5.3 BIXAFEN (262)

RESIDUE AND ANALYTICAL ASPECTS

Bixafen is a pyrazole-carboxamide fungicide used to control diseases on rape plants and cereals. It inhibits fungal respiration by binding to mitochondrial respiratory complex II. It was considered for the first time by the 2013 JMPR for toxicology and residues, when an ADI of 0-0.02 mg/kg bw and an ARfD of 0.2 mg/kg bw were established.

The 2013 Meeting also recognized that bixafen residues are persistent in soil and may lead to significant residues in rotational crops. Since no field rotational crop studies addressing estimated soil plateau levels were available, no recommendations on maximum residue levels in plant or animal commodities could be given and consequently a dietary risk assessment was not conducted.

However, the 2013 Meeting recommended the following residue definition for bixafen:

Definition of the residue (for compliance with MRLs) for plant commodities: *bixafen*

Definition of the residue (for compliance with MRLs) for animal commodities and (for dietary exposure assessment) for plant and animal commodities: *sum of bixafen and N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen*

The residue is fat soluble.

At the 47th Session of CCPR, bixafen was scheduled for the evaluation of additional data in the 2016 JMPR. The current Meeting received new information on residues in rotational crops grown in the field supported by additional analytical methods and storage stability data for the metabolites M43 and M44/45. Since the current residue definition includes residues of parent bixafen and bixafen-desmethyl only, they are not discussed further in the appraisal.

Environmental fate in soil

For bixafen the Meeting concluded in 2013 that the active substance is persistent in soil, accumulating after subsequent years of annual treatment. Confined rotational crop studies indicate a potential uptake of residues for bixafen and M21 (bixafen-desmethyl) into plant commodities.

The Meeting also recognized that field rotational crop studies involve soil treatment rates not addressing the soil concentrations expected after subsequent annual treatment. The Meeting concluded that bixafen residues accumulate in soil after subsequent annual treatments. Under consideration of the highest annual application rate reported in the authorised GAPs of 0.25 kg ai/ha, soil residue concentrations equivalent to single application rates to bare soil of 0.9 kg ai/ha could be reached.

Additional field rotational crop studies were submitted to the present Meeting. In three trials conducted in Europe (2 from Germany and one from the UK), the ground was treated with rates equivalent to 0.93 kg ai/ha and carrots, lettuce or wheat/barley were grown as rotational crops at plant-back intervals (PBI) of 19–31 days. In the UK trial the same crops (but in different order) were additionally sown as second and third rotations with PBIs of 124–181 days and 332–363 days, respectively. For the first rotation, residues for bixafen and bixafen-desmethyl (M21) in the rotated crops were:

Commodity	Residue in mg bixafen equivalents per kg (mean value)		
	Bixafen	Bixafen-desmethyl (M21)	Total
Carrot, tops	2 × < 0.01, 0.021 (0.014)	3 × < 0.01	2 × < 0.02, 0.031 (0.024)
Carrot, roots	0.014, 0.019, 0.028 (0.02)	3 × < 0.01	0.024, 0.029, 0.038 (0.03)
Lettuce, head	3 × < 0.01	3 × < 0.01	3 × < 0.02
Wheat, forage	3 × < 0.01	3 × < 0.01	3 × < 0.02

Commodity	Residue in mg bixafen equivalents per kg (mean value)		
	Bixafen	Bixafen-desmethyl (M21)	Total
Wheat, straw	< 0.01, 0.019, 0.049 (0.026)	0.036, 0.043, 0.07 (0.05)	0.036, 0.062, 0.12 (0.076)
Wheat, grain	3 × < 0.01	3 × < 0.01	3 × < 0.02

For the second and third rotation, which was conducted in one trial only, residues of bixafen and M21 were generally below 0.01 mg/kg, except for carrot roots (bixafen: 0.018 mg/kg, M21: < 0.01 mg/kg, total: 0.018 mg/kg) and wheat/barley straw (bixafen: 0.034 mg/kg, M21: 0.048 mg/kg, total: 0.082 mg/kg).

One additional trial utilised test-sites from long-term soil accumulation studies, which were treated with bixafen subsequently for over six years. Before sowing, the soil was analysed for the accumulated residues of bixafen still present at concentrations equivalent to 0.43–0.47 kg ai/ha (based on the first 20 cm layer). The residues being subject to sorption/desorption effects in soil ("aging") were complemented with an additional treatment of bixafen to bare soil for a total nominal soil concentration equivalent to 0.93 kg ai/ha (e.g., 0.43 kg ai/ha aged residue plus 1 × 0.5 kg ai/ha new treatment). Again, carrot, lettuce and wheat were grown in one crop rotation with PBIs of 19–21 days.

In carrots and lettuce, no residues of bixafen or M21 above the LOQ of 0.01 mg/kg were found. Wheat forage and grain were also < 0.01 mg/kg for all analytes, except for 0.012 mg/kg bixafen and 0.023 mg/kg M21 in the straw (total: 0.035 mg/kg).

The Meeting concluded that the transfer of bixafen and its metabolites bixafen-desmethyl (M21) into rotational crops is low. In aerial parts of rotated crops, residues of both compounds were mostly below the LOQ of 0.01 mg/kg, except for a single sample of carrot tops (0.021 mg/kg for bixafen) and in wheat straw (< 0.01–0.05 mg/kg). In soil covered parts (carrot roots), residues of bixafen were found in almost all samples analysed, but also at levels near the LOQ (0.014–0.028 mg/kg). M21 was not found in these samples.

Taking into account the very conservative basis for the estimated soil plateau concentration equivalent to 0.93 kg ai/ha, which addresses many years of subsequent application at the maximum annual GAP rate (up to 0.25 kg ai/ha and year), the Meeting concluded that under realistic field conditions no significant uptake (≥ 0.01 mg/kg) of bixafen or bixafen-desmethyl from soil into plants is to be expected.

No representative crops from the group of pulses/oilseeds or fruiting vegetables have been investigated as rotational crops to date. In view of the low transport of bixafen residues from soil into the investigated crops (root crops, leafy crops and cereal grains), significant residues at or above the LOQ are also not expected for pulses/oilseeds and fruiting vegetables.

Results of supervised residue trials on crops

The 2013 JMPR Meeting already assessed uses of bixafen on rape, barley and wheat according to European GAP.

The 2013 Meeting concluded that field rotational crop studies did not address residues in soil expected after subsequent annual application of bixafen and decided that no recommendations on maximum residue levels and median/highest residues could be made for bixafen in non-permanent crops.

Since such studies were submitted to the current Meeting, which indicate no significant contribution to plant residues by soil uptake, maximum residue levels and STMR values can be estimated based on the 2013 Report.

Therefore, median and highest residues already estimated by the 2013 Meeting for rape seed, small cereal grains (barley, wheat) and feed commodities thereof were directly transferred into

estimations of maximum residue levels, STMR values and median/highest residue values by the present Meeting.

Residue values referred to as "total" describe the sum of bixafen and M21 (bixafen-desmethyl), expressed as bixafen.

Barley and oats

In 2013 the Meeting identified the following residues of bixafen and total bixafen for barley grain based on a GAP on barley and oats from the UK:

For MRL compliance purposes residues of parent bixafen in barley grain in the whole of Europe were (n = 19): 0.02, 0.03, 0.04(5), 0.05, 0.06, 0.06, 0.07, 0.08, 0.08, 0.09, 0.09, 0.1, 0.1, 0.25 and 0.34 mg/kg.

For dietary intake purposes the total residues in barley grain in the whole of Europe were (n = 19): 0.03, 0.04, 0.05(5), 0.06, 0.08(3), 0.1(3), 0.11(3), 0.29 and 0.38 mg/kg.

The 2016 Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR value of 0.08 mg/kg for barley grain and decided to extrapolate its estimations to oats.

Wheat, rye and triticale

In 2013 the Meeting identified the following residues of bixafen and total bixafen for wheat grain based on a GAP for rye, triticale and wheat from the UK:

For monitoring purposes residues of parent bixafen in wheat grain in the whole of Europe were (n = 20): < 0.01(12), 0.01(3), 0.02, 0.02, 0.03, 0.03 and 0.03 mg/kg.

For dietary intake purposes the total residues in wheat grain in the whole of Europe were (n = 20): < 0.02(12), 0.02(3), 0.03, 0.03, 0.04, 0.04 and 0.04 mg/kg.

The 2016 Meeting estimated a maximum residue level of 0.05 mg/kg and an STMR value of 0.02 mg/kg for wheat grain and decided to extrapolate its estimations to rye and triticale grain also.

Rape seed

In 2013 the Meeting identified the following residues of bixafen and total bixafen for rape seed based on a GAP for oilseed rape from the UK:

For MRL compliance purposes residues of parent bixafen in rape seeds were (n = 10): < 0.01(6), 0.01(3), 0.017 mg/kg.

For dietary intake purposes the total residues in rape seeds were (n = 10): < 0.02(5), 0.02(4), 0.028 mg/kg.

The 2016 Meeting estimated a maximum residue level of 0.04 mg/kg and an STMR value of 0.02 mg/kg for rape seed.

Animal feeds

Barley, oats, rye, triticale and wheat – forage of cereals

In 2013 the Meeting identified the following residues of total bixafen in barley and wheat forage based on GAPs from the UK for barley/oats and rye/triticale/wheat:

For the calculation of the livestock animal dietary burden the total residues in barley forage (as received) in Europe were (n = 19): 2.1, 2.5, 2.6, 2.7, 2.9, 3.0, 3.2, 3.4, 3.4, 3.5, 3.7, 3.8, 3.9, 4.0, 4.3, 4.4, 4.5, 6.0, 7.3 mg/kg.

For the calculation of the livestock animal dietary burden the total residues in wheat forage (as received) in Europe were (n = 20): 1.5, 2.4, 2.6, 2.7, 2.8, 2.9, 2.9, 3.0, 3.1, 3.4, 3.6, 3.8, 3.9, 4.2, 4.5, 4.7, 4.8, 5.2, 5.5, 7.3 mg/kg.

The 2016 Meeting estimated a highest residue of 7.3 mg/kg and a median residue of 3.5 mg/kg for barley and wheat forage (as received) and decided to extrapolate the estimations to oats, rye and triticale forage also.

Oilseed rape, forage

The 2013 Meeting concluded that the reported GAP for bixafen is not relevant for the utilisation of oilseed rape as an animal forage crop.

Barley, oats, rye, triticale and wheat-straw and fodder, dry

In 2013 the Meeting identified the following residues of bixafen and total bixafen for barley and wheat straw:

For MRL compliance purposes residues of parent bixafen in barley straw (as received) in Europe were (n = 19): 0.46, 0.64, 0.7, 0.76, 0.77, 0.86, 1.1, 1.1, 1.2, 1.5, 1.9, 3.1, 3.7, 4.8, 5.2, 5.4, 5.7, 6.2, 10 mg/kg.

For the calculation of the livestock animal dietary burden the total residues in barley straw (as received) in Europe were (n = 19): 0.5, 0.72, 0.74, 0.85, 1.0, 1.0, 1.2, 1.2, 1.3, 1.6, 2.1, 3.3, 3.9, 5.2, 5.6, 5.6, 6.1, 6.7, 11 mg/kg.

For MRL compliance purposes residues of parent bixafen in wheat straw (as received) in Europe were (n = 20): 0.52, 0.79, 0.93, 0.95, 1.3, 1.4, 1.7, 1.8, 1.8, 1.9, 2.6, 3.2, 3.3, 3.6, 3.6, 4.1, 5.4, 5.7, 8.4, 10 mg/kg.

For the calculation of the livestock animal dietary burden the total residues in wheat straw (as received) in Europe were (n = 20): 0.78, 1.2, 1.2, 1.3, 1.5, 1.9, 1.9, 2.1, 2.2, 2.5, 3.2, 3.7, 3.9, 3.9, 4.1, 4.4, 6.0, 6.2, 9.6, 11 mg/kg.

The 2016 Meeting noted that straw and fodder of small cereal grains (barley, oats, rye, triticale and wheat) are very similar and difficult to distinguish. Therefore it was decided to consider residue distributions in barley and wheat straw for mutual support. Since the residue populations for barley and wheat straw reported in the 2013 Report are not significantly different (Kruskal-Wallis-Test), residues were combined for a more robust estimate:

For MRL compliance purposes residues of parent bixafen in barley and wheat straw (as received) in Europe were (n = 39): 0.46, 0.52, 0.64, 0.7, 0.76, 0.77, 0.79, 0.86, 0.93, 0.95, 1.1, 1.1, 1.2, 1.3, 1.4, 1.5, 1.7, 1.8, 1.8, 1.9, 1.9, 2.6, 3.1, 3.2, 3.3, 3.6, 3.6, 3.7, 4.1, 4.8, 5.2, 5.4, 5.4, 5.7, 5.7, 6.2, 8.4, 10 and 10 mg/kg.

For the calculation of the livestock animal dietary burden the total residues in barley and wheat straw (as received) in Europe were (n = 39): 0.5, 0.72, 0.74, 0.78, 0.85, 1.0, 1.0, 1.2(4), 1.3, 1.3, 1.5, 1.6, 1.9, 1.9, 2.1, 2.1, 2.2, 2.5, 3.2, 3.3, 3.7, 3.9(3), 4.1, 4.4, 5.2, 5.6, 5.6, 6.0, 6.1, 6.2, 6.7, 9.6, 11 and 11 mg/kg.

The 2016 Meeting estimated a maximum residue level of 20 mg/kg (dry-weight basis, based on 89% DM content), a highest residue of 11 mg/kg (as received) and a median value of 2.2 mg/kg (as received) for barley and wheat, straw and fodder, and decided to extrapolate the estimations to oats, rye and triticale straw and fodder, also.

Fate of residues during processing

The 2013 Meeting received information on the hydrolysis of radio-labelled bixafen as well as processing studies using unlabelled material on grown residues in oilseed rape, barley and wheat.

In a hydrolysis study using radio-labelled bixafen typical processing conditions were simulated (pH 4,5 and 6 with 90 °C, 100 °C and 120 °C for 20, 60 and 20 minutes). In duplicate samples of sterile buffer solution no degradation was observed.

The 2013 Meeting received information on the fate of bixafen and bixafen-desmethyl residues following simulating household and commercial processing of rape seed. Processing factors estimated by the 2013 Meeting, maximum residue levels and STMR-P values for the commodities considered by the 2016 Meeting are summarised below.

Raw commodity	Processed commodity	Bixafen		Total bixafen	
		Processing factor	Maximum residue level in mg/kg	Processing factor	STMR-P in mg/kg
Rape seed (STMR: 0.02 mg/kg, MRL: 0.04 mg/kg)	Oil, crude	0.75	n.n.	0.83	0.016
	Oil, refined	2	0.08	1.5	0.03
	Meal	2	n.n.	1.5	0.03
Barley (STMR: 0.08 mg/kg, MRL: 0.4 mg/kg)	Pearl barley	0.22	n.n.	0.25	0.02
	Beer	<0.065	n.n.	< 0.11	0.009
	Brewers grain	0.93	n.n.	0.93	0.074
	Brewers malt	0.86	n.n.	0.95	0.076
Wheat (STMR: 0.02 mg/kg, MRL: 0.05 mg/kg)	Flour	0.23	n.n.	0.37	0.007
	Bran, processed	2.7	0.15	2.6	0.052
	White bread	0.2	n.n.	< 0.37	0.007
	Wholemeal	0.9	n.n.	0.91	0.018
	Wholemeal bread	0.5	n.n.	0.63	0.012
	Germs	1	n.n.	1.1	0.022

n.n.not necessary, covered by the maximum residue level for the raw commodity or commodity is not relevant in trade

Residues in animal commodities

Farm animal feeding studies

The 2013 Meeting received feeding studies involving bixafen on lactating cows and laying hens. In the 2013 Report the following conclusions were presented:

"Three groups of lactating cows were dosed daily at levels of 4, 12 and 40 ppm in the diet (0.15, 0.45 and 1.5 mg/kg bw) for 28 consecutive days. Milk was collected throughout the whole study and tissues were collected on day 29 within 24 hrs after the last dose.

In milk highest mean total residues were 0.039 mg/kg for the 4 ppm group, 0.077 mg/kg for the 12 ppm group and 0.218 mg/kg for the 40 ppm group. Investigation of the distribution of the residue in cream gave a 9.9 fold higher concentration than in whole milk (15 between whole milk and milk fat).

Total residues in muscle for the 4, 12 and 40 ppm groups were 0.039–0.065 mg/kg (mean: 0.052 mg/kg), 0.081–0.26 mg/kg (mean: 0.162 mg/kg) and 0.63–1.0 mg/kg (mean: 0.82 mg/kg), respectively. In liver residues were 0.42–0.69 mg/kg (mean: 0.57 mg/kg) for the 4 ppm group, 1.2–1.7 mg/kg (mean: 1.4 mg/kg) for the 12 ppm group and 4.8–5.4 mg/kg (mean: 5.0 mg/kg) for the 40 ppm group. Kidney contained total residues of 0.1–0.15 mg/kg (mean: 0.14 mg/kg), 0.28–0.37 mg/kg (mean: 0.34 mg/kg) and 1.0–1.3 mg/kg (mean: 1.2 mg/kg) for the for the 4, 12 and 40 ppm group.

For fat three different tissues were analysed (perirenal, mesenteric and subcutaneous fat). Highest residues were found in perirenal fat with 0.14–0.21 mg/kg (mean: 0.18 mg/kg) for the 4 ppm group, 0.33–0.48 mg/kg (mean: 0.43 mg/kg) for the 12 ppm group and 0.8–1.9 mg/kg (mean: 1.4 mg/kg) for the 40 ppm group.

For laying hens three groups of animals were dosed with rates of 1.5, 4.5 and 15 ppm in the dry weight feed (0.1, 0.3 and 1.0 mg/kg bw) for 28 consecutive days. Eggs were collected throughout the whole study and tissues were collected on day 29 after the last dose.

In eggs total residues at the plateau phase were < 0.02–0.02 mg/kg (highest daily mean: 0.02 mg/kg) for the 1.5 ppm group and ranged between 0.05 to 0.07 mg/kg (highest daily mean: 0.063 mg/kg) for the 4.5 ppm and between 0.13 to 0.22 mg/kg (highest daily mean: 0.178 mg/kg) for the 15 ppm group.

In tissues no residues above the LOQ were found in muscle. Total residues in fat for the 1.5, 4.5 and 15 ppm groups were < 0.02–0.02 mg/kg (mean: 0.02 mg/kg), 0.05–0.06 mg/kg (mean: 0.057 mg/kg) and 0.06–0.09 mg/kg (mean: 0.07 mg/kg), respectively. In liver residues were < 0.02–0.02 mg/kg (mean: 0.02 mg/kg) for the 1.5 ppm group, 0.02–0.04 mg/kg (mean: 0.03 mg/kg) for the 4.5 ppm group and 0.03–0.05 mg/kg (mean: 0.04 mg/kg) for the 15 ppm group."

Estimated maximum and mean dietary burdens of livestock and animal commodities maximum residue levels

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex IX. The calculations were made according to the livestock diets from US-Canada, EU, Australia and Japan in the OECD Table (Annex 6 of the 2006 JMPR Report).

	Livestock dietary burden, Total bixafen, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max.	mean	max.	mean	max.	mean	max.	mean
Beef cattle	2.0	0.45	8.3	4.0	29 [A]	14 [C]	0.09	0.09
Dairy cattle	8.3	4.0	8.3	4.0	27 [B]	13 [D]	1.3	0.65
Poultry - broiler	0.07	0.07	0.07	0.07	0.03	0.03	0.01	0.01
Poultry - layer	0.07	0.07	3.0 [E]	1.5 [F]	0.05	0.02	0.005	0.05

[A] Highest maximum beef cattle burden suitable for MRL estimates for mammalian meat

[B] Highest maximum dairy cattle burden suitable for MRL estimates for milk

[C] Highest mean beef cattle burden suitable for STMR estimates for mammalian meat

[D] Highest mean dairy cattle burden suitable for STMR estimates for mammalian meat and milk

[E] Highest maximum broiler or laying hen burden suitable for MRL estimates for poultry products and eggs

[F] Highest mean broiler or laying hen burden suitable for STMR estimates for poultry products and eggs

Animal commodities maximum residue levels

For beef cattle a maximum and mean dietary burden of 29 ppm and 14 ppm were estimated, respectively. For dairy cattle a maximum and mean dietary burden of 27 ppm and 13 ppm were estimated. The estimated dietary burdens are evaluated against the dose levels of 12 and 40 ppm from a lactating cow feeding study.

Bixafen feeding study	Feed level	Total residue				
	(ppm)	(mg/kg) in milk	(mg/kg) in muscle	(mg/kg) in kidney	(mg/kg) in liver	(mg/kg) in fat
Maximum residue level: dairy cattle						
Feeding study (HR for each dose group, except for milk)	12 40	0.077 0.218	0.26 1.0	0.37 1.3	1.7 5.4	0.48 1.9

Bixafen feeding study	Feed level	Total residue				
	(ppm)	(mg/kg) in milk	(mg/kg) in muscle	(mg/kg) in kidney	(mg/kg) in liver	(mg/kg) in fat
Dietary burden and residue estimate	29 (beef) 27 (dairy)	 0.15	0.71	0.93	3.9	1.3
STMR dairy cattle						
Feeding study (Mean for each dose group)	12 40	0.077 0.218	0.16 0.82	0.34 1.2	1.4 5.0	0.43 1.4
Dietary burden and residue estimate	14 (beef) 13 (dairy)	 0.082	0.21	0.4	1.7	0.5

The Meeting estimated HR and STMR values of 0.71 and 0.21 mg/kg for muscle, 3.9 and 1.7 mg/kg for liver, 0.93 and 0.4 mg/kg for kidney and 1.3 and 0.5 mg/kg for fat. Corresponding maximum residue levels were estimated at 4 mg/kg for edible offal, mammalian (based on liver) and 2 mg/kg for meat (based on the fat) and mammalian fat (except for milk fat).

For milk, a STMR value and a maximum residue level of 0.082 mg/kg and 0.2 mg/kg were estimated, respectively. Based on an average fat content in whole milk of 4%, the Meeting also estimated a STMR value and a maximum residue level of 2.05 mg/kg and 5 mg/kg for bixafen in milk fat, respectively.

For poultry (laying hens) a maximum and mean dietary burden of 3 ppm and 1.5 ppm were estimated, respectively. The estimated dietary burdens are evaluated against the dose levels of 1.5 and 4.5 ppm from a laying hen feeding study.

Bixafen feeding study	Feed level	Total residue			
	(ppm)	(mg/kg) in eggs	(mg/kg) in muscle	(mg/kg) in liver	(mg/kg) in fat
Maximum residue level: laying hens					
Feeding study (HR)	1.5 4.5	0.02 0.07	< 0.02 < 0.02	0.02 0.04	0.02 0.06
Dietary burden and residue estimate	3	0.047	0.02* (<LOQ at all dose levels)	0.03	0.04
STMR laying hens					
Feeding study (Mean for each dose group)	1.5	0.02	< 0.02	0.02	0.02
Dietary burden and residue estimate	1.5	0.02	0 (< LOQ at all dose levels)	0.02	0.02

The Meeting estimated HR and STMR values of 0 and 0 mg/kg for poultry muscle, 0.03 and 0.02 mg/kg for poultry, edible offal of and 0.04 and 0.02 mg/kg for poultry fat. Corresponding maximum residue levels were estimated at 0.05 mg/kg for poultry, edible offal of, 0.02* mg/kg for poultry meat and 0.05 mg/kg for poultry fat.

For eggs, a STMR value, a HR value and a maximum residue level of 0.02 mg/kg, 0.047 mg/kg and 0.05 mg/kg were estimated, respectively.

RECOMMENDATIONS

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

Definition of the residue (for compliance with MRLs) for plant commodities: *bixafen*

Definition of the residue (for compliance with MRLs) for animal commodities and (for dietary exposure assessment) for plant and animal commodities: *sum of bixafen and N-(3',4'-*

dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen

The residue is fat soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The International Estimated Daily Intakes (IEDI) for bixafen was calculated from recommendations for STMRs for raw and processed commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 3.

The IEDI of the 17 GEMS/Food cluster diets, based on the estimated STMRs represented 1% to 9% of the maximum ADI of 0.02 mg/kg bw. The Meeting concluded that the long-term exposure to residues of bixafen from uses considered by the Meeting is unlikely to present a public health concern.

Short-term dietary exposure

The International Estimated Short term Intake (IESTI) for bixafen was calculated for all food commodities and their processed fractions for which maximum residue levels were estimated and for which consumption data were available. The results are shown in Annex 4.

The IESTI represented 0–20% of the ARfD (0.2 mg/kg bw) for the general population and 0–20% of the ARfD for children. The Meeting concluded that the short-term dietary exposure to residues of bixafen, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.