

Cyprodinil

NOTIFICATION OF AN ACTIVE SUBSTANCE UNDER COMMISSION REGULATION (EU) 844/2012

DOCUMENT F

STATEMENT OF INTENTION TO SUBMIT A DOSSIER

COPY OF COVERING LETTER ACCOMPANYING SYNGENTA LTD APPLICATION FOR THE RENEWAL OF THE APPROVAL OF CYPRODINIL MADE UNDER COMMISSION REGULATION (EU) 844/2012:



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29 April 2014

EFSA
European Food Safety Authority (EFSA), Pesticide Risk Assessment (PRAPeR)
Attention of Ms. K. Lheureux
Via Carlo Magno 1A
IT-43126-Parma

Italy

“AIR-3” Application Cyprodinil

Dear Ms. Lheureux

Please find enclosed Syngenta’s application for the renewal of approval of the active substance cyprodinil in accordance with Commission Implementing Regulation (EU) No 844/2012 of 18th September 2012 and Commission Implementing Regulation (EU) No 686/2012. This application has also been sent to the RMS (France) and to the co-RMS (Bulgaria).

Syngenta at the time of application for renewal expects that the technical dossier will include the studies mention in the application document. However Syngenta would like to state, that if the outcome of ongoing studies indicates to us that a further study or studies are necessary to clarify the conclusions these will be added as circumstances allow.

Syngenta has also made diligent efforts to identify those studies, generated since the publication of the monograph and prior to the list of studies identified for the AIR review. However, if it becomes clear from the expert discussions, that an exception has occurred and a relevant study has been overlooked or included into the application although not deemed necessary the application form will be updated to reflect this.

As the application might get published, I took the liberty to also provide a sanitized version of the application form. In this document we claim confidentiality for some parts, i.e. for information and data relating to personal contacts.

Syngenta File no: CGA219417_11539



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For your convenience I also enclose a copy of the Commission Review Report (SANCO/10014/2006-Final rev 1 of 9 July 2010).

Please do not hesitate to contact me if you have any questions.

Yours sincerely,

A handwritten signature in blue ink, appearing to read "S. Micheletti". The signature is written in a cursive style with a large, stylized initial "S".

Sebastien Micheletti
Regulatory Affairs Manager

COPY OF THE APPLICATION FOR RENEWAL, MADE UNDER COMMISSION REGULATION (EU) No. 844/2012 ARTICLE 2(1) AND IN ACCORDANCE WITH THE FORMAT PROVIDED IN ANNEX I OF COMMISSION REGULATION (EU) No. 844/2012:

Please refer to the enclosed **Document F** report (*Micheletti S., 2014*).

Report:	Document F/02, Micheletti S. (2014). Cyprodinil Application for Renewal under Commission Regulation (EU) No. 844/2012, Syngenta Crop Protection AG, Basel, Switzerland. (Syngenta File No. CGA219417_11542)
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