

Annex III¹

Two additional substances listed by PAN in mid-term report (April 2017)²

Substance	Status of the Confirmatory information	Status of the evaluation
1. Pinoxaden ³	The request of confirmatory information concerned: (a) a validated method for the analysis of certain metabolites in the ground water and (b) the relevance of the assessment of certain metabolites only in the case of a classification of the substance.	The deadline for delivering the information requested under point (a) has not yet expired (30 June 2018). The deadline for delivering the information requested under point (b) has also not yet expired. In this case, the deadline is linked to the date of the classification of the substance, if the classification occurs. In case no classification will be identified, the request will become obsolete and there will be no longer a need for submission of the confirmatory information package.
2. Sulfuryl fluoride ^{4,5}	The request of confirmatory information relates to residues of fluoride ions in milling products present in the machinery during the fumigation and monitoring data on tropospheric concentrations of sulfuryl fluoride.	The data were submitted and assessed according to the procedures. The assessment of the data resulted in the amendments of the conditions of the approval provided for in Regulation (EU) No 2017/270. The Commission considered that the information submitted has not demonstrated the steady state of sulfuryl fluoride in the troposphere. For this reason, in the same Regulation (EU) 2017/270, an additional request for further monitoring data of tropospheric concentrations of sulfuryl fluoride, on a regular basis every fifth year, is included in order to ensure that the steady state is fully proven. This last request is to be seen as falling under the provisions of Article 6(i) of Regulation (EC) No 1107/2009 which provides for

¹ Substances approved in accordance with provisions laid down in Directive 91/414/EEC. In the Directive 91/414/EEC no specific provision for confirmatory information was included.

² Mid-term review of EU Ombudsman's verdict regarding DG SANTE's pesticide decision taking methods. <http://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/ombudsman-confirmatory-data-mid-term-review-april-2017.pdf>

³ Commission Implementing Regulation (EU) 2016/370 of 15 March 2016 approving the active substance pinoxaden, in accordance with Regulation (EC) No 1107/2009.

⁴ Commission Directive 2010/38/EU of 18 June 2010 amending Council Directive 91/414/EEC to include sulfuryl fluoride as active substance

⁵ Commission Implementing Regulation (EU) 2017/270 of 16 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance sulfuryl fluoride

		<p>the need to impose monitoring after use. In this specific case Article 6(i) applies because due to the nature of the request of monitoring data, it is not possible to solve the issue at National level.</p>
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