

Annex A – Further information related to the implementation of the scientific criteria for the determination of the endocrine properties – Metiram

During the AIR3 process for metiram, on February 22nd, 2019, Ref. MT/BV/mc(2019)-out-20966708, BASF SE was informed that - after the consultation with the RMS and the other Member States - EFSA was able to conclude that the scientific criteria for the determination of the endocrine properties for metiram are met. A justification of this conclusion was also submitted to the applicant.

The process foresees that the applicant should be informed and should be given the possibility to demonstrate that metiram may be used such that exposure is negligible and/or should submit evidence for the application of the derogation under Art. 4.7 of Regulation (EC) No 1107/2009.

BASF SE is still of the opinion that no firm conclusion could be taken for metiram, both for toxicology and for ecotoxicology area. Justifications are reported respectively into BASF Doc Id 2019/1075961 and BASF Doc Id 2019/1075962.

Despite the different opinion, BASF SE submits an amendment to the AIR 3 dossier, to demonstrate that the exposure of metiram, via the representative formulation BAS 222 28 F on potato is negligible when evaluated under the provision of the Technical Guidance Sanco 2014-12096.

Moreover, BASF SE collected the information requested by the protocol for the evaluation of data concerning the necessity of the application of fungicide active substances to control a serious damage to plant health which cannot be contained by other available means, including non-chemical methods.

The analysis has been performed for all the EU Member States where metiram is registered.

In some cases, there are reported also active ingredient which are no longer authorized, no longer used in practice for different reasons (no efficacy, phytotoxicity effects, etc.), those substances have been excluded from the calculations.

According to BASF's views, for different crop/pathogen combination in some countries there are no alternatives to protect the crops and to manage resistance.