REASONED OPINION

Modification of the existing MRLs for thiamethoxam in carrots[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

According to Article 6(2) of the Regulation (EC) No 396/2005, The Netherlands received an application from Syngenta Crop Protection BV to modify the existing MRL for thiamethoxam in carrots. In order to accommodate the intended GAP in The Netherlands, the applicant proposes to raise the existing MRL of 0.1 mg/kg to 0.3 mg/kg. The Netherlands as the Evaluating Member State (EMS) 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 29 May 2009.

EFSA derives the following conclusions regarding the application based on the above mentioned evaluation report and the Draft Assessment Report prepared by Spain in the framework of the peer review.

In the peer review the metabolism of thiamethoxam was investigated in four crop groups following three different application modes. The peer review concluded that for the representative uses evaluated under the peer review thiamethoxam and its metabolite clothianidin (CGA 322704) are relevant residues. Therefore the risk assessment and enforcement residue definition was established as "sum of thiamethoxam and CGA 322704, expressed as thiamethoxam". Regarding carrots, the most representative metabolism study from the peer review is the metabolism study in potatoes after the seed treatment. The study indicates that the parent is the major residue of concern in roots/tubers. EFSA concludes that metabolism of thiamethoxam in carrots would proceed in a similar pathway as in potatoes and therefore no additional metabolism studies in carrots are required. Adequate analytical methods are available to enforce the proposed MRL in carrots.

Submitted supervised field trials indicate that a higher MRL of 0.3 mg/kg would be necessary to accommodate the intended GAP in The Netherlands.

Residue occurrence in rotational crops was also investigated under the current application, since carrots can be grown in rotation with other crops and since the active substance and several of its metabolites show slow degradation in the soil. Considering the proposed application rates of thiamethoxam and the mode of application, EFSA concludes that significant residue levels in rotational crops are not expected, provided that thiamethoxam is applied according to the proposed GAP.

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Carrots are not a common livestock feeding item, therefore nature and magnitude of thiamethoxam residues in livestock was not considered under the current MRL application.

Consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs as established in Regulation (EC) No 396/2005 as well as the STMR value as derived for the intended use on carrots as input values. Acute intake assessment for carrots was performed with the HR value as derived from the supervised field trials.

No chronic intake concerns were identified for any European diets. Total calculated intake values ranged from 5.8 – 26.6% of the ADI. The contribution of carrots to the total dietary intake is insignificant amounting for a maximum of 0.41 % of the ADI for French infant diet. No acute intake concerns were identified with regard to carrots (2.3 % of the ARfD).

Consequently EFSA concludes that the intended use of thiamethoxam on carrots is acceptable with regard to consumer safety.

RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Thiamethoxam and CGA 322704, expressed as thiamethoxam			
Carrots	0.1	0.3	The MRL proposal is supported by data and no risk for consumers was identified for the proposed use.

KEY WORDS

Thiamethoxam, carrots, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, neonicotinoids insecticide, clothiadin (CGA 322704)