

RMS note and overall conclusion (Ctgb, The Netherlands)

6 March 2020:

The RMS (The Netherlands) has assessed the proposals and statements, waivers and matching reasoning of the applicant.

Conclusion of the RMS is that data matching can be shown sufficiently (depending on Cat. 4 data to be submitted).

This is indicated as follows:

- Accepted data matching study or argumentation
- Accepted Cat.4 studies with **agreed date of submission**
- Argumentation for Cat. 4 or alternative study **not acceptable**. LoA or alternative study must be submitted.

The RMS shall evaluate whether the (cat. 4) studies/statements of the applicant are matching with the studies of the notifier(s) upon submission.

The RMS for the active substance did not consider whether or not data protection applies to all studies for which data protection has been claimed. It is the responsibility of MSs to ensure that data protection standards as laid down in Regulation (EC) No 1107/2009 are respected.

The RMS did not check whether valid Letters of Access were submitted. It is the responsibility of MSs to ensure that appropriate Letters of Access, valid for the respective MSs are available.

The conclusion is stated in the table below, for each aspect.

Details can be found in the data matching tables for each aspect.

Conclusion on data matching for the active substance acetamiprid– dossier Nufarm

Conclusion of the RMS is that data matching can be shown sufficiently (depending on Cat. 4 data to be submitted) (6th March 2020):

Aspect	Is current dossier acceptable for matching?	Cat. 4 data applied for?	Can all Cat. 4 data be granted?	Deadline submission Category 4 data	Conclusion*
Physical and chemical properties	N	Y	Y	30 April 2020	Data matching is possible, pending the final study reports submitted under CA 2.7/05, CA 2.7/07 and CA 4.2/03. <ol style="list-style-type: none"> CA 2.7/05 and CA 2.7/07: a Cat. 4 term of 4 months is granted to generate these studies (Finalization date: end of April 2020). The applicant claims to provide studies for CA 2.7/05 and CA 2.7/07 in Q1-2020 (if study plan is signed) or as soon as possible. CA 4.2/03: a Cat. 4 term of 4 months is granted to generate this study (Finalization date: end of April 2020). Applicant claims that the ILV will be finalized before 1 April 2020.
Toxicology	Y	N	Not applicable	Not applicable	Data matching can be shown sufficiently (all waivers accepted, submitted alternative studies are acceptable)
Residues	Y	N	Not applicable	Not applicable	Member States are advised to pay attention to data points KCA 6.1, KCA 6.3.2/1, KCA 6.3.3/1-4, KCA 6.6.1/1, and KCA 6.6.2/1. These data/studies have to be evaluated in the frame of the product renewal and its intended uses.
Environmental Fate and Behaviour	Y	N	Not applicable	Not applicable	Data matching can be shown sufficiently (all argumentation accepted, submitted alternative studies are acceptable)
Ecotoxicology	Y	N	Not applicable	Not applicable	Data matching can be shown sufficiently (all argumentation accepted, submitted alternative studies are acceptable)