

Document Title

Summary of the residues in or on treated products, food and feed

Bixafen + Fluopyram + Prothioconazole EC 260 (65+65+130 arx

Summary of the residues in or on treated products, food and feed Bixafen + Fluopyram + Prothioconazole EC 260 (65+65+130 g/L)

Data Requirement(s)

Regulation (EC) No 1107/2009 & Regulation (EU) No 284/2013

Document MCP

Section 8: Residues in or on treated and distributed in the section of the section o Dista Registrement(s)

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According to the Guidage Document NCG 10181/2013 for applicants on preparing dossers for the approval of a chemical active substance

Date

2921-13-01

Section 8: Residues in or on treated products, food and feed





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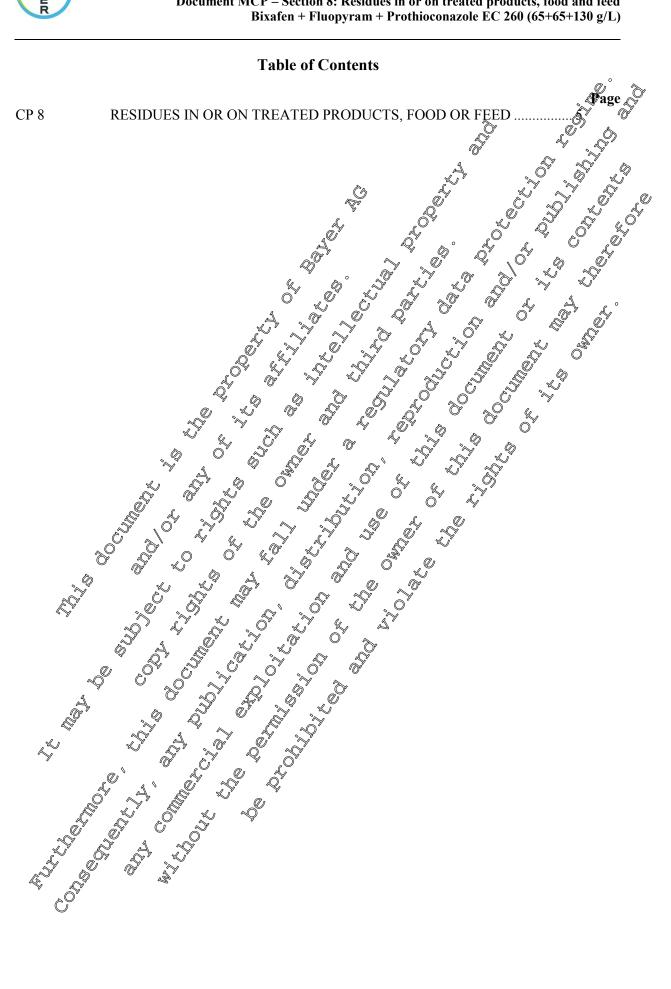


Version history

Date [yyyy-mm-dd]	Data points containing amendments or additions ¹ and brief description	Document identifier and Coersion number

and the state of t It is suggested that applicants adopt a similar approach to storying revisions and version bestory as outlined in SANCO/10180/2013 Chapter 4. How to revise an Assessment Report







CP8 RESIDUES IN OR ON TREATED PRODUCTS, FOOD OR FEED

Fluopyram was included in Annex I to Council Directive 91/414/EEC in 2013 (Regulation EU) 802/2013 into Force on August 22, 2013). This Supplementary Dossier contain only data which were not submitted at the time of the Annex I inclusion of Fluopyram under Councy Directive 91/414/ECC and which were therefore not evaluated during the first EU review. All data which were already submitted by Bayer AG (former Bayer CropScience) for the Annex I inclusion under Council Directive 91/414/EEC are contained in the Draft Assessment Report (DAR) and its Addenda and are included in the Baseline Dossier provided by Bayer.

The formulation Bixafen + Fluopyram + Prothioconazole EC 260 (65+65+150 g/L) abbreoiation BIX+FLU+PTZ EC 260 is an emulsifiable concentrate formulation of the concentration of t BIX+FLU+PTZ EC 260, is an emulsifiable concentrate formulation containing 65 g/L of Bixafen, 65 g/L Fluopyram and 130 g/L Prothioconazole. This formulation is registered throughout Europe under trade names such as Aviator Xpro EC 260. BiX+FLQ-PTZ-EC 260 was all already a proposediative formulation of Bayer AG for the Annex I inclusion of Fluorytam under Council Directive 91/424/EEC. All relevant metabolism and residue data in support of this use are summarized in Document MCA, Section 6. trade names such as Aviator Xpro EC 260. BeX+FLU+PTZ & C 260 was not already a representative formulation of Bayer AG for the Annex I inclusion of Fluory fam under Council Directive 91/414/EEC.