Prochloraz 249

5.19 PROCHLORAZ (142)

RESIDUE AND ANALYTICAL ASPECTS

Prochloraz is a broad-spectrum imidazole fungicide that is active against a range of diseases in field crops, fruit and vegetables and is also used on mushrooms, as a post-harvest treatment of fruit and as a seed treatment on cereals. It was evaluated initially in 1983 for residues and toxicology, and subsequently six additional reviews of residues were carried out between 1985 and 1992. Under the CCPR Periodic Review Programme the toxicology was re-evaluated in 2001, when an ADI of 0-0.01 mg/kg bw and an ARfD of 0.1 mg/kg bw were established. In 2004, a Periodic Review of the residue and -analytical aspects of prochloraz was conducted.

In the 2004 review the Meeting estimated a maximum residue level for mushrooms of 40 mg/kg and noted acute intake concerns relating to this level. As a consequence the CCPR at its Thirty-seventh and and Thirty-eighth Sessions did not advance this level as an MRL. In 2007, the Committee was informed that the manufacturer would provide alternative GAP information on mushroom and corresponding trial data for evaluation by the 2009 JMPR (ALINORM 07/30/24 – Rev. 1).

The Meeting received new data on supervised trials on mushrooms in several European countries, as well as current European labels on mushrooms.

Methods of analysis

The Meeting received descriptions and validation data for an analytical method for residues of prochloraz in mushrooms. Mushrooms were analysed for the total prochloraz derived residue by analytical method RESID/88/72 which was evaluated before in the 2004 JMPR. All results were expressed as a total prochloraz derived residue by correcting the measured 2,4,6-trichlorophenol concentration for the molecular weight factor of 1.9

The method performed satisfactorily, and was validated in the range of 0.05–50 mg/kg.

Results of supervised trials on crops

The 2004 JMPR noted two distinct patterns of use of prochloraz on mushrooms: one established in the United Kingdom, involving two to three casing sprays of 0.3–0.6 g ai/m², with a PHI of 2 days, and the other common in a number of other European countries, Australia and New Zealand, involving one or more treatments at 1.5 g ai/m² and a PHI of 10–14 days.

JMPR 2004 identified seven trials in The Netherlands, Switzerland and the United Kingdom matching GAP in Denmark, Italy, the Netherlands, New Zealand and Poland (one or two treatments at 1.5 g ai/m², 10-day PHI), the residue levels were: 0.21, 0.25, 0.48, 0.71 and 0.74 mg/kg.

As reported by JMPR 2004, the maximum GAP of two sprays of $0.6~g~ai/m^2$ (2 day PHI) in the United Kingdom was supported by the results of trials in Germany and the United Kingdom, with residue levels of: 0.81, 3.6, 6.2 and 37~mg/kg.

The 2004 Meeting noted that these two residue populations are different and, on the basis of the data supporting the United Kingdom GAP (with a PHI of 2 days), estimated a maximum residue level of 40 mg/kg for prochloraz in mushrooms, an STMR of 4.9 mg/kg and a highest residue level of 37 mg/kg.

The 2009 Meeting noted, that still two distinct patterns of use of prochloraz on mushrooms exist; one with a relatively low dose and a short (2–4 day) PHI, and one with a higher dose and a PHI of 10 days.

250 Prochloraz

For this years evaluation another set of trials conducted in Germany, France, Ireland and Belgium was provided together with current GAP from Belgium, France, Ireland, Italy, the Netherlands, Poland, Spain and the UK. Trials agreeing with the 'alternative GAP' (for an explanation see the JMPR 2006 report, General considerations point 2.3) involving one or more treatments at 1.5 g ai/m² and a PHI of 10 days (GAP in Italy and Poland) yielded residues of 1.3, 1.4 mg/kg.

Together with the data set of 2004 matching the same GAP, the total data set was: 0.21, 0.25, 0.48, 0.71, 0.74, 1.3, 1.4 mg/kg; the Meeting estimated a maximum residue level of 3 mg/kg for prochloraz in mushroom, an STMR of 0.71 and a highest residue level of 1.4 mg/kg.

Use of the NAFTA calculator resulted in an estimated maximum residue level of 3.5 mg/kg. The Meeting noted that the trials yielding the high residues were exactly at GAP, and over-all the distribution was relatively uniform.

Farm animal dietary burden

This Meeting estimated a maximum residue level for mushrooms. As mushrooms are not a feed item the Meeting decided it was unnecessary to revisit the farm animal dietary burden.

DIETARY RISK ASSESSMENT

Long-term intake

Due to the low contribution of mushrooms to the total diet, no revision of the chronic dietary exposure assessment has been carried out.

In 2004 the Meeting concluded that the long term intake of residues of prochloraz from uses that have been considered by the JMPR is unlikely to present a public health concern. The IEDI in the five GEMS/Food Consumption Cluster Diets, on the basis of the estimated STMRs, represented 7-10% of the maximum ADI of 0.01 mg/kg bw.

Short-term intake

The International Estimated Short-term Intake (IESTI) was calculated for mushrooms. The short-term intake of mushrooms represented 10% of the ARfD for children ≤ 6 years and 7% of the ARfD for the general population. The Meeting concluded that the short-term intake of residues of prochloraz from its uses on mushroom was unlikely to present a public health concern.