Meeting already considered the registered Australian uses. In 2013 it was decided to exclude feed and fodder commodities (e.g., soya bean forage and fodder) from the calculation for the Australian livestock animal dietary burden, as penthiopyrad is not registered for such uses in Australia and respective feed items are not imported due to quarantine constraints. Thus the maximum and mean livestock animal dietary burdens for ruminants and poultry were estimated for the US-Canadian and EU region, respectively, which were also the basis for the estimation of maximum residue levels, STMR and HR values in animal commodities.

Since both the US-Canadian and the EU livestock animal dietary burdens are unaffected by the confirmative Australian GAP information sent to this Meeting, the 2013 recommendations for penthiopyrad in animal commodities are confirmed. The Meeting points out, that the maximum residue levels recommended in 2013 for penthiopyrad are already based on a refined estimation of the livestock animal dietary burden and that residues in animal commodities were derived using intrapolation between dose levels of the feeding studies available.

GAP information provided by Australia allowed no consideration for an alternative GAP for mustard greens. Supervised field trial data on mustard greens are available from Canada and the USA (see 2012 Evaluation), but did not match the newly submitted GAP information from Australia.

3.2 OTHER MATTERS OF INTEREST

3.2.1 Bentazone (172)

Background

Bentazone is the International Organization for Standardization (ISO)–approved common name for 3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one-2,2-dioxide (International Union of Pure and Applied Chemistry), with the Chemical Abstracts Service (CAS) number 25057-89-0. Bentazone is a post-emergence herbicide that acts by interfering with photosynthesis.

Bentazone was evaluated by JMPR in 2012, as part of the periodic review programme of the Codex Committee on Pesticide Residues (CCPR). The 2012 Meeting established an acceptable daily intake (ADI) of 0–0.09 mg/kg body weight (bw), based on a no-observed-adverse-effect level (NOAEL) of 9 mg/kg bw per day from a 2-year study of toxicity and carcinogenicity in rats for prolonged blood coagulation and clinical chemistry changes indicative of effects on liver and kidney at 35 mg/kg bw per day and application of a safety factor of 100. The 2012 Meeting also reaffirmed its previous conclusion that no acute reference dose (ARfD) was necessary, as the Meeting considered that the post-implantation loss seen in the rat developmental toxicity study was not caused by a single dose and that no other effects were observed in repeated-dose toxicity studies that could be due to a single dose.

During the review of the background document on bentazone for the development of the WHO Guidelines for Drinking-water Quality, which was based on the 2012 JMPR evaluation, two comments were received that pertained to JMPR's conclusion that an ARfD for bentazone was unnecessary. The first comment, received from the European Food Safety Authority (EFSA), referred to its evaluation of bentazone, published in 2015, which concluded that an ARfD of 1 mg/kg bw was required based on the NOAEL of 100 mg/kg bw per day for increased post-implantation loss, reduced number of live fetuses and retarded fetal development observed in the developmental toxicity study in rats and application of an uncertainty factor of 100. The second comment, from Health Canada, identified an acute neurotoxicity study in rats, published in 2012, that was used by the USEPA in 2014 to set an ARfD of 0.5 mg/kg bw.

JMPR, at its meeting in 2015, recommended that bentazone be re-evaluated specifically to determine whether there is a need to establish an ARfD.

Biochemical and toxicological data

Several new biochemical and toxicological studies were made available to the present Meeting. The Meeting evaluated these studies and concluded that only the acute neurotoxicity study would have an impact on the consideration of the need to establish an ARfD for bentazone.

In an acute neurotoxicity study in which rats were administered bentazone by gavage at a single dose of 0, 50, 150 or 400 mg/kg bw, the NOAEL was 50 mg/kg bw, based on decreased motor activity in males observed on day 0 at 150 mg/kg bw.

Toxicological evaluation

Owing to the availability of new data, the Meeting established an ARfD of 0.5 mg/kg bw, based on a NOAEL of 50 mg/kg bw for decreased motor activity in males observed on day 0 in an acute neurotoxicity study in rats, using a safety factor of 100.

An addendum to the toxicological monograph was prepared.

Residue and analytical aspects

Bentazone, a post-emergence herbicide to control dicotyledonous weeds, it was originally evaluated by the JMPR in 1991 and re-evaluated under the periodic review program for toxicology in 2012 and for residues in 2013. The 2012 JMPR established an ADI for bentazone of 0-0.09 mg/kg bw and concluded that no ARfD was necessary. In the present Meeting, the WHO Core Assessment Group reviewed new data and established an ARfD for bentazone of 0.5 mg/kg bw.

Based on the uses assessed by the 2013 Meeting, the short-term dietary exposure for bentazone was estimated by the present Meeting. In the 2013 Meeting, the following residue definition was derived by the Meeting:

Definition of the residue (for compliance with the MRL and for dietary risk assessment for plant and animal commodities): *bentazone*

The residue is not fat soluble.

Dietary risk assessment

In 2013 no HR values were derived for bentazone by the Meeting. Based on the highest residues from datasets used for recommendations, the following HR values were estimated for the short-term dietary exposure calculation, if required: onion, bulb (0.02 mg/kg); spring onions (0.04 mg/kg); sweet corn on the cob (0.01 mg/kg); peas (pods and succulent = immature seeds) (0.74 mg/kg); beans except broad beans and soya beans (0.01 mg/kg); beans, shelled (0); potato (0.06 mg/kg); peanuts (0); herbs, except dry hops (0.05 mg/kg); poultry meat (0); poultry fats (0); poultry edible offal (0) and eggs (0).

Long-term dietary exposure

No changes to the established ADI of 0-0.09 mg/kg bw or additional GAPs were considered by the current Meeting. The previous conclusion, that the long-term exposure to residues of bentazone, resulting from the uses that have been considered by JMPR, is unlikely to present a public health concern, is confirmed.