Final Review report for the active substance ferric phosphate
finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on
29 May 2015
in view of the renewal of the approval of ferric phosphate as active substance in accordance
with Regulation (EC) No 1107/2009

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the evaluation of ferric phosphate, in
No 1141/2010\(^3\) following the submission of an application to renew the approval of this active
substance expiring in December 2015.

Commission Regulation (EU) No 1141/2010, as amended by Commission Implementing
Regulation (EU) No 380/2013\(^4\), lays down the procedure for the renewal of the second group
of active substances in Annex I to Directive 91/414/EEC\(^5\) and includes ferric phosphate.

Ferric phosphate is a substance that was included in Annex I to Council Directive 91/414/EEC
concerning the placing of plant protection products on the market, by Commission
Directive 2001/87/EC\(^6\). Ferric phosphate is deemed to have been approved under Regulation
(EC) No 1107/2009 and is listed in Part A of the Annex to Commission Implementing
Regulation (EU) No 540/2011\(^7\).

In accordance with the provisions of Article 5 of Directive 91/414/EEC, Neudorff GmbH KG
and Bayer SAS notified to the Commission of their wish to renew the approval of the active
substance ferric phosphate in Annex I to the Directive.

Commission Directive 2010/77/EU\(^8\) extended until 31 December 2015 the period of approval
of ferric phosphate to allow the completion of its review.

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1 Does not necessarily represent the views of the Commission.
Commission Regulation (EU) No 1141/2010 designated the rapporteur Member States and the co-rapporteur Member States which had to submit the relevant renewal assessment reports and recommendations to the European Food Safety Authority (EFSA).

For ferric phosphate the rapporteur Member State was Germany and the co-rapporteur Member State was Poland.

Germany finalised in April 2013 its examination, in the form of a renewal assessment report. This Report was sent to the Commission and the European Food Safety Authority on 30 April 2013 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of ferric phosphate for the supported uses.

In accordance with Article 16 of Commission Regulation (EU) No 1141/2010, the Commission requested the EFSA to review the rapporteur Member State’s renewal assessment report and to deliver its conclusions.

It was concluded that additional information was needed from the applicant but that an intensive consultation of technical experts from Member States was not necessary. Therefore, the EFSA reviewed the renewal assessment report and the comments received thereon (peer review).

The EFSA sent to the Commission its conclusion on the risk assessment (Conclusions regarding the peer review of the pesticide risk assessment of the active substance) on 17 December 2014. This conclusion refers to background document A (renewal assessment report and its compiled addendum) and background document B (EFSA peer review report).

According to the provisions of Article 17 of Regulation (EU) No 1141/2010, the Commission referred a draft review report on the renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for examination on 20 March 2015. The draft review report on renewal of approval was finalized in the meeting of the Standing Committee on 29 May 2015.

The present review report on renewal of approval contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (part of background document C), these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Implementing Regulation (EU) 2015/1166 concerning the renewal of approval of ferric phosphate as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing ferric phosphate they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011.

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10 OJ L 188, 16.7.2015, p. 34–36.
This review report provides also for the evaluation required under part I, Section A.2 (b) of the above mentioned uniform principles, as well as under several specific sections of chapter B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the requirements of Regulation (EU) No 544/2011\(^\text{12}\), submitted for the purpose of (renewal of) approval of the active substances, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 18 of Regulation (EU) No 1141/2010, this review report will be made available to the public.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this review report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

**3. Overall conclusion in the context of Regulation (EC) No 1107/2009**

The overall conclusion from the evaluation is that it may be expected that plant protection products containing ferric phosphate will still fulfil the safety requirements laid down in Article 4(1) to (3) of Regulation (EC) No 1107/2009. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each ferric phosphate containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the applicant and mentioned in the summary of representative uses evaluated (attached as Appendix II to this review report).

The following reference values have been finalized as part of this evaluation:

- ADI: 0.8 mg/kg bw per day (iron),
- AOEL: 0.4 mg/kg bw per day (iron),
- ARfD: not necessary.

With particular regard to residues, no MRLs are required, according to Commission Regulation (EC) No 149/2008\(^\text{13}\) amending Reg. (EC) 396/2005.

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

The review has identified several acceptable exposure scenarios for operators, workers, bystanders and groundwater which require however to be confirmed for each plant protection product in

\(^{13}\) OJ L 58, 1.3.2008, p. 1.
accordance with the relevant sections of the above mentioned uniform principles. In particular for the risk to operators, this conclusion has been reached under the assumption of use of standard protective equipment (such as gloves and work wear) during mixing, loading and application.

The risk characterisation to aquatic organisms was considered as open by EFSA (2015), due to the uncertainty in the potential for and nature of the exposure. However, a low risk to aquatic organisms is expected from the iron and HPO$_4^{2-}$ and H$_2$PO$_4^-$ ions since the amount of elemental ions present in surface water consequent from the representative uses will be limited compared to the background levels.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this report.

Ferric phosphate does not meet any of the criteria listed in point 5 of Annex II to Regulation (EC) No 1107/2009. Only the persistence criterion can be subject to discussion. Ferric phosphate is very persistent due to its low water solubility. However, Iron and phosphate ions are considered ubiquitous in the environment and are also essential for animal and plant functions. Additionally, ferric phosphate is a natural constituent of the human diet. The amounts of elemental iron ions and HPO$_4^{2-}$ / H$_2$PO$_4^-$ ions that will be present in upper soil layers and water consequent from the representative uses will be limited compared to the iron naturally present in soil and surface water systems that results from the weathering of mineral material or phosphate related ions that are applied to agricultural soils as fertiliser and that move to surface water. Good quality quantitative information regarding these natural background concentrations and concentrations that can result from fertiliser practice is contained in the dossier and the DAR and RAR. The growing crops and aquatic plants will utilise these ions as nutrients. It could also never be present in groundwater above the parametric drinking water limit for pesticides due to its very low water solubility. Based on this information, the review concludes that ferric phosphate shall be considered a low risk active substance in accordance with Article 22 of Regulation (EC) No 1107/2009.

4. Identity and Physical/chemical properties

The main identity of ferric phosphate is given in Appendix I.

The active substance ferric phosphate shall have a minimum purity of 703 g/kg, equivalent to 260 g/kg iron and 144 g/kg phosphorus.

The technical specification of the active substance ferric phosphate 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$^{14}$:

- Lead: 3 mg/kg,
- Mercury: 0.1 mg/kg,
- Cadmium: 1 mg/kg.

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5. **Endpoints and related information**

In order to facilitate Member States, in granting or reviewing authorizations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA.

6. **Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorizations of plant protection products containing ferric phosphate**

On the basis of the representative uses evaluated (as listed in Appendix II), no issues have been identified as requiring particular and short term attention from all Member States.

7. **List of studies to be generated**

No further information was identified which is at this stage considered necessary in relation to the approval of ferric phosphate under the current approval conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. This might in particular be the case for the risk to aquatic organisms following broadcast applications close to water bodies.

A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (page 14).

8. **Information on studies with claimed data protection**

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the applicant has claimed data protection and which during the re-evaluation process were considered as essential with a view to approval under Regulation (EC) No 1107/2009. This information is only given to facilitate the operation of the provisions of Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

9. **Updating of this review report**

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalized in the Standing Committee on Plants, Animals, Food and Feed, in connection with any amendment of the approval conditions for ferric phosphate.
## APPENDIX I

### Main identity

**FERRIC PHOSPHATE**

<table>
<thead>
<tr>
<th><strong>Common name (ISO)</strong></th>
<th>Ferric phosphate</th>
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<tbody>
<tr>
<td><strong>Chemical name (IUPAC)</strong></td>
<td>Ferric phosphate</td>
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<tr>
<td><strong>Chemical name (CA)</strong></td>
<td>Ferric phosphate</td>
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<tr>
<td><strong>CIPAC No</strong></td>
<td>629</td>
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<tr>
<td><strong>CAS No</strong></td>
<td>10045-86-0</td>
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<tr>
<td><strong>EC No (EINECS or ELINCS)‡</strong></td>
<td>233-149-7</td>
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<tr>
<td><strong>FAO SPECIFICATION</strong></td>
<td>Not available.</td>
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<tr>
<td><strong>Minimum purity</strong></td>
<td>Ferric phosphate 703 g/kg equivalent to 260 g/kg iron and 144 g/kg phosphorus.</td>
</tr>
</tbody>
</table>
| **Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured** | Lead: 3 mg/kg  
Mercury: 0.1 mg/kg  
Cadmium: 1 mg/kg |
| **Molecular formula** | FePO4 |
| **Molar mass** | 150.82 g/mol (anhydrous) |
| **Structural formula** | ![FePO4 structural formula](image) |
**APPENDIX II**

**Summary of representative uses evaluated**

**FERRIC PHOSPHATE**

<table>
<thead>
<tr>
<th>Crop and/or situation</th>
<th>Member State or Country</th>
<th>Product name</th>
<th>F, G or I</th>
<th>Pests or Group of pests controlled</th>
<th>Formulation</th>
<th>Application</th>
<th>Application rate per treatment</th>
<th>PHI (days)</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td>All edible and non-edible crops</td>
<td>Germany</td>
<td>NEU 1165 M</td>
<td>F, G</td>
<td>Pest slugs and snails</td>
<td>GB</td>
<td>10.0 g/kg ferric phosphate</td>
<td>Strew, each row At beginning of infestation</td>
<td>Not applicable (because ready-to-use GB) Not applicable (because ready-to-use GB)</td>
<td>0.12 - 0.5</td>
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<tr>
<td>Crop and/or situation</td>
<td>Member State or Country</td>
<td>Product name</td>
<td>F G or I</td>
<td>Pests or Group of pests controlled</td>
<td>Formulation</td>
<td>Application</td>
<td>Application rate per treatment</td>
<td>PHI (days)</td>
<td>Remarks</td>
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<tr>
<td>Vegetables <em>such as</em> turnip cabbage, chinese cabbage, kale cabbage (green cabbage), head cabbage (including Savoy cabbage and Brussels sprout), cauliflower, broccoli, lettuce, spinach, beetroot, common beans etc.</td>
<td>Germany</td>
<td>Bayer Garten Schnecken-kom Biomol</td>
<td>F, G</td>
<td>Slugs Snails</td>
<td>RB</td>
<td>16.2 g/kg broadcast</td>
<td>At infestation</td>
<td>1-6</td>
<td>2-4 weeks</td>
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<td>Fruits <em>such as</em> pome and stone fruits as well as soft fruits like strawberries</td>
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<td>Potatoes</td>
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<td>Ornamentals</td>
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(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure).  
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I).  
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds  

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialvalcarb-isopropyl).
| (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) | (j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application |
| (f) All abbreviations used must be explained | (k) Indicate the minimum and maximum number of applications possible under practical conditions of use |
| (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench | (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha) |
| (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated | (m) PHI - minimum pre-harvest interval |