

5.29 TRIFLOXYSTROBIN (213)

RESIDUE AND ANALYTICAL ASPECTS

Trifloxystrobin was first evaluated by the JMPR in 2004 (T, R) and in 2012 (R). The 2004 Meeting established an ADI of 0–0.04 mg/kg bw and decided that ARfD was not necessary. The Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin per se, for animal commodities and dietary intake assessment the residue definition should be parent compound and CGA 321113 (expressed as trifloxystrobin equivalents) for plant and animal commodities.

Trifloxystrobin was listed by the Forty-sixth Session of CCPR (2014) for the evaluation by the 2015 JMPR for additional MRLs. Supervised trials data were submitted for evaluation on dry soya bean, lentil, chick pea and pea.

Analytical methods used for supervised trials were also provided.

Analytical methods

The Meeting received descriptions and validation data for analytical methods for residues of trifloxystrobin, CGA 321113 and several other metabolites in different plant matrices.

The plant materials are generally extracted with a mixture of acetonitrile/water. After filtration and concentration to the aqueous remainder, the acidified crude extract is purified, where necessary, by liquid-liquid partition. The residues are quantified by reverse-phase HPLC with MS/MS-detection. The average recoveries of trifloxystrobin and CGA 321113 and their relative standard deviations from test portions spiked at 0.01–2 mg/kg levels were for peas (100–101%, 3.1–4.7%) and soya beans (86–91%, 6.4, 19%). The limits of quantification ranged between 0.01–0.02 mg/kg.

The DFG method S19, evaluated in 2004, is suitable for enforcement.

Residues resulting from supervised trials on crops

The sum of trifloxystrobin and CGA 321113 was calculated and expressed as trifloxystrobin on the basis of the relative molecular masses. A conversion factor of 1.036 is required to express CGA 321113 as trifloxystrobin. As CGA 321113 does not generally constitute a significant proportion of the residue in crops, when the levels of trifloxystrobin or CGA 321113 were below the LOQ, their sum was calculated according to the method used by the 2004 JMPR.

| Trifloxystrobin (mg/kg) | CGA 321113 (mg/kg) | Total (expressed as trifloxystrobin) (mg/kg) |
|-------------------------|--------------------|--|
| < 0.01 | < 0.01 | < 0.01 |
| < 0.01 | 0.011 | 0.021 |
| 0.10 | < 0.02 | 0.10 |
| 0.92 | 0.16 | 1.1 |

In field trials duplicate samples were taken from each treated plot. Of the duplicate results the non-detected residues were disregarded in the calculation of average residue. As a conservative approach, if the residues measured were 0.015 and < 0.01, the calculated average was taken as 0.015 mg/kg.

Pulses

Soya bean

The GAP in Canada allows maximum 2 times 0.0625 kg/ha treatment with a 20 day PHI. In 4 trials conducted according to GAP the residues in soya bean seeds were < 0.01 mg/kg (4).

The Brazilian GAP permits up to 4 treatments with 0.060 kg/ai/ha or 2 treatments with 0.075 kg ai/ha with a PHI of 20 days. Following treatment according to GAP the trifloxystrobin

residues were below the LOQ (< 0.01 or < 0.02 mg/kg). CGA 321113 residues occurred in seven samples at 0.01–0.02 mg/kg level.

The US GAP permits 3 applications at rates between 0.0913–0.127 kg ai/ha and a PHI of 21 days. In 2003 a total of 20 trials were conducted in the USA applying trifloxystrobin three times at rates of 0.086–0.095 kg ai/ha. In addition, another 20 trials were performed in 2005 with application rates of 0.13 kg ai/ha and samples were taken at 21 days. Duplicate samples were taken from each site.

The US use patterns represent the critical GAP. The nominal application rates in US trials are within $\pm 25\%$ of the GAP. The residues of parent compound in rank order were: < 0.01 (28), 0.01 (4), 0.012, 0.014, 0.016 (2), 0.021, 0.027, and 0.041 mg/kg.

The sum of residues were in rank order: < 0.01 (24), 0.012 (4), 0.021 (2), 0.023 (2), 0.024, 0.025, .026, 0.027, 0.039, 0.043, 0.057 and 0.058 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg for trifloxystrobin in soya beans, and an STMR residue of 0.01 mg/kg for the sum of trifloxystrobin and CGA 321113.

Beans and peas, dry

The use of trifloxystrobin in/on dry pea, chickpea and lentil is registered in Canada and the USA.

Nine trials were conducted on dry peas and nine trials on dry beans according the GAP in Canada (1-2 application with 0.132 kg ai/ha, the PHI is 30 days). Duplicate samples were taken at each sampling interval.

In beans, the average residues of trifloxystrobin at about 30 days were < 0.01 mg/kg in all (9) samples.

The sum of trifloxystrobin and CGA 321113 residues expressed as trifloxystrobin were in rank order: < 0.01 (5), 0.021 (2), 0.022, and 0.023 mg/kg.

In peas, the residues of trifloxystrobin at about 30 days were all < 0.01 mg/kg in all (9) samples.

The sum of residues of trifloxystrobin and CGA 321113 expressed as trifloxystrobin (mg/kg) at about 30 days were: < 0.01 (3), 0.021 (2), 0.022, 0.023, 0.027 and 0.033 mg/kg.

The use pattern is the same for beans and peas and the residues are not different. Consequently the residue datasets can be combined for mutual support.

The residues of trifloxystrobin in dry bean and pea seeds were < 0.01 mg/kg.

The sum of residues in beans and peas in rank order were: < 0.01 (8), 0.021 (4), 0.022, 0.023 (2), 0.025, 0.027 and 0.033 mg/kg.

As the use pattern for lentils is the same as for beans and peas, the Meeting decided that the database is sufficient for making recommendation for these three commodities.

The Meeting estimated a maximum residue level of 0.01* mg/kg and an STMR residue of 0.021 mg/kg for dry beans, lentils, and pea.

Animal feed

Soya bean forage and hay

Altogether 40 trials were conducted in USA in accordance with registered use patterns. Residues in forage and hay were measured and reported. However, grazing animals on soya bean fields or using forage and hay as animal feed are not permitted, therefore the results of trials were not evaluated.

Pea forage and hay

The average residues of trifloxystrobin and CGA 321113 measured in pea green materials (pea vine) obtained from trials conducted according to Canadian GAP are listed below.

Trifloxystrobin residues: 0.61, 0.78, 0.91, 0.92, 1.05, 1.10, 1.30, 1.50 and 1.95 mg/kg.

The sum of trifloxystrobin and CGA 321113 residues: 0.64, 0.81, 0.94, 0.95, 1.09, 1.15, 1.35, 1.54 and 1.98 mg/kg.

The Meeting estimated highest residue of 2 mg/kg and median residue of 1.1 mg/kg for the sum of trifloxystrobin and CGA321113 in pea vine for animal burden calculations.

The residues of trifloxystrobin and CGA 321113 (TFSA) measured in pea hay obtained from trials conducted according to Canadian GAP are listed below. Trifloxystrobin residues: 2.1, 3.0, 3.1, 3.3, 4.2, 5.3, 6.0, 6.7 and 6.8 mg/kg.

The sum of residues were in rank order: 2.2, 3.2, 3.3, 3.6, 4.5, 5.6, 6.3, 6.9 and 7.1 mg/kg

The Meeting estimated a maximum residue level of 17 mg/kg (dry weight) for peanut hay.

The Meeting estimated highest residue of 7.1 mg/kg and median residue of 4.5 mg/kg for the sum of trifloxystrobin and CGA321113 in pea hay for animal burden calculation.

Fate of Residues in Storage and Processing

Soya bean was treated with reifloxystrobin three times at a rate of 0.446–0.471 kg/ha and harvested 19 days after last application. The average total trifloxystrobin residue was 0.26 mg/kg in soya bean seed (raw agricultural commodity (RAC)), 18.2 mg/kg in soya bean aspirated grain fractions, 0.12 mg/kg in hulls, < 0.01 mg/kg in meal, and 0.03 mg/kg in refined oil. Concentration of the total trifloxystrobin residue was seen only in the soya bean aspirated grain fractions (processing factor about 70). No concentration of the total trifloxystrobin residue was seen in soya bean hulls, meal, or refined oil.

For the purpose of animal burden calculation, the Meeting estimated median residue of 0.7 mg/kg for aspirated grain fraction, 0.01 mg/kg for hull and < 0.0008 mg/kg for meal of soya bean.

Residues in animal commodities

Animal feeding studies were evaluated by the 2004 Meeting. Dairy cows were dosed with trifloxystrobin in capsules at the equivalent of 2, 5.9 or 21 ppm in the diet for 28–30 days. The residues measured in various samples are summarised below:

| Sample | Day | Maximum trifloxystrobin residues (mg/kg) | | | | | | | | |
|---------------|-------|--|--------|--------|--------------|--------|--------|-------------|--------|--------|
| | | Dose 2 ppm | | | Dose 5.9 ppm | | | Dose 21 ppm | | |
| | | Parent | 321113 | Total | Parent | 321113 | Total | Parent | 321113 | Total |
| Milk | 26 | - | - | - | - | - | - | < 0.01 | < 0.01 | < 0.02 |
| Liver | 28-30 | < 0.02 | < 0.02 | < 0.04 | < 0.02 | < 0.02 | < 0.04 | < 0.02 | 0.09 | 0.11 |
| Kidney | 28-30 | < 0.02 | < 0.02 | < 0.04 | < 0.02 | < 0.02 | < 0.04 | < 0.02 | 0.02 | 0.04 |
| Perirenal fat | 28-30 | < 0.02 | < 0.02 | < 0.04 | | | | 0.06 | < 0.02 | 0.08 |
| Omental fat | 28-30 | < 0.02 | < 0.02 | < 0.04 | < 0.02 | < 0.02 | < 0.04 | 0.05 | < 0.02 | 0.07 |
| Round | 28-30 | - | - | - | - | - | - | < 0.02 | < 0.02 | < 0.04 |
| Tenderloin | 28-30 | - | - | - | - | - | - | < 0.02 | < 0.02 | < 0.04 |

Laying hens were dosed at 1.5, 4.5 and 15 ppm level for 29 days. At the highest treatment level no residues (< 0.02 mg/kg) were detected in composite tissue samples of breast plus thigh, skin plus attached fat, peritoneal fat, liver and eggs.

The Meeting estimated the dietary burden of trifloxystrobin in farm animals on the basis of the diets listed in Annex 6 of the 2009 JMPR Report and using the estimated residues in livestock feed commodities evaluated by the present and previous Meetings.

| | Trifloxystrobin animal dietary burden, ppm, of dry matter diet | | | | | | | |
|-------------------|--|------|-------------------|-------------------|-----------|------|-------|-------|
| | US-Canada | | EU | | Australia | | Japan | |
| | Max | Mean | Max | Mean | Max | Mean | Max | Mean |
| Beef cattle | 2.17 | 1.15 | 26.6 ^a | 6.97 ^b | 8.24 | 5.00 | 4.53 | 0.84 |
| Dairy cattle | 2.79 | 1.27 | 23.2 ^c | 6.37 ^d | 8.21 | 4.11 | 2.11 | 0.43 |
| Poultry - broiler | 0.11 | 0.11 | 0.069 | 0.069 | 0.15 | 0.15 | 0.03 | 0.03 |
| Poultry – layer | 0.11 | 0.11 | 1.83 ^e | 0.78 ^f | 0.15 | 0.15 | 0.079 | 0.079 |

^a Suitable for estimation maximum residue levels in meat

^b Suitable for estimation of median residues in meat

^c Suitable for estimation maximum residue levels in milk

^d Suitable for estimation median residue levels in milk

^e Suitable for estimation maximum residue levels in poultry meat and edible offal

^f Suitable for estimation median residue levels in poultry meat and edible offal

The maximum dietary burden of beef cattle and dairy cattle is about 30% higher than the maximum feeding level of 21 ppm. The Meeting concluded that the residues observed at the highest feeding level can still be used as a basis for estimation of maximum residues in meat, offal and milk.

The Meeting concluded that the current Codex limits cover the residues derived from the uses of trifloxystrobin and maintains its previous recommendations.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI assessment.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of trifloxystrobin were calculated for the 17 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2004, 2012 and the current meeting. The results are shown in Annex 3.

The ADI is 0–0.04 mg/kg bw and the calculated IEDIs were 1–4% of the maximum ADI. The Meeting concluded that the long-term intake of residues of trifloxystrobin from the uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2004 JMPR decided that it was unnecessary to establish an ARfD. The present Meeting therefore concluded that the short-term intake of trifloxystrobin residues is unlikely to present a public health