Final Renewal report for the active substance pymetrozine

finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 14 June 2018 in view of the non-renewal of the approval of pymetrozine as
active substance in accordance with Regulation (EC) No 1107/2009¹

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the evaluation of pymetrozine, in accordance
with Regulation (EC) No 1107/2009² and Commission Regulation (EU) No 1141/2010³ following
the submission of an application to renew the approval of this active substance expiring in
June 2019.

Commission Regulation (EU) No 1141/2010, as amended by Commission Implementing
Regulation (EU) No 380/2013⁴, lays down the procedure for the renewal of the second group of
active substances in Annex I to Directive 91/414/EEC⁵ and includes pymetrozine.

Pymetrozine 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/EC⁶. Pymetrozine 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 540/2011⁷.

In accordance with the provisions of Article 5 of Directive 91/414/EEC, Syngenta Crop Protection
AG notified to the Commission of their wish to renew the approval of the active substance
pymetrozine in Annex I to the Directive.

Commission Directive 2010/77/EU⁸ extended until 31 December 2015 the period of approval of
pymetrozine to allow the completion of its review.

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¹ Review Report established in accordance with Art. 17 of Regulation (EU) No 1141/2010; does not
necessarily represent the views of the European Commission.
Commission Implementing Regulation (EU) 2015/1885 further extended until 30 June 2016 the period of approval of pymetrozine to allow the completion of its review.

Commission Implementing Regulation (EU) 2016/549 further extended until 30 June 2017 the period of approval of pymetrozine to allow the completion of its review.

Commission Implementing Regulation (EU) 2017/841 further extended until 30 June 2018 the period of approval of pymetrozine to allow the completion of its review.

Commission Implementing Regulation (EU) 2018/917 further extended until 30 June 2019 the period of approval of pymetrozine to allow the completion of its review.

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 pymetrozine the rapporteur Member State was Germany and the co-rapporteur Member State was Belgium.

Germany finalised in June 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 28 June 2013 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of pymetrozine for the supported uses.

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

Therefore, the EFSA organised an intensive consultation of technical experts from Member States, to review 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 25 August 2014. This conclusion refers to several background documents: the renewal assessment report and its compiled addendum and the peer review report.

According to the provisions of Article 17 of Regulation (EU) No 1141/2010, the Commission referred a draft review report concerning the non-renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for examination on 26 January 2015. The draft review report on non-renewal of approval was finalised in the meeting of the Standing Committee on 14 June 2018.

The present review report on non-renewal of approval contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and its background documents, these are also considered to be part of this review report.

2. **Purposes of this review report**

This review report, including the background documents, has been developed and finalised in support of Commission Implementing Regulation (EU) 2018/1501\(^{15}\) concerning the non-approval of pymetrozine.

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**

As part of the updated evaluation of pymetrozine the following reference values have been finalised:

- **ADI:** 0.03 mg/kg bw per day,
- **ARfD:** 0.1 mg/kg bw,
- **AOEL:** 0.03 mg/kg bw per day,
- **AAOEL:** 0.1 mg/kg bw.

To note, the above values have not changed compared to the previous EU agreed reference values.

The overall conclusion of the evaluation, based on the information available and the proposed conditions of use, is that:

* **indicates that the approval criteria** as set out in Article 4(1) to (3) of Regulation (EC) No 1107/2009 are not satisfied as **concerns were identified** with regards to:

  - The potential for groundwater exposure above the parametric drinking water limit of 0.1 μg/L for the toxicologically relevant metabolite CGA371075, in all pertinent groundwater scenarios, for all representative uses. Several other toxicologically relevant metabolites are also predicted to occur above 0.1 μg/L in some or all scenarios for the representative uses evaluated. Therefore it has not been established that the presence of metabolites of pymetrozine in groundwater will not result in unacceptable effects on groundwater and in harmful effects on human health as required under Article 4(2) of Regulation (EC) No 1107/2009.

\(^{15}\) OJ L 254, 10.10.2018, p. 4.
It was indicated in the Renewal Assessment Report that use of pymetrozine on oilseed rape every 3\textsuperscript{rd} year at a maximum rate of 75 g/ha could result in CGA371075 to occur below 0.1 μg/L in some pertinent FOCUS scenarios.

Aside from the fact that this GAP was not a representative use in the renewal dossier, nor is it a forced agronomic rotation, EFSA concluded that the risk assessment for oilseed rape in territories where anaerobic soil conditions can occur could not be finalised:

- for soil dwelling and aquatic organisms and for the potential for impacts on groundwater quality for the anaerobic soil metabolites CGA180777 and GS23199 and
- for soil dwelling organisms and for the potential for impacts on groundwater quality for the anaerobic soil metabolite CGA249257.

Therefore the use on oilseed rape cannot be considered to fulfil the approval criteria in relation to protection of groundwater, nor the protection of non-target organisms based on the information available.

- The endocrine disrupting properties of pymetrozine.
  Pymetrozine produced adverse effects on endocrine organs across different species and timelines. However, the scientific assessment for potential endocrine disruption properties of pymetrozine could not be finalised based on the information available in the dossier.

* the information available is insufficient to satisfy the requirements set out in Article 4(1) to (3) of Regulation (EC) No 1107/2009, in particular with regard to:

- The toxicological profile of metabolites included in the plant residue definition for risk assessment – no conclusion could be drawn based on the information available. Subsequently the residue definition in plant commodities for risk assessment purposes could not be fully confirmed.
- The risk to aquatic organisms from exposure to metabolite M3MF.

In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing the active substance concerned is expected to satisfy in general the requirements laid down in Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011.

The approval of pymetrozine in accordance with Regulation (EC) No 1107/2009 should therefore be withdrawn.