REASONED OPINION

Modification of the existing MRLs for abamectin in apricots and peaches (including nectarines)[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, France, herewith referred as the evaluating Member State (EMS), received an application from Syngenta Agro SAS to modify the existing MRLs for the active substance abamectin in peaches, including nectarines and apricots. In order to accommodate for the intended uses of abamectin, it is proposed to raise the existing MRLs from the limit of quantification value of 0.01 mg/kg to 0.02 mg/kg. 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 24 March 2010.

EFSA derives the following conclusions regarding the application, based on the above mentioned Evaluation Report, the EFSA conclusion in the framework of the peer review, the Draft Assessment Report prepared under Directive 91/414/EEC and the JMPR reports.

The toxicological profile of abamectin was investigated under the peer review and the data were sufficient to conclude on an ADI value of 0.0025 mg/kg bw/day and an ARfD value of 0.005 mg/kg bw.

The metabolism of abamectin in plants was investigated in three crop categories (fruits and fruiting vegetables, leafy vegetables and pulse and seeds) and resulted essentially qualitative similar in all tested crops. Avermectin B_{1a} degraded rapidly, thus forming a variety of products. The only residues of toxicological significance were abamectin (a mixture of two components: avermectin B_{1a} and B_{1b}, the first being the major component) and the degradation product 8,9-Z-isomer (also named δ-8,9 isomer) of avermectin B_{1a}, therefore the residue definition for risk assessment was established as "*abamectin*, sum *of avermectin* B_{1a}*, avermectin* B_{1b} *and δ-8,9 isomer of avermectin* B_{1a}". The same residue definition applies for monitoring purposes. Adequate analytical methods are available to enforce the proposed MRLs in the crops under consideration according to the residue definition.

The submitted supervised residue field trials on peaches were sufficient to derive a MRL proposal for abamectin on peaches, which can be extrapolated to apricots. These data indicated that a higher MRL of 0.02 mg/kg would be necessary to accommodate for the intended uses of abamectin.

The occurrence of abamectin residues in rotational crops was not assessed in the framework of this evaluation since the crops under consideration are perennial and not grown in rotation.

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2 Correspondence: praper.mrl@efsa.europa.eu

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The nature and magnitude of residues in commodities of animal origin was also not relevant because peaches, nectarines and apricots are not livestock feeding items.

The effect of processing on the nature of abamectin has been evaluated under the framework of the peer review and for processed commodities the same residue definition as for raw agricultural commodities is applicable. Specific studies investigating the effect of processing on the magnitude of abamectin in apricots and peaches are not necessary as no significant residues occur in the fruits to be processed.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo, Pesticide Residues Intake Model. For the chronic intake assessment EFSA used the STMR value derived from the submitted supervised residue trials. For the remaining crops, the existing MRLs as established in Annex II and IIIB of Regulation (EC) No 396/2005 were used. The acute intake assessment was performed only with regard to the crops under consideration applying the highest residue (HR) value as derived from the supervised residue trials. The estimated long-tem and short-term exposures were compared with the ADI and the ARfD, respectively.

No long-term consumer risk was identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated dietary intake ranged from 5 to 24 % of the ADI. For the crops under consideration, the contribution to the total abamectin consumer exposure was low. No acute consumer risk was identified in relation to the MRL proposals for peaches, nectarines and apricots. The calculated maximum exposure of children and adults was 12 % and 3.5 % of the ARfD for peaches and 6.2 % and 1.5 % of the ARfD for apricots, respectively.

Consequently, EFSA concludes that the intended use of abamectin on apricots and peaches, including nectarines and similar hybrids, will not result in an exceedance of the toxicology reference values and derived the following recommendations:

Code number	Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: abamectin (sum of avermectin B_{1a}, avermectinB_{1b} and δ-8,9 isomer of avermectin B_{1a})				
140010	Apricots	0.01*	0.02	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses. The proposed MRL for apricots is based on studies on peaches.
140030	Peaches (Nectarines and similar hybrids)	0.01*	0.02	

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

KEY WORDS

Abamectin, peaches, nectarines, apricots, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, macrocyclic lactones, avermectin (AVM) B_{1a}, avermectin (AVM) B_{1b}, δ-8,9 isomer of avermectin B_{1a}.