Annex II

Substances listed by PAN (2013)

Substance	Status of the Confirmatory information	Status of the evaluation
1. Bromuconazole Approved through Commission Directive 2010/92/EU[1].	The request for confirmatory information concerned: - further information on residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin, - information to further address the long-term risk to herbivorous mammals. The confirmatory data were submitted by the applicant within the prescribed deadline.	The assessment was finalised by the rapporteur Member State, Belgium (Addendum of July 2013) and followed by a commenting round, including the applicant, all Member States and EFSA. The addendum was updated in October 2013. A revised Review Report was noted at the Standing Committee on Plants, Animals, Food and Feed in March 2016, which set out residue definitions. Approval conditions remained unchanged.
2. Myclobutanil Approved through Commission Directive 2011/2/EU[2].	The request for confirmatory information concerned the residues of myclobutanil and its metabolites in following growing seasons and information confirming that the available residue data cover all compounds of the residue definition. The confirmatory data were submitted by the applicant within the prescribed deadline.	The assessment was finalised by the rapporteur Member State, Belgium (Addendum of July 2013) and followed by a commenting round, including the applicant, all Member States and EFSA. A revised Review Report was noted at the Standing Committee on Plants, Animals, Food and Feed in January 2016, which set out residue definitions. Approval conditions remained unchanged.
3. Hymexazol Approved through Commission Directive 2011/5/EU[3]	The request for confirmatory information concerned the nature of residues in root crops and the risk for granivorous birds and mammals.	The assessment was finalised by the rapporteur Member State, Finland (Addendum of November 2013) and followed by a commenting round, including all Member States and EFSA.

[1] Commission Directive 2010/92/EU of 21 December 2010 amending Council Directive 91/414/EEC to include bromuconazole as active substance (OJ L 338, 22.12.2010, p. 44).

[2] Commission Directive 2011/2/EU of 7 January 2011 amending Council Directive 91/414/EEC to include myclobutanil as active substance and amending Decision 2008/934/EC (OJ L 5, 8.01.2011, p. 7).

[3] Commission Directive 2011/5/EU of 20 January 2011 amending Council Directive 91/414/EEC to include hymexazol as active substance and amending Decision 2008/934/EC (OJ L 18, 21.1.2011, p. 34)

	The confirmatory data were submitted by the applicant within the prescribed deadline.	A revised review report was noted at the Standing Committee on the Food Chain and Animal Health in December 2014. Approval conditions remained unchanged.
4. Pyridaben Approved through Commission Directive 2010/90/EU[4].	The request for confirmatory information concerned: - the risks for the water compartment resulting from the exposure to aqueous photolysis metabolites W-1 and B-3, - the potential long term risk for mammals, - the assessment of fat soluble residues. The confirmatory data were submitted by the applicant within the prescribed deadline.	The assessment of the confirmatory data was finalised by the rapporteur Member State Netherlands (Addendum of December 2013). EFSA published the peer review in January 2016[5]. A revised Review Report was noted at the Standing Committee on Plants, Animals, Food and Feed in May 2016. Approval conditions remained unchanged.
5. Haloxyfop-p Approved through Commission Directive 2010/86/EU[6].	The request for confirmatory information concerned the groundwater exposure assessment as regards the active substance and its soil metabolites DE-535 phenol, DE-535 pyridinol and DE-535 pyridinone. The confirmatory data were submitted by the applicant with a delay of one month.	The assessment of the confirmatory was finalised by the rapporteur Member State Austria (Addendum of October 2013). EFSA published its conclusions in December 2014[7]. The Commission adopted the Implementing Regulation (EU) 2015/2233 amending the conditions of approval of the active substance haloxyfop-P[8]. Implementing Regulation 2015/2233 restricts the authorisations for rates not exceeding 0,052 kg active substance per hectare per application, and only one application may be authorised every 3 years.
6. Quinmerac Approved under Directive 2010/89/EU[9].	Request for confirmatory information concerned : - the potential of plant metabolism to result in an opening of the quinoline ring; - residues in rotational crops and the long term risk for	The assessment was finalised by the rapporteur Member State UK (Addendum of October 2014) and followed by a commenting round, including the applicant, all Member States and EFSA[10]. A revised Review Report was noted at the Standing Committee on

[4] Commission Directive 2010/90/EU of 7 December 2010 amending Council Directive 91/414/EEC to include pyridaben as active substance and amending Decision 2008/934/EC (OJ L 322, 8.12.2010, p. 38).

[5] https://www.efsa.europa.eu/en/efsajournal/pub/4376

[6] Commission Directive 2010/86/EU of 2 December 2010 amending Council Directive 91/414/EEC to include haloxyfop-P as an active substance (OJ L 317, 3.12.2010, p. 36).

[7] http://www.efsa.europa.eu/en/efsajournal/pub/3931.htm

[8] Commission Implementing Regulation (EU) 2015/2233 of 2 December 2015 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance haloxyfop-P (OJ L 317, 3.12.2015, p. 26)

[9] Commission Directive 2010/89/EU of 6 November 2010 amending Council Directive 91/414/EEC to include quinmerac as active substance and amending Decision 2008/934/EC (OJ L 320, 7.12.2010, p. 3).

[10] http://www.efsa.europa.eu/en/supporting/pub/767e.htm

	earthworms due to the metabolite BH 518-5. The confirmatory data were submitted by the applicant within the prescribed deadlines.	Plants, Animals, Food and Feed in May 2017. Approval conditions remained unchanged.
7. Metosulam Approved under Commission Directive 2010/91/EU[11].	The request for confirmatory information concerned: 1) potential pH dependence of soil adsorption, groundwater leaching and surface water exposure for metabolites M01 and M02; 2) potential genotoxicity of one impurity.' The confirmatory data were submitted by the applicant within the prescribed deadlines.	1) The assessment was finalised by the rapporteur Member State FR. A revised review report of metosulam was noted at the Standing Committee on the Food Chain and Animal Health in November 2012. 2) The assessment was finalised by the rapporteur Member State FR (Addendum of October 2013) and followed by a commenting round, including the applicant, all Member States and EFSA. A revised review report was noted at the Standing Committee on the Food Chain and Animal Health in December 2014. Approval conditions remained unchanged.
8. Napropamide Approved through Commission Directive 2010/83/EU[12].	The request for confirmatory information concerned - the surface water exposure assessment as regards the photolysis metabolites and - the metabolite NOPA and information for the risk assessment of aquatic plants. Confirmatory data were provided by the applicant with some delay because of certain technical difficulties.	The assessment of the confirmatory data submitted was finalised by the rapporteur Member State UK (Addendum of October 2015). EFSA published the outcome of the consultation in February 2016[13] A revised review report was noted at the Standing Committee on Plants, Animals, Food and Feed in July 2017. Approval conditions remained unchanged.
9. Oryzalin Approved by Directive 2011/27/EU[14].	The request for confirmatory information concerned: 1) the specification of the technical material, as commercially manufactured 2) the relevance of the test material used in the toxicity dossiers in view of the specification of the technical	The assessment of the confirmatory information for was finalised by the Rapporteur Member State FR (Addendum June 2012). EFSA conclusions were published in August 2013[15]. A revised review report for oryzalin was noted in the Standing Committee on Food Chain and Animal Health in its meeting of 20

[11] Commission Directive 2010/91/EU of 10 December 2010 amending Council Directive 91/414/EEC to include metosulam as active substance and amending Decision 2008/934/EC (OJ L 327, 11.12.2010, p. 40).

[12] Commission Directive 2010/83/EU of 30 November 2010 amending Council Directive 91/414/EEC to include napropamide as active substance (OJ L 315, 01.12.2010, p. 29).

[13] https://www.efsa.europa.eu/en/supporting/pub/1004e

[14] Commission Directive 2011/27/EU of 4 March 2011 amending Council Directive 91/414/EEC to include oryzalin as active substance and amending Decision 2008/934/EC (OJ L 60, 5.03.2011, p. 12).

[15] http://www.efsa.europa.eu/en/efsajournal/pub/3351.htm

	material; 3) the risk assessment for aquatic organisms; 4) the relevance of the metabolites OR13 and OR15, and the corresponding groundwater risk assessment, provided that oryzalin becomes classified under Regulation (EC) No 1272/2008 as "suspected of causing cancer". The confirmatory data for points 1 to 3 were submitted by the applicant within the prescribed deadlines. The request for confirmatory information regarding the point 4 did not need to be submitted as oryzalin has not been assigned any classification under Regulation (EC) No 1272/2008.	March 2014. Approval conditions remained unchanged.
10. Malathion Approved under Directive 2010/17/EU[16]	The request for confirmatory information concerned: - information confirming the consumer risk assessment and the acute and long-term risk assessment for insectivorous birds; - information on the quantification of the different potency of malaoxon and malathion. Although no regulatory deadline for the submission was set, the requested information was submitted by the applicant within the customary timelines.	The assessment of the confirmatory information was finalised by the rapporteur Member State UK (Addendum dated October 2015). EFSA published the outcome of the consultation in February 2016[17]. A Commission Implementing Regulation amending the conditions of approval of the active substance malathion is in preparation. The draft regulation provides for a restriction to uses in greenhouses with permanent structure.

[16] Commission Directive 2010/17/EU of 9 March 2010 amending Council Directive 91/414/EEC to include malathion as active substance (OJ L 60, 10.03.2010, p. 17).
[17] https://www.efsa.europa.eu/en/supporting/pub/951e