

Document Title

Document A

Statement of the context in which the dossier is submitted for

Flupyradifurone (BYI 02960)

Data Requirements

**Regulation (EC) No 1107/2009
Regulatory Directive 2003-01/Canada/PMRA
OPPTS guidelines/US/EPA**

According to OECD format guidance for industry data submissions
on plant protection products and their active substances

Date

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Statement

Statement of the context in which the dossier is submitted

This dossier is submitted to the Dutch authority Ctgb as Rapporteur Member State for the EU in order to support to the approval of the active substance Flupyradifurone (BYI 02960) according to EC Regulation 1107/2009.

The Annex II dossier for the active substance is therefore supported by an Annex III dossier to show the safe use scenarios for the formulation Flupyradifurone 200 SL on hops, lettuce field and lettuce greenhouse.

Trade name for the formulations has been determined as “Sivanto” plus suffix. The product has not yet been submitted to any other country and therefore, no labels are yet available. A generic label can be provided.

Beyond, Flupyradifurone will undergo an international Global Joint Review comprising the agencies EPA, USA; PMRA, Canada; APVMA, Australia; ANVISA/IBAMA, Brazil and Mexico. China agreed to participate in the role of an observer and The Netherlands also accorded to be an observer, since Ctgb agreed to evaluate the residues from the GJR countries outside the EU together with all intended uses in the EU with the aim to establish mutually agreed Import Tolerances and MRLs allowing international trade of treated commodities throughout the world and to avoid trade barriers between the EU and the GJR-partners.

The submission of the Annex II dossier and the different Annex III dossiers for the GJR partner countries is scheduled for July 2012.