Summary of the residues in or on treated products, food and feed with regard to the representative formulation isoxaflutole + cyprosulfamide SC 480 (240+240g/L) 

Data Requirements
EU Regulation 1107/2009 & EU Regulation 284/2013

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

According to the guidance document, SANCO 10181/2013, for preparing dossiers for the approval of a chemical active substance.

Date 2013-11-29

Author(s) Bayer CropScience

M-472501-01-3

This document is the property of Bayer AG and/or any of its affiliates. Furthermore, this document may fall under an intellectual property or regulatory data protection regime. Consequently, any publication, distribution and/or publishing and any commercial exploitation and use of this document or its contents and/or any publication, distribution and/or publishing and any commercial exploitation and use of this document or its contents without the permission of the owner may therefore be prohibited and violate the rights of the owner.
OWNERSHIP STATEMENT

This document, the data contained in it and copyright therein are owned by Bayer CropScience. No part of the document or any information contained therein may be disclosed to any third party without the prior written authorisation of Bayer CropScience.

The summaries and evaluations contained in this document are based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either:

- From Bayer CropScience; or
- From other applicants once the period of data protection has expired.
### Version history

<table>
<thead>
<tr>
<th>Date</th>
<th>Data points containing amendments or additions(^1) and brief description</th>
<th>Document identifier and version number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report
CP 8 RESIDUES IN OR ON TREATED PRODUCTS, FOOD OR FEED

The formulation IFT + CSA SC 480 (also called Merlin® Flexx) is a suspension concentrate (SC) containing 240 g/L of isoxaflutole and 240 g/L of the safener cyprosulfamide. IFT + CSA SC 480 is intended to be used until growth stage BBCH 13 on maize and in pre-emergence on sweet corn at rates up to 100 g isoxaflutole/ha and 100 g cyprosulfamide/ha.

The uses of the formulation IFT + CSA SC 480 on maize and sweet corn are the representative uses supported in the Annex II dossier for isoxaflutole renewal. Please refer to document M section KCA 6 of the Annex II dossier for isoxaflutole renewal where all relevant metabolism and residue data in support of these uses are summarized.

Based on the available information on isoxaflutole, it can be concluded that the use of the formulation IFT + CSA SC 480 on maize and sweet corn according to the supported GAPs is unlikely to present a public health concern.