg/kg, 35,700 mg/kg and 33,300 mg/kg (measured with X-ray fluorescence spectrometry) respectively, while the median dissolved iron levels in European stream waters is 67 µg/L (measured with ICP-MS).

Elemental iron applied to a field has the potential to form rust i.e. react with oxygen in the presence of water to form Fe^{3+}. Once oxidised, the active substance is not distinguishable from the naturally occurring iron compounds already present in the soil in high amounts (FOREGS, 2005). The oxidised form of iron (Fe^{3+}) is the most thermodynamically stable and abundant in the environment, while the reduced form (Fe^{2+}) is very readily oxidised back to Fe^{3+} in the environment and is generally used by plants as a micronutrient. In the soil, Fe^{3+} and Fe^{2+} ions readily combine with other compounds, mainly oxygen-containing compounds, to produce several products that are the common constituents of soils/minerals/ores. Data concerning route and rate of degradation are not applicable since elemental iron and its ions cannot be mineralised or form metabolites/degradation products. Since elemental iron and its ions are elemental atomic particles, they are stable and have the potential to accumulate in soil after field application for molluscicide use. Nevertheless, the addition of iron according to the GAP is several orders of magnitude lower than the natural abundance of total iron occurring in European topsoil and is lower than the addition of iron after treatment with iron-containing fertiliser in agriculture soils.

The elemental iron is insoluble in water and not accessible to transport in soil or aqueous media. Elemental iron has eventually the potential to rust and be oxidised to insoluble ferric (Fe^{3+}) oxides and hydroxides, or in anoxic conditions to produce ferrous (Fe^{2+}) compounds which are the major constituents of dissolved iron in the aquatic systems. Once oxidised, the active substance is not distinguishable from the naturally occurring iron compounds that are present in surface waters and sediments at high amounts (FOREGS, 2005). The application of the active substance as granular bait and its water insolubility indicated that run-off of soil particles containing elemental iron was the sole possible entry route in surface water, particularly after heavy meteorological events. A **surface water** exposure assessment (predicted environmental concentrations (PEC) calculations) was not carried out since elemental iron is insoluble in water. A **sediment** exposure assessment was carried out using the FOCUS (FOCUS, 2001) Step 1 approach (version 3.2 of the Step 1–2 in FOCUS calculator) assuming the total mass of iron entering the water body via run-off (10% of iron applied) and the complete transfer into the sediment. Potential accumulation of iron in the sediment was considered estimating a 20-year period of use. This still resulted in concentrations several orders of magnitude below the background levels of total iron.

A **groundwater** exposure assessment was not carried out since elemental iron is insoluble in water and iron input from the pesticide use is not considered to significantly contribute to background levels of elemental iron and its ions in soil and groundwater. It should be noted that the indicative parameter for iron in the applicable Drinking Water Directives[15,16] is set at 200 µg/L.

The applicant provided appropriate information to address the potential effect of water treatments processes on the nature of the residues that might be present in surface water and groundwater, when abstracted for drinking water, including expected residues from iron used in wastewater and drinking water treatment processes, e.g. as precipitation or coagulation agent. The conclusion of this consideration was that potentially relevant by-products, apart from soluble or insoluble Fe^{3+} or Fe^{2+} species, which may affect the assessment on human health, animal health and/or the environment, will not be formed.

The PEC in soil and sediment covering the representative uses assessed can be found in Appendix B of this conclusion. These values are of academic interest, but also demonstrate that iron input from pesticide use hardly affects the background concentration of iron in soil and sediment.

[15]Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1988, pp. 32–54.

[16]Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption. OJ L 435, 23.12.2020, pp. 1–62.

5 | ECOTOXICOLOGY

The risk assessment was based on the following documents: European Commission (2002), SETAC (2001) and EFSA (2009). Additionally, aspects of the ecotoxicology assessment were discussed at the Pesticides Peer Review Teleconference (TC) 114–117 (September 2023).

In the area of ecotoxicology fully valid studies with the active ingredient were not available. Therefore, an assessment of the compliance of the material tested with the specifications was not required.

The hazard and risk assessment for **birds** and wild **mammals** was discussed at the meeting.[17] For birds, a valid acute study with a formulation different than the one for representative uses was available. For mammals, an acute study with the formulation for representative uses was submitted. Furthermore, open literature studies were submitted which were considered supplementary information for the dietary consumption of elemental iron by birds and mammals. Overall, low acute and reproductive risk for birds and mammals was concluded considering the lines of evidence listed under Section 6.

For **aquatic organisms**, valid acute studies with the formulation for representative uses on invertebrates and algae were available. Considering the physical chemical properties of elemental iron and the available information (see Section 4), low risk to aquatic and sediment organisms from exposure to the active substance was concluded, considering that the representative uses are expected to cause a low increase in environmental concentrations relative to the background levels.

No toxicity study on bees was submitted. However, low exposure, hence risks, for **bees** relative to the background levels can be expected from the representative uses of elemental iron, considering the representative uses.

Based on the representative uses of elemental iron, studies on the **non-target arthropod (NTAs)** indicator species were not required. Low risk to NTAs other than bees was concluded for all representative uses based on the endpoints for the additional species *Aleochara bilineata*, *Poecilus curpeus* and *Pardosa* spp.

The toxicity to **soil macroorganisms** was investigated in two laboratory studies with earthworms, where exposure to the formulation for representative uses occurred via soil incorporation or surface application. Additionally, a higher-tier, open-field effect study with the formulation for representative uses was available. Two additional species (i.e. *Folsomia candida* and *Hypoaspis aculeifer*) were tested in chronic laboratory studies with the formulation for representative uses. The hazard and risk assessment for soil organisms was discussed at the meeting.[18] For elemental iron, low risk for earthworms and soil macroorganisms was concluded, considering that its increase in soil concentrations caused by the representative uses is expected to be low (see Section 4). For the formulation for representative uses, high risk to earthworms, but not *F. candida* and *H. aculeifer* was initially indicated by the Tier-1 calculations. However, low risk to the formulation was finally concluded for all macroorganisms based on the results of the higher tier effect study.

Low risk to elemental iron was concluded for **soil microorganisms** based on the results of a laboratory study conducted with a different formulation than the one for representative uses. The use of this test for the risk assessment of the formulation for representative uses was discussed at the meeting,[19] where no concern was raised based on the assessment of the ecotoxicity profile of its individual components.

Based on the available data and the representative uses a low risk was concluded for **non-target terrestrial plants**.

No concern was raised for organisms involved in the **biological methods for sewage treatment**, considering that no increase of the elemental iron concentration in exceedance of the background levels is expected due to the representative uses.

6 | ENDOCRINE DISRUPTION PROPERTIES

The potential endocrine disruption properties of elemental iron were discussed at the Pesticides Peer Review Experts' Teleconference (TC) 114 (September 2023).[20]

With regard to the assessment of the endocrine disruption potential of elemental iron for **humans and non-target organisms** according to the ECHA/EFSA ED guidance (ECHA/EFSA, 2018), although no (eco)toxicological data are available to assess the endocrine disrupting properties of the active substance, this does not appear scientifically necessary due to the following reasons:

- Iron is an essential trace element, which serves as essential nutrient in animal and plant physiology, and it is naturally occurring ubiquitously in the environment.
- For all animal species, the FEEDAP Panel endorsed an opinion related to the safety and efficacy of iron compounds (E1) as feed additives (EFSA FEEDAP Panel, 2016 [updated 2018]).

[17] See Expert's consultation points 5.1 to 5.4 at the Pesticide Peer Review Experts' TC 114–117 (September 2023) (EFSA, 2024).

[18] See Expert's consultation point 5.5 at the Pesticide Peer Review Experts' TC 114–117 (September 2023) (EFSA, 2024).

[19] See Expert's consultation point 5.7 at the Pesticide Peer Review Experts' TC 114–117 (September 2023) (EFSA, 2024).

[20] See reports of the Pesticides Peer-review TC 114 for mammalian toxicology section and 114–117 for the ecotoxicology section (EFSA, 2024).

- Iron is authorised in Europe as human food additive and as food supplement (in case of iron deficiency) and in 2015, a scientific opinion was issued by EFSA on the dietary reference values for iron (EFSA ANS Panel, 2015; EFSA NDA Panel, 2015; Commission Regulation (EC) 1170/2009[21]).
- There is no indication or evidence of ED properties of elemental iron, or its ions found in the available toxicological studies nor in the studies from open literature including the Toxcast data.
- Low toxicity is observed in the available publications (from literature and previous EFSA evaluations) (see Section 2 for further information). Known toxicity of iron is related to accidental overdose or prolonged overdose due to genetically defined diseases (e.g. hemochromatosis, Pelusi et al., 2016) (this argument is only relevant for human health).
- It is not expected that the additional exposure to iron deriving from use of elemental iron as a plant protection product will increase the risk to human health from its intake as a food supplement and/or food additive (this argument is only relevant for human health).
- Elemental iron is insoluble in water (this argument is only relevant for environment).
- The iron input from pesticide uses is not considered to significantly contribute to the background levels of total iron in soil/sediment or groundwater/surface water (see Section 4 for further information).

Based on the available information, it can be concluded that it is unlikely that elemental iron meets the criteria for endocrine disruption for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

7 | OVERVIEW OF THE RISK ASSESSMENT OF COMPOUNDS LISTED IN RESIDUE DEFINITIONS TRIGGERING ASSESSMENT OF EFFECTS DATA FOR THE ENVIRONMENTAL COMPARTMENTS (TABLES 1–4)

TABLE 1 Soil.

Compound (name and/or code)	Ecotoxicology
Elemental iron	Low risk to soil organisms

TABLE 2 Groundwater.[a]

Compound (name and/or code)	>0.1 µg/L at 1 m depth for the representative uses[b] Step 2	Biological (pesticidal) activity/ relevance Step 3a.	Hazard identified Steps 3b. and 3c.	Consumer RA triggered Steps 4 and 5	Human health relevance
Elemental iron	No	Yes	–	–	Yes

[a]Assessment according to European Commission guidance of the relevance of groundwater metabolites (European Commission, 2003).

[b]Elemental iron is an inorganic molluscicide. The parametric drinking water limit of 0.1 µg/L for pesticides and their relevant metabolites, as defined by the drinking water directives 98/83/EEC[22] and 2020/2184[23] is not applicable. However, both the drinking water directives set a value of **200 µg/L as an indicator parameter for iron**.

TABLE 3 Surface water and sediment.

Compound (name and/or code)	Ecotoxicology
Elemental iron	Low risk to aquatic organisms

TABLE 4 Air.

Compound (name and/or code)	Toxicology
None	–

[21]Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements (Text with EEA relevance) OJ L 314, 1.12.2009, p. 36–42.

[22]Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1988, p. 32–54.

[23]Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption. OJ L 435, 23.12.2020, pp. 1–62.

8 | PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT BY RISK MANAGERS

Risk mitigation measures (RMMs) identified following consideration of Member State (MS) and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level.

Use of gloves during mixing/loading and application (ML&A) for manual application is required.

9 | CONCERNS AND RELATED DATA GAPS

9.1 | Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[24] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related:

Issues or assessments that could not be finalised were not identified.

9.2 | Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:

Critical areas of concern were not identified.

9.3 | Overview of the concerns identified for each representative use considered (Table 5)

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5).

[24]Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

TABLE 5 Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios.

Representative use		All edible and non-edible crops F/G	Amenity vegetation F/G
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Resident/bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised		
Risk to wild non-target terrestrial vertebrates	Risk identified		
	Assessment not finalised		
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified		
	Assessment not finalised		
Risk to aquatic organisms	Risk identified		
	Assessment not finalised		
Groundwater exposure to active substance	Legal parametric value breached		
	Assessment not finalised		

Notes: The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2 to 7 for further information.

10 | LIST OF OTHER OUTSTANDING ISSUES

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.

These data gaps refer only to the representative uses assessed and are listed in the order of the sections:

- Data on the content of elemental iron in at least five batches of the technical active substance measured using a specific analytical method for elemental iron were not provided (relevant for all representative uses evaluated; see Section 1).
- Data on the content of additional relevant impurities in at least five batches of the technical material were not provided (relevant for all representative uses evaluated; see Section 1).
- Data on the content of the elemental iron in the formulation before and after accelerated storage conditions and before and after 2 years storage at ambient temperature were not provided (relevant for all representative uses evaluated; see Section 1).
- Validated and specific analytical methods for the determination of elemental iron in the technical active substance and the formulation for the representative uses were not provided (relevant for all representative uses evaluated; see Section 1).
- Information on the identity of a formulant according to the EU Regulation 284/2013 was not available (relevant for all representative uses evaluated; see Section 1).
- Literature search according to the EFSA guidance on submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011) (Section 3).

ABBREVIATIONS

AAOEL	acute acceptable operator exposure level
AF	assessment factor
AOEL	acceptable operator exposure level
a.s.	active substance
BMDL	Benchmark Dose lower confidence bound
bw	body weight
DAR	draft assessment report
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)

FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
K_{Foc}	Freundlich organic carbon adsorption coefficient
LOD	limit of detection
LOQ	limit of quantification
M/L	mixing and loading
MOA	mode of action
MRL	maximum residue level
PEC	predicted environmental concentration
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
SC	suspension concentrate
TMDI	theoretical maximum daily intake
TWA	time-weighted average
UF	uncertainty factor
WHO	World Health Organization

ACKNOWLEDGEMENTS

EFSA wishes to thank the rapporteur Member State Austria for the preparatory work on this scientific output.

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-2018-00624

COPYRIGHT FOR NON-EFSA CONTENT

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

REFERENCES

Austria. (2021). Draft Assessment Report (DAR) on the active substance elemental iron prepared by the rapporteur Member State Austria, in the framework of Regulation (EC) No 1107/2009, July 2021. www.efsa.europa.eu

Austria. (2024). Revised Draft Assessment Report (DAR) on elemental iron prepared by the rapporteur Member State Austria in the framework of Regulation (EC) No 1107/2009, February 2024. www.efsa.europa.eu

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), 5311. https://doi.org/10.2903/j.efsa.2018.5311

EFSA (European Food Safety Authority). (2009). Guidance on risk assessment for birds and mammals on request from EFSA. *EFSA Journal*, *7*(12), 1438. https://doi.org/10.2903/j.efsa.2009.1438

EFSA (European Food Safety Authority). (2011). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under regulation (EC) No 1107/2009. *EFSA Journal*, *9*(2), 2092. https://doi.org/10.2903/j.efsa.2011.2092

EFSA (European Food Safety Authority). (2012). Conclusion on the peer review of the pesticide risk assessment of the active substance iron sulfate. *EFSA Journal*, *10*(1), 2521. https://doi.org/10.2903/j.efsa.2012.2521

EFSA (European Food Safety Authority). (2014a). Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. *EFSA Journal*, *12*(10), 3874. https://doi.org/10.2903/j.efsa.2014.3874

EFSA (European Food Safety Authority). (2014b). Outcome of the consultation with member states, the applicant and EFSA on the pesticide risk assessment of confirmatory data submitted for the active substance iron sulfate. *EFSA Supporting Publication*, *11*(10), EN-667. https://doi.org/10.2903/sp.efsa.2014.EN-667

EFSA (European Food Safety Authority). (2015). Conclusion on the peer review of the pesticide risk assessment of the active substance ferric phosphate. *EFSA Journal*, *13*(1), 3973. https://doi.org/10.2903/j.efsa.2015.3973

EFSA (European Food Safety Authority). (2020). Conclusion on the peer review of the pesticide risk assessment of the active substance ferric pyrophosphate. *EFSA Journal*, *18*(1), 5986. https://doi.org/10.2903/j.efsa.2020.5986

EFSA (European Food Safety Authority), Charistou, A., Coja, T., Craig, P., Hamey, P., Martin, S., Sanvido, O., Chiusolo, A., Colas, M., & Istace, F. (2022). Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. *EFSA Journal*, *20*(1), 7032. https://doi.org/10.2903/j.efsa.2022.7032

EFSA (European Food Safety Authority). (2024). Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance elemental iron. www.efsa.europa.eu

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources). (2009). Scientific Opinion of the panel on food additives and nutrient sources added to food on a request from the European Commission on ferrous phosphate added for nutritional purposes to food supplements. *EFSA Journal*, *7*(2), 951. https://doi.org/10.2903/j.efsa.2009.951

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources). (2010). Scientific Opinion on the safety of ferrous ammonium phosphate as a source of iron added for nutritional purposes to foods for the general population (including food supplements) and to foods for particular nutritional uses. *EFSA Journal*, *8*(5), 1584. https://doi.org/10.2903/j.efsa.2010.1584

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources Added to Food). (2015). Scientific Opinion on the re-evaluation of iron oxides and hydroxides (E 172) as food additives. *EFSA Journal*, *13*(12), 4317. https://doi.org/10.2903/j.efsa.2015.4317

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain). (2010). Scientific opinion on Lead in food. *EFSA Journal*, *8*(4), 1570. https://doi.org/10.2903/j.efsa.2010.1570

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain). (2012). Scientific opinion on the risk for public health related to the presence of mercury and methylmercury in food. *EFSA Journal*, *10*(12), 2985. https://doi.org/10.2903/j.efsa.2012.2985

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain). (2024). Update of the risk assessment of inorganic arsenic in food. *EFSA Journal*, *22*(1), e8488. https://doi.org/10.2903/j.efsa.2024.8488

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2016). Scientific opinion on the safety and efficacy of iron compounds (E1) as feed additives for all animal species: Ferrous carbonate; ferric chloride, hexahydrate; ferrous fumarate; ferrous sulphate, heptahydrate; ferrous sulphate, monohydrate; ferrous chelate of aminoacids, hydrate; ferrous chelate of glycine, hydrate, based on a dossier submitted by FEFANA asbl. *EFSA Journal*, *14*(2), 4396. https://doi.org/10.2903/j.efsa.2016.4396

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies). (2015). Scientific Opinion on dietary reference values for iron. *EFSA Journal*, *13*(10), 4254. https://doi.org/10.2903/j.efsa.2015.4254

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck, D., Bohn, T., Castenmiller, J., de Henauw, S., Hirsch-Ernst, K.-I., Knutsen, H. K., Maciuk, A., Mangelsdorf, I., McArdle, H., Pentieva, K., Siani, A., Thies, F., Tsabouri, S., Vinceti, M., Aggett, P., Fairweather-Tait, S., de Sesmaisons Lecarré, A., Fabiani, L., … Naska, A. (2024). Scientific opinion on the tolerable upper intake level for iron. *EFSA Journal*, *22*(6), e8819. https://doi.org/10.2903/j.efsa.2024.8819

European Commission. (2000a). Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3029/99-rev. 4, 11 July 2000.

European Commission. (2000b). Technical material and preparations: guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3030/99-rev. 4, 11 July 2000.

European Commission. (2002). Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002-rev. 2 final, 17 October 2002.

European Commission. (2003). Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 final, 25 February 2003.

European Commission. (2013). Guidance document on data requirements on efficacy for the dossier to be submitted for the approval of new active substances contained in plant protection products. SANCO/10054/2013-rev. 3, 11 July 2013.

European Commission. (2015). Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005. SANCO/11188/2013 Rev. 2, 14 September 2015.

FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use). (2001). FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Document Reference SANCO/4802/2001-rev. 2, 245 pp., as updated by Generic guidance for FOCUS surface water scenarios, v. 1.4, May 2015.

FOREGS (Forum of European Geological Surveys), Salminen, R., Batista, M. J., Bidovec, M., Demetriades, A., De Vivo, B., De Vos, W., Duris, M., Gilucis, A., Gregorauskiene, V., Halamic, J., Heitzmann, P., Lima, A., Jordan, G., Klaver, G., Klein, P., Lis, J., Locutura, J., Marsina, K., … Tarvainen, T. (2005). Geochemical atlas of Europe. Part 1: Background information, methodology and maps. Espoo, Geological Survey of Finland, 526 pages, 36 figures, 362 maps. https://www.gtk.fi/publ/foregsatlas/

FAO/WHO (Food and Agriculture Organization & World Health Organisation of the United Nations), (1983). Evaluation of certain food additives and contaminants: twenty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives. WHO technical report series; 696. ISBN: 92-4-120696-9

Pelusi, C., Gasparini, D. I., Bianchi, N., & Pasquali, R. (2016). Endocrine dysfunction in hereditary hemochromatosis. *Journal of Endocrinological Investigation*, *39*(8), 837–847. https://doi.org/10.1007/s40618-016-0451-7

SETAC (Society of Environmental Toxicology and Chemistry), Candolfi MP, Barrett KL, Campbell PJ, Forster R, Grandy N, Huet MC, Lewis G, Oomen PA, Schmuck R and Vogt H (eds), 2001. Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. ESCORT 2 workshop.

How to cite this article: EFSA (European Food Safety Authority), Álvarez, F., Arena, M., Auteri, D., Batista Leite, S., Binaglia, M., Castoldi, A. F., Chiusolo, A., Colagiorgi, A., Colas, M., Crivellente, F., De Lentdecker, C., De Magistris, I., Egsmose, M., Fait, G., Ferilli, F., Giner Santonja, G., Gouliarmou, V., Halling, K., … Villamar-Bouza, L. (2024). Peer review of the pesticide risk assessment of the active substance elemental iron. *EFSA Journal*, *22*(10), e9056. https://doi.org/10.2903/j.efsa.2024.9056

APPENDIX A

Consideration of cut-off criteria for elemental iron according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion[a]
CMR	**Carcinogenicity (C)**	Elemental Iron is not considered to be a carcinogen according to point 3.6.3 of Annex II of Regulation (EC) No 1107/2009
	Mutagenicity (M)	Elemental Iron is not considered to be a mutagen according to point 3.6.2 of Annex II of Regulation (EC) No 1107/2009
	Toxic for Reproduction (R)	Elemental Iron is not considered to be toxic to reproduction according to point 3.6.4 of Annex II of Regulation (EC) No 1107/2009
Endocrine disrupting properties		Based on the available information, it can be concluded that it is unlikely that elemental iron meets the criteria for endocrine disruption for humans and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605
POP	**Persistence** **Bioaccumulation** **Long-range transport**	Elemental iron is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009
PBT	**Persistence** **Bioaccumulation** **Toxicity**	Elemental iron is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009
vPvB	**Persistence** **Bioaccumulation**	Elemental iron is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009

[a]Origin of data to be included where applicable (e.g. EFSA, ECHA RAC, Regulation).

APPENDIX B

List of end points for the active substance and the formulation(s) for representative uses

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2024.9056