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CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance ferric pyrophosphate

European Food Safety Authority (EFSA),
Maria Anastassiadou, Maria Arena, Domenica Auteri, Alba Brancato, Laszlo Bura, Luis Carrasco Cabrera, Eugenia Chaideftou, Arianna Chiusolo, Daniele Court Marques, Federica Crivellente, Chloe De Lentdecker, Mark Egsmose, Gabriella Fait, Luna Greco, Alessio Ippolito, Frederique Istace, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Alfonso Lostia, Christopher Lythgo, Iris Mangas, Ileana Miron, Tunde Molnar, Laura Padovani, Juan Manuel Parra Morte, Ragnor Pedersen, Hermine Reich, Miguel Santos, Rositsa Serafimova, Rachel Sharp, Alois Stanek, Juergen Sturma, Csaba Szentes, Andrea Terron, Manuela Tiramani, Benedicte Vagenende and Laura Villamar-Bouza

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 Poland for the pesticide active substance ferric pyrophosphate 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 use of ferric pyrophosphate as a molluscicide on all edible and inedible crops. The reliable end points, appropriate for use in regulatory risk assessment are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

Keywords: ferric pyrophosphate, peer review, risk assessment, pesticide

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Correspondence: pesticides.peerreview@efsa.europa.eu

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Summary

Ferric pyrophosphate is 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), Poland received an application from BROS Sp. z o.o. Sp.k. on 28 December 2015 for approval. 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 24 June 2016.

An initial evaluation of the dossier on ferric pyrophosphate 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 the European Food Safety Authority (EFSA) in accordance with Article 12 of Regulation (EC) No 1107/2009. The following conclusions are derived.

The uses of ferric pyrophosphate according to the representative uses as a molluscicide on all edible and inedible crops, as proposed at the European Union (EU) level result 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/chemical properties and analytical methods.

In the area of mammalian toxicology and non-dietary risk assessment, no critical areas of concern were identified.

In the area of residues and consumer exposure, no concerns were identified. An maximum residue level (MRL) application for inclusion of ferric pyrophosphate into Annex IV of Regulation (EC) No 396/2005 has also been submitted. Ferric pyrophosphate satisfies the criteria outlined in the guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005 (SANCO/11188/2013 rev.2) according to the representative uses.

The information available regarding environmental fate and behaviour were considered sufficient to complete the assessments necessary regarding the environmental exposure assessment at the EU level for the representative uses assessed, with the exception that a data gap was identified to address the impact of the concentrations of iron ions in the sediment compartment that arise from the use of ferric pyrophosphate. This is in the context of comparison to their background levels in the sediment compartment, occurring naturally or from anthropogenic origin.

In the area of ecotoxicology, the risk to birds and mammals, aquatic organisms, non-target arthropods, earthworms, soil macro-, meso- and microorganisms, was considered to be low and no critical areas of concern were identified. An issue that could not be finalised was identified for the aquatic sediment-dwelling organisms and for honeybees.

Ferric pyrophosphate is not an endocrine disruptor 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.

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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).

Ferric pyrophosphate is a new active substance for which, in accordance with Article 7 of the Regulation, the RMS, Poland (hereinafter referred to as the 'RMS'), received an application from BROS Sp. z o.o. Sp.k. on 28 December 2015 for approval of the active substance ferric pyrophosphate. 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 24 June 2016.

The RMS provided its initial evaluation of the dossier on ferric pyrophosphate in the DAR, which was received by EFSA on 21 August 2018 (Poland, 2018). The peer review was initiated on 23 October 2018 by dispatching the DAR for consultation of the Member States and the applicant, BROS Sp. z o.o. Sp.k., 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 telephone conference between EFSA and the RMS on 22 February 2019. 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 telephone conference, 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 expert 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 where this 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 ferric pyrophosphate 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 took place with Member States via a written procedure in November-December 2019.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative use of ferric pyrophosphate as a molluscicide on all edible and inedible crops 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 are presented in the conclusion. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005, provided 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

[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.

IV proposal 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 A.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2019), 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:

- the comments received on the DAR;
- the reporting table (22 February 2019);
- the evaluation table (20 November 2019);
- 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 (Poland, 2019) and the peer review report, both documents are considered as background documents to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the European Union (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 formulated product

Ferric pyrophosphate is a common name for iron(3+) diphosphate (4:3) (IUPAC).

The representative formulated product for the evaluation was 'BW01 GB', a granular bait (GB) containing 24 g/kg ferric pyrophosphate.

The representative uses evaluated were manual application or by applicator for granular formulations in edible and inedible plants grown in field and under protection (both permanent and non-permanent greenhouses) for control of slugs and snails species. Full details of the Good Agricultural Practices (GAPs) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the use of ferric pyrophosphate according to the representative uses proposed at EU level results in a sufficient molluscicidal efficacy against the target organisms, following the guidance document SANCO/10054/2013 - rev. 3 (European Commission, 2013).

A data gap has been identified for a detailed reporting of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with effects on the environment and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).

Conclusions of the evaluation

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,b, 2010).

The proposed specification for ferric pyrophosphate is based on batch data from industrial plant production. The proposed minimum purity of the technical material is 802 g/kg. Mercury, lead and cadmium were considered as relevant impurities with maximum contents of 0.1 mg/kg, 3 mg/kg and 1 mg/kg, respectively (see Section 2). The batches used in the (eco)toxicological assessment support the proposed specification (See Sections 2 and 5). There is no FAO specification available for ferric pyrophosphate.

The main data regarding the identity of ferric pyrophosphate and its physical and chemical properties are given in Appendix A.

Adequate methods are available for the generation of data required for the risk assessment. Methods of analysis are available for the determination of the active substance in the technical material and the representative formulation and for the determination of the respective impurities in the technical material.

No monitoring methods were needed since MRLs in food/feed of plant origin and animal products were not set. Monitoring method for soil, air and for biomonitoring in body fluids and tissues were also considered not needed. Pending the conclusion on the risk assessment for sediments (See Sections 4 and 5) a monitoring method for water might be needed.

2. Mammalian toxicity

The toxicological profile of the active substance ferric pyrophosphate was discussed at the Pesticides Peer Review Experts' Meeting 11 and assessed based on the following guidance documents: SANCO/221/2000 – rev. 10-final (European Commission, 2003) and SANCO/10597/2003 – rev. 10.1 (European Commission, 2012).

The technical specification of the active substance ferric pyrophosphate is considered of food chemical quality and therefore the maximum content of relevant heavy metals impurities should comply with the limits established in the EU legislation[2] (See Section 1). The toxicological batches are considered representative of the technical specification.

The applicant only submitted a limited data package with the ferric pyrophosphate including acute oral and inhalation toxicity, eye and skin irritation studies, a genotoxicity test battery and short-term oral toxicity studies in rats. These studies demonstrated that ferric pyrophosphate is of low acute and repeated dose oral toxicity, it does not have skin irritating properties and it is unlikely to be genotoxic. It is considered that the criteria for classification according to Regulation (EC) No 1272/2008[3] may be met for eye irritation but there is currently no harmonised classification for the active substance.

Iron and phosphate ions are considered ubiquitous in the environment and are also essential for animal and plant functions. Because of the limited data package for ferric pyrophosphate, the risk assessment mainly relied on clinical and epidemiological studies in humans with iron salts (use of iron as a food supplement in humans). Given the low toxicity of phosphate, the risk from exposure to phosphate is covered by the assessment made for iron.

Previous evaluations of ferrous and phosphate salts as food additives and nutrient sources and as plant protection products did not identify any toxicological effects (EFSA ANS Panel, 2010; EFSA 2012, 2015).

For a quantitative risk assessment of ferric pyrophosphate as a plant protection product, the RMS used the safe long-term intake of iron supplements of 50 mg iron/day (for a 60 kg individual) in pregnant women as the reference point for long-term consumer risk assessment of iron (i.e. acceptable daily intake (ADI)), i.e. 0.8 mg/kg body weight (bw) per day in line with the previous conclusions on iron sulfate and ferric phosphate (EFSA, 2012, 2015). The RMS also used the same basis for setting the reference point for non-dietary risk assessment (i.e. acceptable operator exposure level (AOEL)) of iron; a correction factor of 50% for oral bioavailability was used as previously agreed during the peer review on iron sulfate and ferric phosphate (EFSA, 2012, 2015). The resulting AOEL is 0.4 mg/kg bw per day. No reference point for acute dietary and non-dietary risk assessment was deemed necessary.

Dermal absorption of iron in ferric pyrophosphate is considered low. In line with the previous conclusions on iron sulfate and ferric phosphate a dermal absorption value of 10% was used as a worst-case scenario (EFSA, 2012, 2015).

Considering the representative use of ferric pyrophosphate in various edible and non-edible crops, the estimated operator exposure is below the AOEL (maximum 15.31% of the AOEL, manual application with gloves and coverall during application). Worker exposure is below the AOEL without the use of personal protective equipment (PPE) (maximum 55.8% of the AOEL). Bystander and resident exposure is well below the reference values. It is noted that an assessment for non-professional application by hand was not performed; however, no data gap is proposed (see reasoning under Data requirement 2.7 in the Evaluation table).

3. Residues

The assessment in the residue section is based on the following guidance documents: OECD (2009, 2011), European Commission (2011) and JMPR, 2004, 2007.

[2] Commission Regulation (EC) No 629/2008 of 2 July 2008 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs. OJ L173, 3.7.2008, (6-9).

[3] 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.

When applied according to the representative uses assessed as a GB broadcast over the soil surface, the ferric pyrophosphate within the pellets will remain on the soil surface until they are eaten by the target pest. From the literature search, there is no evidence that ferric pyrophosphate can be absorbed by plants from soil in view of its low water solubility. It is therefore expected that a very minor fraction of this compound may degrade in phosphates and iron. The uptake of iron ions and phosphate ions by plants is actively controlled by the plants. Furthermore, in case a pellet gets lodged in a leaf, it is very likely that it will be removed by normal food processing, e.g. washing and removal of outer leaves of the crops. Considering that ferric pyrophosphate is of low toxicity and based on the representative uses, the consumer dietary exposure to ferric pyrophosphate residues can be concluded as negligible.

Based on these considerations, the data requirement to determine the residues of ferric pyrophosphate in pollen and bee products can be considered as addressed.

Ferric pyrophosphate satisfies the criteria outlined in the guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005 (SANCO/11188/2013 rev.2) according to the representative uses. No MRLs are therefore required.

4. Environmental fate and behaviour

Information on the fate and behaviour of ferric pyrophosphate in the environmental compartments was based on peer reviewed scientific literature supplied by the applicant. Ferric pyrophosphate is a stable non-volatile inorganic salt that may undergo dissociation reactions in soil to transform into its corresponding Fe^{3+}/Fe^{2+} and $P_2O_7^{4-}$ ions. After broadcast application as in the representative uses assessed as a GB formulation, ferric pyrophosphate within the pellets will remain on the soil surface until they are eaten by the target pest or non-target organisms. The ferric pyrophosphate released from any pellets not consumed will then be stable, so very persistent due to the very low water solubility of this salt (40 μg/L at 20°C and pH 7). The very small proportion of the salt present at the soil surface that does not form insoluble ligand complexes but goes into solution will then be present as iron ions (primarily Fe^{3+}) and, depending on the soil pH, $H_2PO_4^-$ ions and/or HPO_4^{2-} ions or other soluble ligand complexes. During periods of heavy rainfall should the soil environment become anaerobic/reducing, Fe^{2+} ions might be formed. The predicted concentrations of ferric pyrophosphate in soil resulting from the broadcast application on all edible and inedible plants were provided. The amounts of elemental iron ions and $H_2PO_4^-/HPO_4^{2-}$ ions that will be present in upper soil layers consequent from the representative uses will be limited compared to the iron naturally present in soil that results from the weathering of mineral material or phosphate related ions that are applied to agricultural soils as fertiliser. Good quality quantitative information regarding these natural background concentrations and concentrations that can result from fertiliser practice is contained in the DAR or retrieved from the Renewal Assessment Report (RAR) of ferric phosphate.

As the representative use includes broadcast application and this can be done with spinning disc spreaders, it is possible that some pellets will directly enter a water course. High rainfall events might also result in a small proportion of pellets being moved to surface water in surface runoff. The applicant was asked to address the possibility of pellets entering surface water and their fate there. Predicted environmental concentration (PEC) values of Fe^{3+} and $P_2O_7^{4-}$ ions in surface water and sediment resulting from runoff and/or drainage when the product is broadcast in the field were calculated using the FOCUS SW models (Step 1 and 2) (FOCUS, 2001). Additionally, the PEC, PEC_{sw} and PEC_{sed}, values for ferric pyrophosphate resulting from application directly to surface water were provided to cover the aquatic exposure due to accidental application with spinning disc spreaders in proximity of water courses. No information was available on the background levels of iron ions in the sediment compartment of surface water bodies occurring naturally or from anthropogenic origin to be compared with the PEC_{sed} to address the risk to sediment-dwelling organisms (data gap). All PEC_{sw} values are above the water solubility limit of ferric pyrophosphate and therefore should be considered as theoretical values. Thus, the aquatic risk assessment can be performed with the maximum environmental concentrations in the aquatic compartment equal to the solubility of ferric pyrophosphate in water (40 μg/L). The small quantities of ions that might enter the water column from the insoluble ferric pyrophosphate salt are expected to be too low, to be of concern regarding eutrophication.

Regarding potential for groundwater exposure, due to its very low water solubility the applied ferric pyrophosphate is expected to be retained in the plough layer of soil. Should any ferric pyrophosphate be physically moved into deeper soil layers via preferential flow it could never be present in

groundwater above the parametric drinking water limit for pesticides of 0.1 μg/L due to its very low water solubility (40 μg/L at 20°C and pH 7). The dissociation products (Fe^{3+}, $H_2PO_4^-$/HPO_4^{2-} ions) will only ever be present in the soil solution in very low amounts due to the very low water solubility of the ferric pyrophosphate salt. $H_2PO_4^-$ and HPO_4^{2-} ions can be considered to be 'degradation products of no concern' following step 1 of SANCO/221/2000 rev. 10 – final (European Commission, 2003) as they are inorganic compounds not containing a heavy metal. Regarding the iron ions, again due to the very low water solubility of the ferric pyrophosphate salt, the concentration of the two possible iron ions in groundwater originating from the uses evaluated could not be above the indicator parameter of 200 μg/L set for iron by Council Directive 98/83/EC.

The PEC in soil and surface water/sediment covering the representative uses assessed can be found in Appendix A of this conclusion.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002), SETAC (2001), EFSA (2009), EFSA PPR Panel (2013) and EFSA (2013).

The information to support the compliance of the batches used in ecotoxicological studies with the technical specification was considered sufficient.

Acute oral and reproductive toxicity data on **birds** were available with the active substance ferric pyrophosphate.

A quantitative acute risk assessment for birds from dietary exposure to granular applications according to EFSA (2009) was available and a low acute risk was concluded for birds ingesting granules accidentally.

A high acute risk was indicated for birds ingesting granules as source of food and as grit. This risk was further addressed and concluded as low by considering the natural occurrence of ferric pyrophosphate in the environment and in living organisms, the use as an iron food supplement, and the fact that no adverse effects on birds at the highest tested doses were detected in the available toxicity studies.

A qualitative risk assessment for slug-eating birds consuming food items with residues from granular application indicated a low acute risk.

The reproductive toxicity exposure ratios (TERs) to birds resulted below the trigger value. However, it was finally considered to be low for the representative use based on the available information for ferric pyrophosphate, as mentioned above.

Acute oral and reproductive toxicity data on wild **mammals** (rat) were available with ferric pyrophosphate and the representative formulation.

Risk assessments were also available for mammals and the exposure scenarios to granular applications according to EFSA (2009). Low acute risk was identified for mammals ingesting granules and slug accidentally. For mammals ingesting granules as source of food, the toxicity exposure ratios did not meet the trigger value but considering the above information for ferric pyrophosphate the risk was concluded to be low.

The risk for birds and wild mammals from exposure via secondary poisoning and via consumption of contaminated water was considered to be low.

For **aquatic organisms**, sufficient toxicity data with the active substance ferric pyrophosphate and the representative formulation were available with fish and aquatic invertebrates. Toxicity data were also available with ferric pyrophosphate and algae.

A quantitative risk assessment for aquatic organisms was available and a high risk to fish, aquatic invertebrates and algae could not be excluded at FOCUS Step 1-2. However, considering (i) that the maximum environmental concentration of ferric pyrophosphate in water is higher than its water solubility (40 μg/L), and (ii) the very low solubility of ferric pyrophosphate in water, a low risk to aquatic organisms from exposure to ferric pyrophosphate could be concluded.

No appropriate data or risk assessments were available for the **sediment-dwelling organisms** and the water and sediment compartment resulting to a data gap leading to an issue that could not be finalised.

Appropriate acute toxicity data were available for honey**bees** with the active substance.

Screening risk assessments based on the EFSA (2013) were also available indicating a low risk to honeybees due to acute oral and contact exposure to ferric pyrophosphate.

No toxicity data were available for bumblebees and solitary bees.

No chronic toxicity data or risk assessment were available for adult honeybees and larvae (data gap leading to issue not finalised). Sublethal effect data and assessment (e.g. hypopharyngeal glands (HPG)) were not available (data gap).

The risk via consumption of guttation fluid and contaminated surface water was assessed as low. No assessment was available for puddle water; however, the risk from this scenario was also considered as low on the basis of the risk assessment for guttation water.

In accordance with the Guidance document on terrestrial ecotoxicology (European Commission, 2002), two Tier-1 toxicity tests were available with the representative formulation and the **non-target arthropod** species *Aleochara bilineata* and *Poecilus cupreus* indicating no adverse effects at application rates at least 2 times higher than the maximum application rate of the representative use. On the basis of the available information a low risk to non-target arthropods was indicated for the representative uses.

Based on the available toxicity data and risk assessment, a low risk to **earthworms** and other **soil macro-organisms**, **soil microorganisms** and **non-target terrestrial plants** was identified.

No data on effects on organisms involved in **sewage treatment** processes were provided or required based on the low risk to soil micro- and macro-organisms.

6. Endocrine disruption properties

The assessment of the endocrine disruption potential of ferric pyrophosphate was discussed at the Pesticides Peer Review Experts' Meeting PREV 11 for mammalian toxicology and PREV 14 for ecotoxicology.

With regard to the assessment of the endocrine disruption potential of ferric pyrophosphate for **humans** according to the ECHA/EFSA guidance (2018), a standard data package on ferric pyrophosphate is not available. The experts agreed to waive the assessment of endocrine disrupting properties of this substance considering the low toxicity observed in the available toxicity studies and the use of iron as a food supplement in humans. This conclusion applies for mammals as non-target organism as well.

In line with the waiver applied for humans and **mammals as non-target organisms**, an assessment of the endocrine disruption potential for **non-target organisms other than mammals** in accordance with the ECHA/EFSA (2018) is not considered scientifically necessary and thus can be waived due to the physico-chemical properties of the substance (i.e. very poor solubility in water) and the use as an iron food supplement.

Based on the above, ferric pyrophosphate is considered not to meet the criteria for endocrine disruption on humans and on 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[4].

[4] 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.

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)	Persistence	Ecotoxicology
Ferric pyrophosphate ($Fe_4(P_2O_7)_3$	Very persistent due to low water solubility	Low risk to soil organisms
Iron ions (Fe^{3+}, Fe^{2+})	The ions will be utilised by plants as nutrients	Low risk to soil organisms
Hydrogen phosphate ions (HPO_4^{2-})	The ions will be utilised by plants as nutrients	Low risk to soil organisms
Dihydrogen phosphate ions ($H_2PO_4^-$)	The ions will be utilised by plants as nutrients	Low risk to soil organisms

Table 2: Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[a]	Pesticidal activity	Toxicological relevance
Ferric pyrophosphate ($Fe_4(P_2O_7)_3$	Expected to be low due to very low water solubility	No, will not be present at > 0.1 µg/L (standard set for pesticide active substances) as levels cannot be present above the water solubility of 40 µg/L	Yes	Yes
Iron ions (Fe^{3+}, Fe^{2+})	Low mobility expected as cations have an affinity for negatively charged inorganic soil components and organic carbon	No, will not be present at > 200 µg/L[b] due to the low solubility of the salt ferric phosphate meaning limited ion formation combined with the relatively low application rate	No	Yes
Hydrogen phosphate ions (HPO_4^{2-})	As an inorganic compound not containing a heavy metal, it is 'a degradation product of no concern'[c]	Water quality standards not set by Council Directive 98/83/EC, it is 'a degradation product of no concern'[c]	No	No
Dihydrogen phosphate ions ($H_2PO_4^-$)	As an inorganic compound not containing a heavy metal, it is 'a degradation product of no concern'[c]	Water quality standards not set by Council Directive 98/83/EC, it is 'a degradation product of no concern'[c]	No	No

(a): At least one FOCUS scenario or a relevant lysimeter.
(b): Indicator parameter of 200 µg/L set for iron by Council Directive 98/83/EC.
(c): As described in Step 1 of SANCO/221/2000-rev 10-final guidance (European Commission, 2003).

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Ferric pyrophosphate ($Fe_4(P_2O_7)_3$	Low risk to aquatic organisms apart from sediment-dwellers
Iron ions (Fe^{3+}, Fe^{2+})	Low risk to aquatic organisms
Hydrogen phosphate ions (HPO_4^{2-})	Low risk to aquatic organisms
Dihydrogen phosphate ions ($H_2PO_4^-$)	Low risk to aquatic organisms

Table 4: Air

Compound(name and/or code)	Toxicology
Ferric pyrophosphate ($Fe_4(P_2O_7)_3$	> 2.69 mg/L air per 4 h (maximum attainable concentration)

8. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of the Regulation concerning information on potentially harmful effects).

- A data gap has been identified for a detailed reporting of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with effects on the environment and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011; information submitted by the applicant but not included and evaluated in the DAR; relevant for all representative uses evaluated, see Section 4).
- Information on background levels of iron ions in surface water bodies across Europe occurring naturally or from anthropogenic origin to be compared with the predicted environmental concentrations in the sediment compartment following the use of ferric pyrophosphate (relevant for all representative uses evaluated; see Section 4).
- Information to address the risk to sediment-dwelling organisms was not available and therefore a low risk could not be concluded for exposure via the water and sediment phase (relevant for all representative uses evaluated; see Section 5).
- Information to address the risk from sublethal effects to honeybee (relevant for all representative uses evaluated; see Section 5).
- Information to address the chronic risk to honeybee adult and larvae (relevant for all representative uses evaluated; see Section 5).

9. Particular conditions proposed to be taken into account to manage the risk(s) identified

- The operator, during manual application should use gloves and coverall during the application to keep exposure below the AOEL (see Section 2).

10. Concerns

10.1. 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 the representative uses in line with the uniform principles in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011[5] 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 the Regulation.

1) The risk assessment to sediment-dwelling organisms from exposure via water and sediment could not be finalised (see Section 5).
2) The chronic risk assessment to honeybee adult and larvae could not be finalised (see Section 5).

10.2. 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 the Regulation 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

[5] 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.

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 the Regulation.

None.

10.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 9, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

Table 5: Overview of concerns

Representative use		Edible or inedible plants (field or greenhouse)
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	X[2]
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	X[1]
Groundwater exposure to active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure to metabolites	Legal parametric value breached	
	Parametric value of 10 μg/L[(a)] breached	
	Assessment not finalised	

Columns are grey if no safe use can be identified. The superscript numbers relate to the numbered points indicated in Sections 10.1 and 10.2. Where there is no superscript number, see Sections 2–6 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission, 2003.

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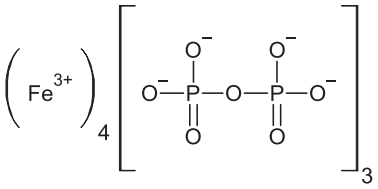
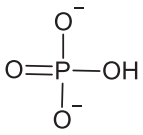
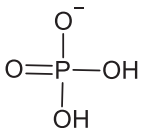
Abbreviations

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
bw	body weight
DAR	draft assessment report
ECHA	European Chemicals Agency
EEC	European Economic Community
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
GB	granular bait
HPG	hypopharyngeal glands
InChiKey	International Chemical Identifier Key
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)
MRL	maximum residue level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PEC_{sed}	predicted environmental concentration in sediment
PEC_{sw}	predicted environmental concentration in surface water
PPE	personal protective equipment
RAR	Renewal Assessment Report
RBC	red blood cells
SMILES	simplified molecular-input line-entry system
TER	toxicity exposure ratio
WHO	World Health Organization

Appendix A – List of end points for the active substance and the representative formulation

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2020.5986

Appendix B – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula[c]
Ferric pyrophosphate	iron(3 +) diphosphate [Fe + 3].[Fe + 3].[Fe + 3].[Fe + 3].[O-]P([O-])(=O)OP([O-])([O-]) = O.[O-]P([O-])(=O)OP([O-])([O-]) = O.[O-]P([O-])(=O)OP([O-])([O-]) = O CADNYOZXMIKYPR-UHFFFAOYSA-B	
Hydrogen phosphate HPO_4^{2-} $[PO_3(OH)]^{2-}$	hydrogen phosphate (ion)	
Dihydrogenphosphate $H_2P0_4^-$ $[PO_2(OH_2)]^-$	dihydrogen phosphate (ion)	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).