

REASONED OPINION

Modification of the existing MRL for bentazone in sweet corn¹

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SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, France received an application from BASF AGRO SAS to modify the existing MRL for bentazone in sweet corn. In order to accommodate the intended use of the active substance in France, the existing MRL for sweet corn which is currently set at the LOQ of 0.1 mg/kg should be raised. The EMS France drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 18 January 2010.

EFSA derives the following conclusions regarding the application, based on the above mentioned evaluation report as well as the Draft Assessment Report prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC.

The toxicological profile of bentazone was investigated under the peer review of Directive 91/414/EEC and an ADI of 0.1 mg/kg bw/d and an ARfD of 0.25 mg/kg bw were derived.

The nature of bentazone residues in primary plants is elucidated in three crop categories: cereals, root and tuber vegetables and pulses and oilseeds. The peer review concluded that metabolism data are sufficient to propose a general risk assessment and enforcement residue definition in plant commodities as “*the sum of bentazone and the conjugates of 6-hydroxy and 8-hydroxy bentazone expressed as bentazone equivalent*”. EFSA concludes that the metabolic pattern of bentazone in maize (sweet corn) is sufficiently addressed and no further studies are required. Adequate analytical enforcement methods are available to control the compliance of the proposed MRL for bentazone in sweet corn.

The submitted residue trials data indicate that an MRL of 0.3 mg/kg would be required to accommodate the intended use of bentazone on sweet corn in France.

The nature of bentazone residues during processing has not been investigated. The applicant did not submit specific studies investigating the effect of processing on the magnitude of bentazone residues in processed sweet corn. Such studies, however, are not considered necessary taking into account the low contribution of sweet corn to the total dietary intake.

The possible occurrence of bentazone residues in rotational crops was also investigated. It is concluded that residue levels exceeding the current LOQ of 0.1 mg/kg will not occur in rotational

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and/or succeeding crops planted after sweet corn provided that bentazone is applied according to the intended GAP.

Sweet corn is not a livestock feed and therefore the nature and magnitude of bentazone residues in livestock was not investigated under the current application.

The consumer exposure assessment was performed with revision 2 of the EFSA PRIMo. For the chronic exposure assessment the STMR value for sweet corn as derived from the residue trials as well as the existing MRLs established for other commodities in Annexes II and III of Regulation (EC) No 396/2005, were used as input values. The acute exposure assessment was performed only with regard to sweet corn and the HR value as derived from the supervised residue field trials was used as an input value. The calculated exposure was compared with the toxicological reference values as derived for bentazone.

No long-term consumer health concerns were identified for any of the European diets. The total calculated exposure values accounted for a maximum of 4.6% of the ADI. The contribution of residues in sweet corn to the total exposure is insignificant (maximum 0.007% of the ADI for IE adult diet).

No short-term consumer health concerns were identified in relation to the intake of sweet corn (6.2% of the ARfD).

EFSA concludes that the intended use of bentazone on sweet corn is acceptable with regard to consumer safety as no acute or chronic consumer health concerns were identified.

Food code ^a	Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: <i>the sum of bentazone and the conjugates of 6-hydroxy and 8-hydroxy bentazone expressed as bentazone</i>				
0234000	Sweet corn	0.1*	0.3	The MRL proposal is sufficiently supported by data and no consumer intake concerns were identified.

(*): Indicates that the MRL is set at the limit of analytical quantification.

^a – according to Regulation (EC) No 396/2005.

KEY WORDS

Bentazone, sweet corn, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, herbicide, 6-hydroxy-bentazone, 8-hydroxy-bentazone