



Document Title

**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 products, food and feed**

According to the Guidance Document SANCO/10181/2013 for applicants  
on preparing dossiers for the approval of a chemical active substance

Date

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[Redacted]

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### Version history

Date [yyyy-mm-dd]	Data points containing amendments or additions <sup>1</sup> and brief description	Document identifier and Version number

<sup>1</sup> It is suggested that applicants adopt a similar approach to showing revision and version history as outlined in SANCO/10180/2013 Chapter 4, 'How to revise an Assessment Report'

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## CP 8 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 contains only data which were not submitted at the time of the Annex I inclusion of Fluopyram under Council Directive 91/414/EEC 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+130 g/L) (abbreviation 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+FLU+PTZ EC 260 was not already a representative formulation of Bayer AG for the Annex I inclusion of Fluopyram under Council Directive 91/414/EEC.

All relevant metabolism and residue data in support of this use are summarized in Document MCA, Section 6.

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