5.28 SEDAXANE (259)

RESIDUE AND ANALYTICAL ASPECTS

Sedaxane was first evaluated by the JMPR in 2012. The 2012 Meeting concluded that the residue definition for MRL compliance and estimation of dietary intake is sedaxane. An ADI of 0–0.1 mg/kg bw and an ARfD of 0.3 mg/kg bw were established. The residue was determined to be fat-soluble. The 2012 Meeting noted that none of the uses resulted in residues in human foods and that those uses are unlikely to present a public health concern.

The Forty-fifth Session of the CCPR listed sedaxane for the evaluation of additional MRLs. The 2014 Meeting received information on GAP and supervised residue trials reflecting the use of sedaxane as a seed treatment on corn/maize, pulses, potatoes, and sorghum. In addition to evaluating those crops, the Meeting was asked to consider use on rice, without residue data, on the basis of residue data supplied to the 2012 and 2014 Meetings for other grains.

Methods of analysis

Acceptable analytical methods were developed and validated for determination of sedaxane and its metabolites in plant and animal matrices. The methods were evaluated by the 2012 Meeting. The reported LOQ for the sedaxane *cis* and *trans* isomers, each, was 0.005 mg/kg, while the LOQ for all metabolites was 0.01 mg/kg in all matrices (plant and animal).

Results of supervised residue trials on crops

Supervised residue trials submitted for evaluation were as seed treatments and were conducted in Canada and/or the USA. All of the trials submitted to the 2014 Meeting are supported by storage stability data evaluated by the 2012 Meeting. Residue values listed below reflect the average for each field trial, unless otherwise noted.

Sweet corn

The critical GAP for sweet corn is from the USA at 40 g ai/100 kg seed. In 13 trials, conducted at rates ranging from 29.7 to 51.2 g ai/100 kg seed, residues of sedaxane were < 0.01 mg/kg in all samples.

Based on the results of previously evaluated metabolism data from wheat (2012 Meeting) and on the results of the submitted residue trials, the Meeting agreed that no sedaxane residues are expected in sweet corn (corn-on-the-cob).

The Meeting estimated a maximum residue level of 0.01* mg/kg for sedaxane on sweet corn (corn-on-the-cob), an HR of 0.01 mg/kg and a STMR of 0 mg/kg.

Pulses (Beans, dry and peas, dry)

The critical GAP for beans, dry and peas, dry is from Canada and the USA for use as a seed treatment at a rate of 5 g ai/100 kg seed.

Eleven trials were conducted on dry bean matching GAP in Canada (5) and the USA (6), with an additional two trials in the USA conducted at approximately a 2.5-fold exaggerated rate.

Ten trials were conducted on dry pea matching GAP in Canada (8) and the USA (2).

Sedaxane residues in harvested dry beans and dry peas from all trials (n=21), including the exaggerate-rate trials, were: < 0.01 mg/kg. Based on the results of previously evaluated metabolism data from soya beans (2012 Meeting) and on the results of the submitted residue trials, the Meeting agreed that no sedaxane residues are expected in pulses.

The Meeting estimated a maximum residue level of 0.01* mg/kg for sedaxane on pulses and an STMR of 0 mg/kg. The Meeting recommended that the individual MRL for soya bean, dry be withdrawn.

Potato

The critical GAP for potato is from Canada, as a seed-piece treatment, at a rate of 2.5 g ai/100 kg seed. Twenty-nine trials were conducted matching GAP in Canada (13) and the USA (16). Three additional trials were conducted in the USA; one at approximately a 0.4× rate and two at approximately a 2× exaggerated rate.

Sedaxane residues in harvested tubers from all at-GAP trials (n=29) were: $\underline{< 0.01}$ (28) and 0.018 mg/kg.

The Meeting estimated a maximum residue level of 0.02 mg/kg for sedaxane on potato, an STMR of 0.01 mg/kg, and an HR of 0.02 mg/kg (from a single sample).

Cereal Grains

Maize and popcorn

The critical GAPs are from Chile for maize (50 g ai/100 kg seed) and from the USA for popcorn (40 g ai/100 kg seed). No trials from Chile were provided; however, data from 15 trials with rates ranging from 40–51.2 g ai/100 kg seed were available from the USA depicting residues of sedaxane in maize. In addition, there are two trials conducted at an exaggerated rate of 120 g ai/100 kg seed.

Sedaxane residues in maize from all trials (n=15) were: < 0.01 mg/kg.

Sorghum

The critical GAP for sorghum is from Canada and the USA as a seed treatment at a rate of 5 g ai/100 kg seed. Twelve trials were conducted at an 8-fold exaggerated rate (ca. 40 g ai/100 kg seed) in the USA, of which ten were determined to be independent.

Sedaxane residues in sorghum grain from all trials (n=10) were: < 0.01 mg/kg.

The Meeting noted that while there are no GAP registrations for cereal grains as a group, there are GAPs around the world with GAPs covering the major cereal grain commodities. Based on the results of previously evaluated metabolism data from wheat (2012 Meeting) and on the results of the submitted residue trials for maize and sorghum, the Meeting agreed that no sedaxane residues are expected in cereal grains.

The Meeting estimated a maximum residue level of 0.01* mg/kg for sedaxane on cereal grains and an STMR of 0 mg/kg, and recommends that the individual MRLs for barley, oats, rye, triticale, and wheat be withdrawn.

Legume animal feeds

The critical GAP is for beans, peas, and lentils from Canada and/or the USA is as a seed treatment at a rate of 5 g ai/100 kg seed. Fifteen trials were conducted matching GAP in Canada and the USA from which forage and/or hay were harvested. An additional trial was conducted in the USA at approximately a 2.5-fold exaggerated rate.

Sedaxane residues in bean and pea forage (n=5) and hay (n=16) from all trials, including the exaggerate-rate trial, were: < 0.01 mg/kg.

The Meeting estimated a maximum residue level of 0.01* mg/kg and a median residue of 0 mg/kg for sedaxane in bean fodder and pea hay or pea fodder (dry).

The Meeting estimated a highest residue of 0.01 mg/kg and a median residue of 0 mg/kg for sedaxane in bean fodder and pea vines.

Straw, fodder, and forage of cereal grains

The critical GAP for maize is from Chile as a seed treatment at a rate of 50 g ai/100 kg seed. Nineteen trials (15 independent) were conducted at GAP in Canada and the USA from which fodder (stover) and/or forage were harvested.

Sedaxane residues in maize fodder (stover; n=15) and forage (n=15) were: < 0.01 mg/kg.

The critical GAP for sorghum is from the USA and Canada as a seed treatment at a rate of 5 g ai/100 kg seed. Twelve trials were conducted at an 8-fold exaggerated rate (ca. 40 g ai/100 kg seed) in the USA, of which ten were determined to be independent.

Sedaxane residues in sorghum forage and stover (n=10) were: < 0.01 mg/kg.

The 2014 Meeting estimates for sorghum forage (dry), a highest residue of 0.01 mg/kg, and a median residue of 0 mg/kg.

The 2012 Meeting estimated residues of sedaxane in barley, oats, rye, triticale, and wheat straw and fodder, on an as-received basis at 0.075 mg/kg (HR) and 0.01 mg/kg (STMR). In estimating those residues, the 2012 meeting noted that these commodities are not always readily distinguishable in trade and the preference for having a common MRL.

Based on the rationale of the 2012 Meeting and on the results from the maize and sorghum residue trials, the 2014 Meeting agreed to estimate residues of sedaxane in straw, fodder of cereal grains and grasses (including buckwheat fodder) (straws and fodders, dry at a maximum residue level of 0.1 mg/kg.

The Meeting estimates a highest residue of 0.075 mg/kg, and a median of 0.01 mg/kg (as received).

The Meeting withdraws its previous recommendations for straw and fodder (dry) of barley, oat, rye, triticale, and wheat.

Fate of residue during food processing

Residues of sedaxane are stable to hydrolysis (2012 JMPR).

The Meeting received processing studies for corn and potato. In the corn study, residues of sedaxane were < 0.01 mg/kg in all commodities.

Raw agricultural commodity (RAC)	STMR, mg/kg	Processed commodity	Processing factor	STMR-P, mg/kg
Potato tuber	0.01	Flakes/granules	0.83	0.0083
		Chips	0.57	0.0057
		Wet peel	4.27	0.0427

Residues in animal commodities

The 2014 Meeting evaluated sedaxane residues in animal feed items from pulses, cereal grains (corn, rice, and sorghum), and potato in addition to the feed items evaluated by the 2012 Meeting (cereal grains) as listed in the OECD feeding table.

Estimated maximum and mean dietary burdens of livestock

Estimated dietary burdens for Australia, the EU, Japan, and the US/Canada are summarized below. The livestock diets are summarized in Annex 6 to the 2014 Report.

Livestock Dietary Burdens (ppm of dry matter diet) for Sedaxane.

	Australia		EU		Japan		US/Canada	
Livestock	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Cattle (beef)	0.106	0.057	0.199	0.169	0.006		0.150	0.126
Cattle (dairy)	0.090	0.039	0.168	0.136	0.014		0.080	0.054
Poultry (broiler)			0.010	0.008				
Poultry (layer)			0.023	0.012				

For all livestock, the sedaxane burdens based on the EU animal diets (bold values in the table) reflect the highest burdens for both MRL estimation (maximum diet) and STMR estimation (mean diet).

Animal commodities residue level estimation

In a cattle feeding study evaluated at the 2012 Meeting, residues in all commodities were < 0.01 mg/kg at all dose levels (0.11–2.2 ppm). The 2012 Meeting estimated a maximum residue level of 0.01* mg/kg and STMR and HR values of 0 mg/kg for mammalian commodities.

The 2014 Meeting confirms the previous recommendations.

In a poultry metabolism study evaluated by the 2012 JMPR Meting, laying hens were dosed at a rate equivalent to 20 ppm (dry matter basis) in their diet. Sedaxane was < 0.01 mg/kg in all tissues at that dose level. Based on the results of that study, the 2012 Meeting estimated a maximum residue level of 0.01* mg/kg and STMR and HR values of 0 mg/kg for poultry commodities.

The 2014 Meeting confirms the previous recommendations.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *sedaxane*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of sedaxane were calculated for the 17 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current and previous Meetings. The ADI is 0–0.1 mg/kg bw and the calculated IEDIs were 0–0% of the maximum ADI (0.1 mg/kg bw). The Meeting concluded that the long-term intakes of residues of sedaxane, when used in ways that have been considered by the JMPR, are unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of sedaxane were calculated for food commodities and their processed commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by

the current Meeting. The ARfD is 0.3 mg/kg bw and the calculated IESTIs were 0% of the ARfD for all commodities. The Meeting concluded that the short-term intake of residues of sedaxane, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.