

5.31 TRIFLOXYSTROBIN (213)

RESIDUE AND ANALYTICAL ASPECTS

Trifloxystrobin was first evaluated for toxicology and residues by the JMPR in 2004. The Meeting derived an ADI of 0.04 mg/kg bw per day and decided that an ARfD is unnecessary. Maximum residue levels, STMRs and STMR-Ps for 73 commodities or commodity groups were estimated.

In 2004 the Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin *per se*. For enforcement of animal commodities and for consideration of dietary intake of plant or animal commodities the residue definition should be parent compound and (*E,E*)-methoxyimino- $\{2-[1-(3\text{-trifluoromethyl-phenyl})\text{ ethylideneaminooxymethyl}]\text{-phenyl}\}$ acetic acid) (expressed as trifloxystrobin equivalents). The metabolite is also known as CGA 321113.

The compound was listed by the Forty-third Session of the CCPR for the review of additional MRLs. The 2012 JMPR received residue data for strawberries, papaya, olives, tomato, lettuce, radish and asparagus.

Methods of analysis

The Meeting received information on analytical methods used for the determination of trifloxystrobin residues and its acid metabolite CGA 321113 in samples derived from supervised trials on asparagus, lettuce, olives, papaya, radish, strawberry and tomatoes. The residues were determined by LC-MS/MS or GC-MS/MS with LOQs of 0.01–0.02 mg/kg.

The freezer storage stability studies carried out with asparagus and papaya showed that the trifloxystrobin residues and the metabolite CGA 321113 were stable for the longest period for which the samples were stored at or below -15 °C. The studies reported by the 2004 JMPR cover the other sample materials evaluated by the present Meeting.

Results of supervised residue trials on crops

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgment. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Strawberry

Based on the Swiss GAP (3 × 0.25 kg ai/ha, PHI 14 days) and five European supervised trials, the 2004 JMPR estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.1 mg/kg.

The 2012 Meeting received additional residue data from the USA and Australia. The Australian trials were carried out with 3 × 0.2 kg ai/ha and did not match the GAP (3 × 0.15 kg ai/ha, PHI 1 day). The registered GAP in the USA is 6 × 0.11 kg ai/ha and a 0-day PHI. In eight trials matching GAP conditions, the residue levels of trifloxystrobin *per se* were (n=8): 0.10, 0.19, 0.20, 0.28, 0.30, 0.44, 0.47 and 0.50 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.23, 0.23, 0.27, 0.31, 0.36, 0.47, 0.51 and 0.56 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.335 mg/kg for trifloxystrobin in strawberries to replace the former recommendation.

Olives

The Spanish GAP is 2×0.005 kg ai/hL and a PHI of 14 days. The first application is recommended in spring, the second in autumn. Eight trials conducted in Southern Europe with one treatment of 0.005 kg ai/hL in autumn and a PHI of 14 days showed residues of trifloxystrobin *per se* of 0.04, 0.05, 0.07, 0.07, 0.10, 0.11, 0.12 and 0.13 mg/kg. In four Southern European trials with two applications (one in spring and one in autumn with 0.006 kg ai/hL, spraying interval of 71–99 days between the two treatments), the residue levels of trifloxystrobin *per se* were 0.02, 0.04, 0.10 and 0.13 mg/kg. The Meeting noticed that the first spray treatment did not influence the residue concentration and decided to combine the two datasets. The trifloxystrobin residues (n=12) were: 0.02, 0.04, 0.04, 0.05, 0.07, 0.07, 0.10, 0.10, 0.11, 0.12, 0.13 and 0.13 mg/kg.

Because the residues of CGA 321113 were below the LOQ, for estimation of STMR (sum of parent and CGA 321113), the trifloxystrobin data were used.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.085 mg/kg for trifloxystrobin in olives.

Papaya

The GAP in the USA is maximal four foliar applications of 0.14 kg ai/ha at a maximal seasonal rate of 0.56 kg ai/ha and a PHI of 0 days. Four trials were conducted on papaya in the USA in 2003 with foliar treatment by 4×0.14 –0.15 kg ai/ha, PHI 0 days. The trifloxystrobin residues were 0.07, 0.15, 0.22 and 0.27 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.07, 0.15, 0.25 and 0.31 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg and an STMR of 0.2 mg/kg for trifloxystrobin in papaya.

Brussels sprouts

The 2004 JMPR estimated a maximum residue level of 0.5 mg/kg and a STMR of 0.17 mg/kg for residues of trifloxystrobin in flowerhead brassica, Brussels sprouts and head cabbage but in the CCPR reports, a CXL of 0.1 mg/kg was listed for Brussels sprouts. The company requested a clarification. No new data were submitted.

The current Meeting noted that the value of 0.1 mg/kg as CXL for Brussels sprouts is an administrative error in the Codex System. The MRL recommendation made by the 2004 JMPR was 0.5 mg/kg.

Tomatoes

Based on the US GAP (4×0.14 kg ai/ha, PHI 3 days) and 18 supervised trials, the 2004 JMPR estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.08 mg/kg.

The 2012 JMPR received six further US outdoor trials according to US GAP. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.03, 0.04, 0.06, 0.06, 0.09 and 0.11 mg/kg.

The Meeting agreed that a new recommendation for trifloxystrobin on tomatoes based on the data submitted to the 2012 JMPR was not necessary. Therefore, the previous recommendations for a maximum residue level and STMR were maintained.

Egg plant

The US GAP of trifloxystrobin on eggplant is 5×0.07 –0.14 kg ai/ha at a maximum of 0.56 kg ai/ha per season and a 3 day PHI, the same GAP is registered for tomatoes.

The Meeting agreed to extrapolate from tomato to eggplant and recommended a maximum residue level of 0.7 mg/kg and an STMR of 0.08 mg/kg for trifloxystrobin in egg plant.

Lettuce, head

The GAP for greenhouse grown lettuce is in the Netherlands 3×0.2 kg ai/ha and a PHI of 7 days. Eight indoor European trials (France (2), Germany (2), Italy (2), Portugal (1), the Netherlands (1)) treated with 3×0.25 kg ai/ha were received.

In eight trials on head lettuce matching the GAP conditions of the Netherlands (application rate +25 %), the residue levels of trifloxystrobin *per se* were: 2.4, 2.5, 2.7, 5.4, 5.6, 5.7, 6.6 and 7.2 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 2.4, 2.7, 2.7, 5.4, 5.7, 5.8, 6.7 and 7.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg and an STMR of 5.55 mg/kg for trifloxystrobin in lettuce, head.

Radish leaves (including Radish tops)

The registered GAP on radish in the USA is 4×0.07 – 0.14 kg ai/ha at a maximal rate of 0.28 kg ai/ha per year and a PHI of 7 days. Six field trials were conducted with 2×0.14 – 0.15 kg ai/ha and a PHI of 6–8 days.

In radish tops, the residue levels of trifloxystrobin *per se* were: 0.07, 0.22, 0.26, 2.3, 5.3 and 6.8 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.13, 0.32, 0.37, 2.4, 5.4 and 7.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg and an STMR of 1.4 mg/kg for trifloxystrobin in radish leaves.

Radish

The registered GAP on radish in the USA is 4×0.07 – 0.14 kg ai/ha at a maximal rate of 0.28 kg ai/ha per year and a PHI of 7 days. Six field trials were conducted with 2×0.14 – 0.15 kg ai/ha and a PHI of 6–8 days.

In radish roots, the residue levels of trifloxystrobin *per se* were: < 0.02 (3), 0.03, 0.04 and 0.05 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: < 0.02, 0.06, 0.06 and 0.07 (3) mg/kg.

The Meeting estimated a maximum residue level of 0.08 mg/kg and an STMR of 0.065 mg/kg for trifloxystrobin in radish.

Asparagus

The GAP in the USA is 3×0.11 – 0.14 kg ai/ha at a maximal seasonal rate of 0.42 kg ai/ha and a PHI of 180 days (California 90 days). Seven trials were conducted on asparagus in the USA in 2002 with foliar treatment by 3×0.14 – 0.15 kg ai/ha and PHIs of 92–188 days. In the sprouts, neither residues of trifloxystrobin (< 0.05 mg/kg) nor the metabolite CGA 321113 (< 0.02 mg/kg) were detected.

The Meeting estimated a maximum residue level of 0.05* mg/kg and an STMR of 0 for trifloxystrobin in asparagus.

Fate of residues during processing

The effect of processing on the level of residues of trifloxystrobin and the metabolite CGA 321113 has been studied for strawberries and olives. The processing factors (PF) were calculated from the total residue levels (sum of trifloxystrobin and CGA 321113). The best estimates of the processing factors are shown below. Processes included in the table are those that lead to STMR-P values useful for dietary intake estimations.

| Raw agricultural commodity (RAC) | Processed commodity | Best estimate processing factor (PF) | RAC STMR | STMR-P |
|----------------------------------|----------------------|--------------------------------------|----------|--------|
| Strawberry | Strawberry jam | 0.58 | 0.335 | 0.194 |
| | Strawberry preserves | 0.29 | | 0.097 |

Trifloxystrobin

| Raw agricultural commodity (RAC) | Processed commodity | Best estimate processing factor (PF) | RAC STMR | STMR-P |
|----------------------------------|---------------------|--------------------------------------|----------|--------|
| Olives | Olive oil, crude | 3 | 0.085 | 0.255 |
| | Olive oil, refined | 4.15 | | 0.353 |

The Meeting estimated the following STMR-P values: 0.194 mg/kg for strawberry jam, 0.097 mg/kg for strawberry, canned, 0.255 mg/kg for olive oil, crude and 0.353 for olive oil, refined.

A maximum residue level for the processed commodity will only be recommended if the resulting residue value is higher than the maximum residue level proposed for the corresponding RAC. Because of the fact that the PF is >1 for olive oils and the oils are commodities in trade, maximum residue levels were proposed for olive oil, crude and olive oil, refined.

The Meeting estimated a maximum residue level for olive oil, crude of 0.9 mg/kg and for olive oil, refined of 1.2 mg/kg.

Residues in animal commodities

As the commodities evaluated by the 2012 JMPR are not included in the OECD farm animal feeding table, there is no need to re-calculate the farm animal dietary burden.

The Meeting concluded that a re-evaluation of the maximum residue levels for animal commodities was not necessary.

DIETARY RISK ASSESSMENT***Long-term intake***

The International Estimated Daily Intakes (IEDIs) of trifloxystrobin were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2004 and 2012. The results are shown in Annex 3.

The ADI is 0–0.04 mg/kg bw and the calculated IEDIs were 1–5 % 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 concern.