5.12 ETOXAZOLE (241)

RESIDUE AND ANALYTICAL ASPECTS

Etoxazole was reviewed for the first time by the JMPR in 2010 where it was noted that during frozen storage residues of etoxazole in several matrices were not stable. Additionally, it was identified that residues might also decompose during sample preparation.

Nevertheless, the 2010 Meeting decided to use the results of residue trials, for those commodities where the storage stability was demonstrated, to estimate maximum residue levels. The Meeting did not recommend the maximum residue levels for pome fruits, stone fruits, strawberry, melons, tomato, cotton seed and cotton gin trash as the storage stability of samples from field trials could not be demonstrated.

The USA submitted a concern following the Forty-third CCPR. No new storage stability data was received. The USA agreed that the storage stability studies demonstrate that etoxazole residues diminish on frozen storage in the matrices apple, stone fruits, strawberry and melon (except watermelon). However, in each case the residue decline as indicated by the storage stability recovery data, demonstrated a relatively low standard deviation of 10% or less. Therefore, the USA requested that JMPR consider making use of the submitted residue field trial data together with appropriate storage stability correction factor(s) to allow for maximum residue level recommendations for these crops. Alternatively, if the use of storage stability correction factors was considered inappropriate, the US requested that JMPR considered correcting the residue levels in the storage stability studies with the concurrent method recovery values reported.

The USA noted that since etoxazole was a reduced risk chemical it would be preferable to use correction factors to estimate maximum residue levels rather than set none for these crops. Furthermore, since the residues were not stable in frozen storage in these crop matrices, they would likely decline faster when the treated commodity was not held in frozen storage as would be the typical practice in commercial operations. Also the JMPR had determined that the residue definition for MRL compliance and dietary intake was parent etoxazole only; thus reducing potential concerns about metabolites/degradates formed during degradation during storage.

Comment by the JMPR

According to the FAO Manual (2009), if more than 30% of the residue is lost during storage prior to analysis, residues from studies involving similar storage periods may not be valid (page 65). It has not been JMPR practice to adjust residue data for possible losses during frozen storage. JMPR would prefer not to encourage the submission of supervised trials data from samples stored for intervals and under conditions where substantial portions of the original residues may have degraded. JMPR considers it preferable to control the problem at the planning stage, i.e., arrangements should be made to operate within storage intervals and temperatures where the residue is known to be stable.

The FAO Manual (2009) states that procedural recoveries (samples spiked and analysed at the time a stored sample is analysed) should be used to decide on the validity of the batch of analyses. The analytical results for the stored sample should not be adjusted for the procedural recoveries (page 66). This is the JMPR practice and it is essentially in line with best analytical practice. The 1999 IUPAC report on Harmonised Guidelines for the Use of Recovery Information in Analytical Measurement (Pure & Applied Chemistry, 71:337-348 (1999)) noted "There is a tendency for the role of Internal Quality Control (IQC) to be confused with the simple estimation of recovery (where deemed appropriate). It is better to regard IQC results solely as a means of checking that the analytical process remains in control. The recovery estimated at method validation time is usually more accurate for application to subsequent in-control runs, because more time can be spent on studying their typical levels and variability."

The Meeting concluded that the residue data should, therefore, not be corrected by procedural recoveries. However, the current Meeting agreed to reconsider the trial data.

Pome fruits

Two independent freezer storage stability studies of etoxazole were conducted on apples. The storage stability study, in which the samples were fortified with etoxazole at 0.1 mg/kg, demonstrated that the residues were stable for 7 months (78% remaining). Another storage stability study, which the samples were fortified at 0.01 mg/kg, indicated that the residues were stable for 41 days (70% remaining). The Meeting took into account the interval (8–95 days) between sampling and analysis, and evaluated the residues of trials on apple and pear based on the marginally acceptable storage stability data.

Apple

Etoxazole is registered in Greece, Italy and Spain for use apples as a foliar application with a maximum rate of 0.055 kg ai/ha and a PHI of 28 days. Residues in apples from trials with an acceptable storage intervals from trials in France, Greece, Italy and Spain, matching GAP were (n = 9): < 0.01 (7), 0.01 and 0.04 mg/kg.

Pear

Etoxazole is registered in Greece for use pears as a foliar application with a maximum rate of 0.055 kg ai/ha and a PHI of 28 days. Residues in pears from trials with the acceptable storage intervals for samples from trials in France and Greece matching GAP were (n = 4): < 0.01 (4) mg/kg.

Since the residue populations from the European trials on apples and pears were similar, the Meeting decided to combine the data. The residues from trials in France, Greece, Italy and Spain matching the GAP of Greece were: (n = 13) < 0.01 (11), 0.01 and 0.04 mg/kg.

Based on the trials from France, Greece, Italy and Spain, the Meeting estimated a maximum residue level and an STMR value for etoxazole in pome fruits of 0.07 and 0.01 mg/kg respectively.

The OECD calculator estimated a maximum residue level of 0.05 mg/kg. However, the Meeting recommended a value of 0.07 mg/kg because the result of the OECD calculator was considered too close to the highest residue value.

Stone fruits

Cherries

A freezer storage stability study was conducted on cherries in which control samples were fortified with etoxazole and analysed both prior to and concurrently with field-treated samples. Storage stability samples fortified at 0.10 mg/kg etoxazole were analysed after 193 days and yielded recoveries (percent remaining) that averaged 64%, i.e., storage stability of etoxazole residues in cherries was not demonstrated in this study.

The Meeting confirmed its previous conclusion.

Plums

A freezer storage stability study was conducted on plums, in which control samples were fortified with etoxazole and analysed both prior to and concurrently with field-treated samples. Storage stability samples of plums, fortified at 0.10 mg/kg etoxazole, were analysed after 207 days, and yielded recoveries (percent remaining) that averaged 43%, i.e., storage stability of etoxazole residues in plums was not demonstrated in the study.

The Meeting confirmed its previous conclusion.

Peach

A freezer storage stability study was conducted on peaches, in which control samples were fortified with etoxazole and analysed both prior to and concurrently with field-treated samples. Storage stability samples fortified at 0.10 mg/kg etoxazole were analysed after 278 days and yielded recoveries (percent remaining) that averaged 50%, i.e., storage stability of etoxazole residues in trials for peaches was not demonstrated in the study.

The Meeting confirmed its previous conclusion.

Strawberry

A freezer storage stability study was conducted on strawberries, in which aliquots of control samples, fortified with a solution of etoxazole at 0.01 mg/kg, were weighed into storage bags and placed in a freezer for 90 days. Residues of etoxazole were found to be unstable in strawberries, with 50–63% of the applied material recovered following 32–90 days of frozen storage. The storage stability of etoxazole residues for strawberries was not demonstrated in this study.

The Meeting confirmed its previous conclusion.

Melons, except Watermelon

A freezer storage stability study was conducted on melons (cantaloupe). Aliquots of control samples, fortified with a solution of etoxazole at 0.01 mg/kg, were weighed into storage bags and placed in a freezer for 126 days. Residues of etoxazole were found to be unstable in cantaloupe with 55–63% of the applied material recovered following frozen storage for a period of 50–126 days, i.e., the storage stability of etoxazole residues in melons (cantaloupe) was not demonstrated in the study.

The Meeting confirmed its previous conclusion.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of etoxazole were calculated for the 13 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting (Annex 3). The ADI is 0–0.05 mg/kg bw and the calculated IEDIs were 0–1% of the maximum ADI. The Meeting concluded that the long-term intakes of residues of etoxazole, resulting from the uses considered by current JMPR, are unlikely to present a public health concern.

Short-term intake

The 2010 JMPR concluded that an ARfD was unnecessary. The Meeting therefore decided that the short-term intake of residues of etoxazole is unlikely to present a public health concern.