

5.19 Pydiflumetofen (309)

RESIDUE AND ANALYTICAL ASPECTS

Pydiflumetofen is a broad-spectrum fungicide belonging to the carboxamide group. It acts through inhibition of succinate dehydrogenase in complex II of fungal mitochondrial respiration. Pydiflumetofen was first evaluated for toxicology and residues by JMPR in 2018. An ADI of 0–0.1 mg/kg bw and an ARfD of 0.3 mg/kg bw were established. The residue definition for compliance with the MRL for plant and animal commodities, and dietary risk assessment for plant commodities is pydiflumetofen. The residue definition for dietary risk assessment for animal commodities other than mammalian liver and kidney is the sum of pydiflumetofen and 2,4,6-TCP and its conjugates, expressed as pydiflumetofen and for dietary risk assessment for mammalian liver and kidney is the sum of pydiflumetofen, 2,4,6-TCP and its conjugates, and SYN547897 and its conjugates, expressed as pydiflumetofen. The residue is fat-soluble.

The 2018 JMPR noted that pydiflumetofen residues may be taken up by rotational crops and considered very persistent in soil (up to 2380 days DT_{50}), and its accumulation, following subsequent years of treatment is expected. Therefore, the 2018 JMPR concluded that the information available did not allow the estimation of pydiflumetofen residues in rotational crops, especially in view of expected plateau soil concentrations being significantly higher than the rate applied in the available field rotational crop study.

The Meeting received information on field soil degradation studies for pydiflumetofen from several regions and field rotational crop studies.

Environmental fate

The Meeting received field soil degradation studies for pydiflumetofen to estimate the expected plateau level of pydiflumetofen in soil treated with pydiflumetofen.

Soil degradation (field studies)

Pydiflumetofen soil DT_{50} values were calculated based on 22 trials conducted in Canada, China, France, Germany, Italy, Japan, Republic of Korea, Spain, the UK, and the USA. DT_{50} values for pydiflumetofen ranged from 96.3 to > 10 000 days, with a geometric mean of 603 days. Noting that the maximum value (> 10 000 days) is not an evidence-based estimate and that field dissipation studies are typically conducted for a duration of 2 years, the Meeting decided that the geometric mean of 603 days was the most suitable value for estimating the plateau level in soil.

Calculation of soil plateau level

Based on the soil DT_{50} (603 days) of pydiflumetofen, the accumulation factor (f_{acc}) was calculated using the equation of $f_{acc} = e^{-kt} / (1 - e^{-kt})$, with degradation rate (k) and an application interval (t) of 365 days. Degradation rate (k) is calculated as $\ln 2 / DT_{50}$ (= 0.001149). Therefore, f_{acc} of pydiflumetofen is 1.918.

The plateau background residue level ($A_{plateau}$) can be calculated as $A_0 f_{soil} f_{acc}$.

A_0 = Total seasonal application rate to target crop (g ai/ha).

f_{soil} = Fraction of the seasonal application rate reaching the soil after crop interception.

Pydiflumetofen is a foliage-applied product, though application timings are variable dependent on crop and timing of disease development. As a reasonable worst case use pattern, pydiflumetofen was assumed to have been applied at the earliest foliar stage (BBCH 10–19: Leaf development stage). According to FOCUS guidance (2015)ⁿ, crop interception rate of 23% was calculated by taking the geometric mean of minimal crop cover stage (BBCH 10–19) of all crops excluding permanent crops such as citrus and olive trees. The amount reaching the soil after crop interception (f_{soil}) was assumed

ⁿ Generic guidance for FOCUS surface water scenarios, Version: 1.4, Date: May 2015

to be 0.77 (77%). The maximum seasonal application rate for pydiflumetofen (A_0) is 400 g ai/ha. Therefore, A_{plateau} of pydiflumetofen ($400 \times 0.77 \times 1.918$) is 591 g ai/ha.

According to OECD rotational crop guidance (2018)^o, application rates employed in crop rotation studies should be the sum of the maximum use rate for the compound (400 g ai/ha) and the calculated soil plateau level (591 g ai/ha), which leads to 991 g ai/ha. Moreover, for the trial design of rotational crop studies involving application to bare soil and subsequent sowing/planting, the proportionality concept is applicable.

Rotational crop studies

The current Meeting received additional field rotational crop studies conducted in European countries.

Field rotational crop studies

Pydiflumetofen SC formulation was applied to bare soil at 0.60 kg ai/ha. The trials were established for each of nine representative rotated crops (kale, tomato, maize, soya bean, bean, strawberry, spinach, carrot and radish) at a number of plant back intervals (30, 120, 270, 330–365 days).

Residues of pydiflumetofen were below the LOQ (0.01 mg/kg) in kale, tomato, maize (whole cobs), bean (fresh seed, remaining plant and dry seed) and strawberry at all plant back intervals.

Residues of pydiflumetofen were found at 0.01–0.02 mg/kg in maize (remaining plant: 120 and 330 day plant back interval (PBI), soya bean (forage: 30, 120, 270 and 330 day PBI), spinach (immature: 30 and 270 day PBI, mature: 120, 270 and 330 day PBI), carrots (roots: 30, 120, 270 and 330–365 day PBI, tops: 30 and 120 day PBI), radish (roots: 120 day PBI, tops: 30 and 120 day PBI).

Residues of pydiflumetofen were found in spinach (mature) at 0.03–0.05 mg/kg (30 and 270 day PBI), carrots (roots) at 0.03 mg/kg (120 day PBI), radish (tops) at 0.03 mg/kg (30 day PBI) and radish (roots) at 0.04 mg/kg (30 day PBI).

In field rotational crop studies submitted to the 2018 JMPR, pydiflumetofen SC formulation was applied to bare ground in European countries and the USA at 0.40–0.50 kg ai/ha (Europe: 1×0.50 kg ai/ha, USA: 2×0.20 kg ai/ha). The trials were established for each of three representative crop types (Europe: spinach, carrot and spring barley, USA: spinach/lettuce, radish and wheat) at each plant back interval (Europe: 30, 60 and 365 days, USA: 30, 60, 90 and 150 days).

Residues of pydiflumetofen were below the LOQ (0.01 mg/kg) in spinach (mature), lettuce, radish and cereal grains (barley and wheat).

Residues of pydiflumetofen were found at 0.01–0.02 mg/kg in spinach (immature: 30 and 60 day PBI), carrot (roots: 30 and 60 day PBI, tops: 60 day PBI) and cereal whole plant (barley: 30 day PBI, wheat: 90 day PBI).

Residues of pydiflumetofen were found in spring barley straw at 0.02–0.09 mg/kg (30 and 60 day PBI), and wheat hay and wheat straw at 0.01–0.11 mg/kg (90 day PBI) with a subsequent decline to < 0.01–0.07 mg/kg (150 day PBI).

Residues in rotated crops following applications at 400–600 g ai/ha were scaled with factors of 1.7–2.5 to estimate the residues expected at the higher application rate of 991 g ai/ha.

Table 1 Scaling of the highest rotational crop residues

Crop	Application rate of rotational crop studies (g ai/ha)	Scaling factor	Highest rotational residue (mg/kg)	Residue scaled to account for 991 g ai/ha
Strawberry (fruit)	600	1.7	< 0.01	< 0.02
Tomato (fruit)	600	1.7	< 0.01	< 0.02
Kale	600	1.7	< 0.01	< 0.02

^o Guidance Document on Residues in Rotational Crops: OECD Environment, Health and Safety Publications Series on Pesticides No. 97, Series on Testing and Assessment No. 279. ENV/JM/MONO(2018)9

Crop	Application rate of rotational crop studies (g ai/ha)	Scaling factor	Highest rotational residue (mg/kg)	Residue scaled to account for 991 g ai/ha
Leaf lettuce	400	2.5	< 0.01	< 0.03
Spinach (immature)	500	2.0	0.02	0.04
Spinach (mature)	600	1.7	0.05	0.09
Bean (whole plant)	600	1.7	< 0.01	< 0.02
Bean (fresh seed)	600	1.7	< 0.01	< 0.02
Bean (remaining plant)	600	1.7	< 0.01	< 0.02
Bean (dry seed)	600	1.7	< 0.01	< 0.02
Soya bean (forage)	600	1.7	0.01	0.02
Soya bean (seed)	600	1.7	< 0.01	< 0.02
Carrot (tops)	500	2.0	0.01	0.02
Carrot (roots)	600	1.7	0.03	0.05
Radish (tops)	600	1.7	0.03	0.05
Radish (roots)	600	1.7	0.04	0.07
Maize (whole cobs)	600	1.7	< 0.01	< 0.02
Maize (remaining plant)	600	1.7	0.02	0.03
Barley (whole plant)	500	2.0	0.02	0.04
Barley (grain)	500	2.0	< 0.01	< 0.02
Barley (straw)	500	2.0	0.09	0.18
Wheat (forage)	400	2.5	0.01	0.03
Wheat (hay)	400	2.5	0.05	0.13
Wheat (grain)	400	2.5	< 0.01	< 0.03
Wheat (straw)	400	2.5	0.11	0.28

Table 2 The residues scaled to plateau level of pydiflumetofen in soil

"Super" Crop Group ^a	Commodity	Trial No.	Residue scaled (mg/kg)		
			Mean	Median	Highest
Root and tuber vegetables	Carrot roots	8	0.03	0.02	0.05
	Radish roots	7	0.02	0.02	0.07
Cereals	Wheat grain	3	< 0.03	< 0.03	< 0.03
	Barley grain	4	< 0.02	< 0.02	< 0.02
	Maize whole cobs	2	< 0.02	< 0.02	< 0.02
Leafy vegetables and Brassicas	Spinach (mature)	7	0.03	0.02	0.09
	Spinach (immature)	10	0.02	0.02	0.04
	Leaf lettuce	1	< 0.03	< 0.03	< 0.03
	Kale	4	< 0.02	< 0.02	< 0.02
Oilseeds and pulses	Soya bean seed	2	< 0.02	< 0.02	< 0.02
	Bean dry seed	3	< 0.02	< 0.02	< 0.02
Fruits and fruiting vegetables	Tomato	4	< 0.02	< 0.02	< 0.02
	Strawberry	3	< 0.02	< 0.02	< 0.02
Root leaves and tops ^b	Radish tops	7	0.02	0.02	0.05
	Carrot tops	8	0.02	0.02	0.02
	Beans fresh seed	3	< 0.02	< 0.02	< 0.02

^a Referred to in the OECD rotational crop guidance.

^b This group is not included in OECD rotational crop guidance.

Table 3 Feed residues scaled to plateau level of pydiflumetofen in soil

Animal Feeds	Commodity	Trial No.	Residue scaled (mg/kg)		
			Mean	Median	Highest
Legume animal feeds	Soya bean forage	3	0.02	0.02	0.02
	Bean forage	4	< 0.02	< 0.02	< 0.02

Animal Feeds	Commodity	Trial No.	Residue scaled (mg/kg)		
			Mean	Median	Highest
Straw and fodder of cereal grains	Maize stover	4	0.02	0.02	0.03
	Barley straw	4	0.05	0.03	0.18
	Wheat hay	3	0.06	0.06	0.11
	Wheat straw	3	0.10	0.08	0.28
Forage of cereal grains	Barley forage	4	0.02	0.02	0.04
	Wheat forage	3	0.03	0.03	0.03

Results of supervised residue trials on crops

For maximum residue level estimation of pydiflumetofen residues in plant commodities, the addition of residues arising from direct treatment in combination with root uptake of pydiflumetofen from previous years must be taken into account. The Meeting decided to use the crop groups for plant food and feed established in the Codex Classification of Foods and Animal Feeds to give recommendations on the overall residue levels of pydiflumetofen expected in these commodities.

The corresponding residue values from supervised trials are obtained from the 2018 JMPR evaluation of pydiflumetofen.

The Meeting noted that the use of statistical methods for the estimation of maximum residue levels is not possible when considering potential carryover of residues in succeeding crops, since the basis arising from the additional root uptake cannot be adequately calculated using the OECD MRL calculator.

The Meeting recognised that the estimation of maximum residue levels for permanent crops and crops cultivated in/on culture soil/medium and water are not needed, as those crops are not expected to be subject to a potential uptake of pydiflumetofen from the soil.

Grapes

Grapes are normally cultivated as permanent crops and are not expected to be subject to a potential uptake of pydiflumetofen from the soil. The Meeting confirmed its previous recommendation for the subgroup of small fruit vine climbing of 1.5 mg/kg.

Bulb vegetables

Although pydiflumetofen is not used for treatment of bulb vegetables, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. However, no residue data on suitable succeeding crops to estimate a maximum residue level for bulb vegetables were available.

The Meeting could not estimate a maximum residue level for the group of bulb vegetables.

Brassica vegetables

Although pydiflumetofen is not registered for use on Brassica vegetables, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in leafy vegetables and Brassicas (spinach) in field studies on succeeding crops of 0.03, 0.02 and 0.09 mg/kg, respectively for the estimation of a maximum residue level, STMR value and HR value for Brassica vegetables.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an STMR value of 0.02 mg/kg and an HR value of 0.09 mg/kg for the group of Brassica vegetables.

Fruiting vegetables, Cucurbits

Based on the outcome of a Kruskal-Wallis H-test, the 2018 JMPR concluded that the residue populations from trials on cucumber, summer squash and cantaloupe were not different and the data could be combined to estimate a maximum residue level for fruiting vegetables, cucurbits.

The combined pydiflumetofen residues in cucumber, summer squash and cantaloupe were in rank order (n = 21): 0.056, 0.061, 0.067, 0.078, 0.10, 0.11 (5), 0.12, 0.14, 0.15, 0.16 (3), 0.17, 0.18, 0.19, 0.23 and 0.26 mg/kg.

In field studies on succeeding crops the scaled highest residue in fruiting vegetables (tomato) was < 0.02 mg/kg. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 0.4 mg/kg, an STMR value of 0.12 mg/kg and an HR value of 0.27 mg/kg (based on the highest residue of replicate samples) for the group of fruiting vegetables, cucurbits.

Fruiting vegetables, other than Cucurbits

Based on the outcome of a Mann-Whitney U-test, the 2018 JMPR concluded that the residue populations from trials on tomatoes and peppers were not different and the data could be combined to estimate a maximum residue level for fruiting vegetables, other than cucurbits except Martynia, Okra and Roselle.

The combined pydiflumetofen residues in tomatoes and peppers were in rank order (n = 21): 0.030, 0.043, 0.062, 0.075, 0.076, 0.077, 0.081, 0.082, 0.083, 0.088, 0.11, 0.13, 0.14, 0.16, 0.17, 0.20, 0.23, 0.26 (2), 0.27 and 0.37 mg/kg.

In field studies on succeeding crops the scaled highest residue in fruiting vegetables (tomato) was < 0.02 mg/kg. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR value of 0.11 mg/kg and an HR value of 0.42 mg/kg (based on the highest residue of replicate samples) for the group of fruiting vegetables, other than cucurbits (except Martynia, Okra and Roselle).

Martynia, Okra and Roselle

Although pydiflumetofen is not registered for use on Martynia, Okra and Roselle, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in fruiting vegetables (tomato) in field studies on succeeding crops of < 0.02, < 0.02 and < 0.02 mg/kg, respectively for an estimation of a maximum residue level, STMR value and HR value in Martynia, Okra and Roselle.

The Meeting estimated a maximum residue level of 0.02 mg/kg, an STMR value of 0.02 mg/kg and an HR value of 0.02 mg/kg for Martynia, Okra and Roselle.

Leafy vegetables

Leafy greens

The residues on head lettuce according to the US GAP were (n = 8): 0.51, 0.78, 1.2, 2.3, 2.4, 2.6, 3.0 and 4.5 mg/kg.

The residues on leaf lettuce according to the US GAP were (n = 8): 1.7, 3.5, 4.4, 5.5, 7.7, 9.7, 11 and 12 mg/kg.

The residues on spinach according to the US GAP were (n = 8): 7.5, 9.2, 9.7, 12, 13 (2), 14 and 16 mg/kg.

Based on the outcome of a Kruskal-Wallis H-test, the 2018 JMPR concluded that the residue populations from trials on head lettuce, leaf lettuce and spinach were significantly different. However, the residues in individual crops were similar (medians were within 5×). Therefore, the 2018 JMPR decided to use the dataset from spinach leading to the highest maximum residue level for leafy greens.

In field studies on succeeding crops the scaled mean, median and highest residues in leafy vegetables and Brassicas (spinach) were 0.03, 0.02 and 0.09 mg/kg, respectively. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 40 mg/kg, an STMR value of 12.5 mg/kg and an HR value of 17 mg/kg (based on the highest residue of replicate samples) for the subgroup of leafy greens.

Brassica leafy vegetables

Although pydiflumetofen is not registered for use on Brassica leafy vegetables, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in leafy vegetables and Brassicas (spinach) in field studies on succeeding crops of 0.03, 0.02 and 0.09 mg/kg, respectively for an estimation of a maximum residue level, STMR value and HR value in Brassica leafy vegetables.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an STMR value of 0.02 mg/kg and an HR value of 0.09 mg/kg for the subgroup of leaves of Brassicaceae.

Leaves of root vegetables

Although pydiflumetofen is not registered for use on leaves of root vegetables, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in root leaves and tops (radish) in field studies on succeeding crops of 0.02, 0.02 and 0.05 mg/kg, respectively for an estimation of a maximum residue level, STMR value and HR value in leaves of root vegetables.

The Meeting estimated a maximum residue level of 0.07 mg/kg, an STMR value of 0.02 mg/kg and an HR value of 0.05 mg/kg for the subgroup of leaves of root and tuber vegetables except leaves of tuber vegetables.

Legume vegetables

Although pydiflumetofen is not registered for use on legume vegetables, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in beans fresh seeds in field studies on succeeding crops of < 0.02, < 0.02 and < 0.02 mg/kg, respectively for an estimation of a maximum residue level, STMR value and HR value in legume vegetables.

The Meeting estimated a maximum residue level of 0.02 mg/kg, an STMR value of 0.02 mg/kg and an HR value of 0.02 mg/kg for the group of legume vegetables.

Pulses

Dry beans and dry peas

Based on the outcome of a Kruskal-Wallis H-test, the 2018 JMPR concluded that the residue populations from trials on dry beans, soya beans and dry peas were not different and the data could be combined to estimate a maximum residue level for subgroup of dry beans and subgroup of dry peas.

The combined pydiflumetofen residues in dry beans, soya bean and dry peas were in rank order (n = 41): < 0.01 (9), 0.011, 0.012, 0.013, 0.014, 0.016 (2), 0.18, 0.023 (2), 0.027, 0.028 (2), 0.029, 0.031,

0.032, 0.035, 0.036, 0.039, 0.041, 0.053, 0.057, 0.059, 0.060 (2), 0.063, 0.064, 0.088, 0.096, 0.10, 0.24, 0.29 and 0.37 mg/kg.

In field studies on succeeding crops the scaled highest residue in oilseeds and pulses (dry beans and soya bean) was < 0.02 mg/kg. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR value of 0.028 mg/kg for the subgroup of dry beans and the subgroup of dry peas.

Root and tuber vegetables

Root vegetables

Although pydiflumetofen is not registered for use on root vegetables, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in root and tuber vegetables (radish) in field studies on succeeding crops of 0.02, 0.02 and 0.07 mg/kg, respectively for an estimation of a maximum residue level, STMR value and HR value in root vegetables.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an STMR value of 0.02 mg/kg and an HR value of 0.07 mg/kg for the subgroup of root vegetables.

Tuberous and corm vegetables

The residues on potatoes according to the US GAP were (n = 22): < 0.01 (21) and 0.014 mg/kg.

In field studies on succeeding crops the scaled mean, median and highest residues in root and tuber vegetables (radish) were 0.02, 0.02 and 0.07 mg/kg, respectively. The Meeting concluded that residues in potatoes, the representative commodity for tuberous and corm vegetables, may be influenced significantly by uptake of pydiflumetofen from the soil. The Meeting decided to add the scaled mean residue found in field studies on succeeding crops of 0.02 mg/kg to the median residue obtained from supervised field trials on potato of 0.01 mg/kg for an overall STMR for potatoes of 0.03 mg/kg.

For the estimation of a maximum residue level the highest residue found in root and tuber vegetables in succeeding crop field trials was 0.07 mg/kg in radish roots. The Meeting estimated a maximum residue level for tuberous and corm vegetables of 0.1 mg/kg. Adding the highest residue of 0.014 mg/kg found in supervised field trials to the highest residue of 0.07 mg/kg for radish roots in the succeeding crops, results in an overall highest residue in tuberous and corm vegetables of 0.084 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an STMR value of 0.03 mg/kg and an HR value of 0.084 mg/kg for the subgroup of tuberous and corm vegetables.

Stalk and stem vegetables

Stalk and stem vegetables – Stems and Petioles

The residues on celery according to the US GAP were (n = 8): 2.6, 2.7, 3.9, 4.3, 4.5, 4.8, 5.4 and 8.1 mg/kg.

For stalk and stem vegetables no data from studies on succeeding crops were available. The Meeting concluded that the scaled mean, median and highest residue values of 0.03, 0.02 and 0.09 mg/kg respectively found in leafy vegetables and Brassicas (spinach) indicate that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 15 mg/kg, an STMR value of 4.4 mg/kg and an HR value of 9.3 mg/kg (based on the highest residue of replicate samples) for the subgroup of stems and petioles.

Cereal grains

Wheat, similar grains, and pseudocereals without husks

The residues on wheat grains according to the US GAP were (n = 29): 0.015, 0.025, 0.035, 0.038, 0.040 (2), 0.048, 0.050, 0.057 (3), 0.062 (2), 0.063 (2), 0.067 (2), 0.10 (2), 0.11, 0.12 (4), 0.13, 0.17, 0.19 and 0.23 (2) mg/kg.

In field studies on succeeding crops the scaled highest residue in wheat grains was < 0.03 mg/kg. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR value of 0.063 mg/kg for the subgroup of wheat, similar grains, and pseudocereals without husks.

Barley, similar grains, and pseudocereals with husks

The combined pydiflumetofen residues in barley grains and oats were in rank order (n = 38): 0.056, 0.068, 0.079, 0.081 (2), 0.11 (2), 0.12, 0.14, 0.15 (3), 0.19 (2), 0.20 (2), 0.21, 0.22, 0.23 (2), 0.24, 0.27, 0.31, 0.32, 0.36, 0.41, 0.44, 0.48, 0.51, 0.54, 0.55, 0.57, 0.66 (2), 0.82, 0.94, 2.1 and 3.0 mg/kg.

In field studies on succeeding crops the scaled highest residue in barley grains was < 0.02 mg/kg. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 3 mg/kg and an STMR value of 0.23 mg/kg for the subgroup of barley, similar grains, and pseudocereals with husks.

Maize Cereals

The residues on field corn and popcorn according to the US GAP were (n = 22): < 0.01 (21) and 0.012 mg/kg.

In field studies on succeeding crops mean, median and highest residues in maize (whole cobs) were < 0.02, < 0.02 and < 0.02 mg/kg, respectively. The Meeting concluded that residues in maize, the representative commodity for maize cereals, may be influenced by additional uptake of pydiflumetofen from the soil. The Meeting decided to add the scaled mean residue found in field studies on succeeding crops of 0.02 mg/kg to the median residue obtained from supervised field trials on field corn and popcorn of 0.01 mg/kg for an overall STMR for maize cereals of 0.03 mg/kg.

For the estimation of a maximum residue level the scaled highest residue found in succeeding crop field trials was < 0.02 mg/kg in maize. The Meeting estimated a maximum residue level of 0.04 mg/kg and an STMR value of 0.03 mg/kg for the subgroup of maize cereals.

Sweet Corns

The residues on sweet corn according to the US GAP were (n = 12): < 0.01 (12) mg/kg.

In field studies on succeeding crops the scaled mean, median and highest residues in maize (whole cobs) were < 0.02, < 0.02 and < 0.02 mg/kg, respectively. The Meeting concluded that residues in sweet corn, the representative commodity for sweet corns, may be influenced by an additional uptake of pydiflumetofen from the soil. It was decided to add the mean and highest residues found in field studies on succeeding crops of 0.02 mg/kg to the median and highest residues obtained from supervised field trials on sweet corn of 0.01 mg/kg for an overall STMR and HR for pydiflumetofen in sweet corns of 0.03 mg/kg.

For the estimation of maximum residue levels the scaled highest residue found in succeeding crop field trials was < 0.02 mg/kg in maize. The Meeting estimated a maximum residue level of 0.03 mg/kg, an STMR value of 0.03 mg/kg and an HR value of 0.03 mg/kg for the subgroup of sweet corns.

Rice Cereals, and Sorghum Grain and Millet

Although pydiflumetofen is not registered for use on rice cereals, sorghum grain and millet, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in cereal grains (wheat) in field studies on succeeding crops of < 0.03, < 0.03 and < 0.03 mg/kg, respectively for an estimation of maximum residue levels and STMR values in these commodities.

The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR value of 0.03 mg/kg for the subgroup of rice cereals and the subgroup of sorghum grain and millet.

Oilseeds and Oilfruits

Small seed oilseeds

The residues on rape seeds according to Canadian and US GAP were (n = 18): 0.020, 0.031, 0.041, 0.046, 0.048, 0.050, 0.056, 0.070, 0.094, 0.095, 0.11, 0.14, 0.15, 0.17, 0.18, 0.35, 0.46 and 0.69 mg/kg.

In field studies on succeeding crops the scaled highest residue in oilseeds and pulses (soya beans seeds and dry beans) was < 0.02 mg/kg. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 0.9 mg/kg and an STMR value of 0.0945 mg/kg for the subgroup of small seed oilseeds.

Peanut

The residues on peanut nutmeat according to Canadian and US GAP were (n = 12): < 0.01 (9), 0.012 and 0.018 (2) mg/kg.

In field studies on succeeding crops the scaled mean, median and highest residue in oilseeds and pulses (soya beans seeds and dry beans) were < 0.02, < 0.02 and < 0.02 mg/kg respectively. The Meeting concluded that residues in peanut nutmeat may be influenced by an additional uptake of pydiflumetofen from the soil. It was decided to add the mean residue found in field studies on succeeding crops of 0.02 mg/kg to the median residue obtained from supervised field trials on peanut nutmeat of 0.01 mg/kg for an overall STMR for pydiflumetofen in peanut of 0.03 mg/kg.

For estimation of a maximum residue level the scaled highest residue found in succeeding crop field trials was < 0.02 mg/kg in soya bean seeds and dry beans. The Meeting estimated a maximum residue level of 0.05 mg/kg and an STMR value of 0.03 mg/kg for peanut.

Sunflower seeds and Cotton seed

Although pydiflumetofen is not registered for use on sunflower seeds and cotton seed, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median highest residues found in wheat straw (worst case) in field studies on succeeding crops of 0.10, 0.08 and 0.28 mg/kg, respectively for an estimation of a maximum residue level and STMR value in these commodities.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR value of 0.08 mg/kg for the subgroup of sunflower seeds and cotton seed.

Residues in animal feeds

Legume animal feeds

The residues on pea vines (as received basis) according to Canadian GAP were (n = 5): 0.36, 0.42, 0.88, 0.90 and 2.8 mg/kg.

The residues on pea hay (dry weight basis) according to Canadian GAP were (n = 5): 1.8, 3.0, 3.4, 5.9 and 17 mg/kg.

The residues on peanut hay (dry weight basis) according to the US GAP were (n = 11): 2.0, 3.1, 4.3, 4.5, 4.7, 9.2, 12 (3), 13 and 15 mg/kg.

The Meeting concluded that the application of pydiflumetofen to pea vines and peanut hay results in the highest residues in legume animal feeds and can be used for estimation of a maximum residue level, a median value and a highest value for the whole group.

In field studies on succeeding crops the scaled mean, median and highest residues in legume animal feeds (soya bean forage) were 0.02, 0.02 and 0.02 mg/kg, respectively. The Meeting concluded that residues in pea vines and peanut hay from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

Based on the residues for pea vines, the Meeting estimated a median residue value of 0.88 mg/kg and a highest residue value of 2.8 mg/kg for forage of legume animal feeds on an “as received” basis.

Based on the residues for peanut hay, the Meeting estimated a maximum residue level of 30 mg/kg, a median residue value of 9.2 mg/kg and a highest residue value of 15 mg/kg for fodder of legume animal feeds on a dry weight basis.

Straw and fodder of barley, oats, rye, triticale and wheat

The combined pydiflumetofen residues in straw and hay of barley, oats and wheat were in rank order (n = 81): 1.4 (2), 1.8, 1.9, 2.0, 2.2, 2.5, 3.0, 3.1, 3.6, 3.7 (2), 3.8, 3.9, 4.0 (2), 4.2, 4.5, 4.7, 5.1, 5.3, 5.5, 5.7 (3), 5.9, 6.0, 6.5 (2), 6.6, 6.8 (2), 7.2, 7.5, 7.7, 8.0 (2), 8.2, 8.3, 8.4, 9.2 (2), 9.5, 9.9, 10 (3), 11 (4), 12 (2), 13 (2), 14 (2), 15, 16, 17 (3), 18 (2), 19 (2), 20 (5), 21, 23 (2), 24, 25, 26, 29, 33, 34 and 40 mg/kg on dry weight basis.

In field studies on succeeding crops the scaled mean, median and highest residues in wheat straw (fresh) were 0.10, 0.08 and 0.28 mg/kg, respectively. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting concluded that residues on straw and fodder from barley, oats and wheat may be extrapolated to straw and fodder from rye and triticale.

The Meeting estimated a maximum residue level of 50 mg/kg, a median residue value of 9.2 mg/kg and a highest residue value of 40 mg/kg for straw and fodder of barley, oats, rye, triticale and wheat on a dry weight basis.

Maize fodder

The residues on maize stover (as received basis) according to Canadian GAP were (n = 23): 0.82, 1.1, 1.3, 1.5, 1.6 (2), 1.9, 2.1, 2.3, 2.6, 3.0, 3.1, 3.2, 3.4, 3.5 (3), 3.7, 4.2, 4.8, 5.0 (2) and 13 mg/kg.

In field studies on succeeding crops the scaled mean, median and highest residues in maize stover were 0.02, 0.02 and 0.03 mg/kg, respectively. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 18 mg/kg (correction for an average 83% dry matter content), a median residue value of 3.1 mg/kg (as received) and a highest residue value of 13 mg/kg (as received) for the maize fodder.

Straw and fodder of millet, rice and sorghum

Although pydiflumetofen is not registered for use on other cereal straw and fodder plants (millet, rice and sorghum), these crops may still be subject to crop rotation and therefore contain pydiflumetofen

residues following uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in wheat straw in field studies on succeeding crops of 0.10, 0.08 and 0.28 mg/kg (fresh-weight) respectively for an estimation of maximum residue levels and STMR values in straw and fodder of millet, rice and sorghum.

The Meeting estimated a maximum residue level of 0.3 mg/kg (dry weight basis), a median residue value of 0.08 mg/kg and a highest residue value of 0.28 mg/kg (as received basis) for pydiflumetofen in straw and fodder of millet, rice and sorghum.

Forage of barley, oats, rye, triticale, wheat, maize and sweet corn

The residues on oats forage (as received basis) according to the US GAP were (n = 28): 0.47, 0.62, 0.65, 0.73, 0.75, 1.0, 1.2, 1.3, 1.5 (2), 1.6, 1.8 (2), 1.9, 2.0, 2.3 (2), 2.7, 2.9, 3.2, 3.3, 3.6, 3.7, 4.2, 5.3, 6.5, 6.6, 7.0 mg/kg.

The residues on wheat forage (as received basis) according to the US GAP were (n = 31): 0.24, 0.52, 0.97, 0.98, 1.2, 1.4, 1.6 (2), 1.7, 1.9 (2), 2.2 (2), 2.3, 2.5, 2.7, 3.3, 3.4, 3.6, 4.0, 4.2, 4.4, 4.8, 4.9, 5.4 (2), 6.2, 6.3, 7.7 and 11 (2) mg/kg.

The residues on maize forage (as received basis) according to the US GAP were (n = 20): 0.38, 0.45, 0.64, 0.67, 0.69, 0.79, 0.91, 1.0 (3), 1.3 (2), 1.5, 1.6, 2.0, 2.1, 2.2, 2.4, 2.8 and 4.9 mg/kg.

The residues on sweet corn forage (as received basis) according to the US GAP were (n = 12): 0.44, 0.49, 0.68, 0.73 (2), 0.75, 0.80, 0.90, 1.0, 1.2 (2) and 3.9 mg/kg.

In field studies on succeeding crops the scaled mean, median and highest residues in barley forage were 0.02, 0.02 and 0.04 mg/kg respectively, and in wheat forage were 0.03, 0.03 and 0.03 mg/kg respectively. The Meeting concluded that residues in forage of oats, wheat, maize and sweet corn from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a median residue value of 1.95 mg/kg and a highest residue value of 7.0 mg/kg for oats forage (as received basis).

The Meeting concluded that residues on forage from oats may be extrapolated to forage from barley.

The Meeting estimated a median residue value of 2.7 mg/kg and a highest residue value of 11 mg/kg for wheat forage (as received basis).

The Meeting concluded that residues on forage from wheat may be extrapolated to forage from rye and triticale.

The Meeting estimated a median residue value of 1.15 mg/kg and a highest residue value of 4.9 mg/kg for maize forage (as received basis).

The Meeting estimated a median residue value of 0.775 mg/kg and a highest residue value of 3.9 mg/kg for sweet corn forage (as received basis).

Forage of cereal grain, except barley, oats, rye, triticale, wheat, maize and sweet corn

Although pydiflumetofen is not registered for use on other cereal forage (except barley, oats, rye, triticale, wheat and maize), these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in wheat forage in field studies on succeeding crops of 0.03, 0.03 and 0.03 mg/kg (fresh-weight) respectively for an estimation of median values and highest values in forage of cereal grain, except barley, oats, rye, triticale, wheat, maize and sweet corn.

The Meeting estimated a median residue value of 0.03 mg/kg and a highest residue value of 0.03 mg/kg for pydiflumetofen in forage of cereal grain, except barley, oats, rye, triticale, wheat, maize and sweet corn (as received basis).

Fate of residues during processing

Processing data on various commodities are reported in the evaluation from 2018 for pydiflumetofen. All data relevant for an estimation of maximum residue levels in processed commodities or for dietary exposure calculations are summarized in the following table.

Although the studies on sweet corn were conducted at an exaggerated application rate compared to the critical GAP, pydiflumetofen residues in the RAC were below the LOQ of 0.01 mg/kg. Processing factors for sweet corn processed commodities cannot be determined.

Table 4 Processing factors and STMR-P/HR-P

Raw commodity [STMR/HR]	Processed commodity	Individual processing factors	Mean or best estimate processing factor	STMR-P = $STMR_{RAC} \times PF$ (mg/kg)	HR-P = $HR_{RAC} \times PF$ (mg/kg)
Tomato [0.11 mg/kg/ 0.42 mg/kg]	Canned	< 0.046, < 0.077	< 0.046	< 0.005	< 0.019
	Dried	9.9, 11	10.5	1.2	4.4
	Juice (Pasteurised)	< 0.046, < 0.077	< 0.046	< 0.005	
	Paste	0.55, 0.82	0.685	0.075	
	Puree	0.26, 0.41	0.335	0.037	
	Wet pomace	3.3, 4.5	3.9	0.43	
Soya bean [0.028 mg/kg]	Refined oil	0.078, 0.29	0.184	0.005	
	Miso	0.091, 0.17	0.131	0.004	
	Milk	< 0.056, < 0.064	< 0.056	< 0.002	
	Flour	< 0.056, < 0.064	< 0.056	< 0.002	
	Soya sauce	< 0.056, < 0.064	< 0.056	< 0.002	
	Tofu	0.14, 0.15	0.145	0.004	
	AGF	121, 156	139	3.9	
	Meal	0.065, 0.090	0.078	0.002	
	Hulls	2.9, 3.7	3.3	0.092	
Pollard	0.26, 0.36	0.31	0.009		
Potato [0.03 mg/kg/ 0.084 mg/kg]	Boiled (peeled)	< 0.45	< 0.45	< 0.014	< 0.038
	Baked (unpeeled)	< 0.45	< 0.45	< 0.014	< 0.038
	Dried pulp	4.3	4.3	0.13	0.36
	Chips	< 0.45	< 0.45	< 0.014	
	Crisps	< 0.45	< 0.45	< 0.014	
	Starch	< 0.45	< 0.45	< 0.014	
	Flakes	< 0.45	< 0.45	< 0.014	
	Wet peel	2.1	2.1	0.063	0.18
Wheat [0.063 mg/kg]	Bran	1.9, 2.6	2.25	0.14	
	Wholemeal bread	0.41, 0.45	0.43	0.027	
	Germs	1.0, 1.9	1.45	0.091	
	Flour	0.30, 0.34	0.32	0.020	
	Starch	0.019, 0.050	0.035	0.002	
	Gluten	1.1, 2.3	1.7	0.11	
	AGF	127, 598	363	23	
	Gluten feed meal	1.3, 2.4	1.85	0.12	
	Milled by-product	2.5, 9.7	6.1	0.38	
Barley [0.23 mg/kg]	Bran	0.24, 0.48	0.36	0.083	
	Flour	0.23, 0.23	0.23	0.053	
	Pearled barley	0.024, 0.062	0.043	0.010	
Oats [0.23 mg/kg]	Bran	0.013, 0.017	0.015	0.003	
	Flour	0.027, 0.068	0.048	0.011	
	Rolled oats	0.012, 0.013	0.013	0.003	

Raw commodity [STMR/HR]	Processed commodity	Individual processing factors	Mean or best estimate processing factor	STMR-P = STMR _{RAC} × PF (mg/kg)	HR-P = HR _{RAC} × PF (mg/kg)
Maize [0.03 mg/kg]	Refined oil	1.5, 2.3 (wet milled)	1.9	0.057	
		< 0.42, < 1.2 (dry milled)	< 0.42	< 0.013	
	Bran (hulls)	3.7, 5.8 (dry milled)	4.75	0.14	
	Grits	< 0.42, < 1.2 (dry milled)	< 0.42	< 0.013	
	Germs	2.0, 2.2 (wet milled)	2.1	0.063	
		0.91, < 1.2 (dry milled)	0.91	0.027	
	Flour	< 0.42, < 1.2 (wet milled)	< 0.42	< 0.013	
		< 1.2, 1.6 (dry milled)	1.6	0.048	
	Meal	0.93, < 1.2 (dry milled)	0.93	0.028	
	Starch	< 0.42, < 1.2 (wet milled)	< 0.42	< 0.013	
	AGF	69, 71	70	2.1	
	Milled by-product	1.7, 2.7	2.2	0.066	
Gluten	0.70, 1.9 (wet milled)	1.3	0.039		
Gluten meal	3.1, 3.3 (wet milled)	3.2	0.096		
Rape seed [0.0945 mg/kg]	Refined oil	0.36, 0.38	0.37	0.035	
	Meal	0.087, 0.094	0.091	0.009	
Peanut [0.03 mg/kg]	Refined oil	2.4	2.4	0.072	
	Meal	< 0.4	< 0.4	< 0.012	

On the basis of the maximum residue level, STMR and HR for fruiting vegetables, other than cucurbits and the default dehydration factor of 10, the Meeting estimated a maximum residue level of 5 mg/kg, an STMR value of 1.1 mg/kg and an HR value of 4.2 mg/kg for chili peppers (dry).

Using the estimated maximum residue level of 0.5 mg/kg for the group of fruiting vegetables, other than cucurbits and applying the processing factor of 10.5, the Meeting estimated a maximum residue level of 7 mg/kg for pydiflumetofen in dried tomato.

Using the estimated maximum residue level of 0.1 mg/kg for the subgroup of tuberous and corm vegetables and applying the processing factor of 4.3, the Meeting estimated a maximum residue level of 0.5 mg/kg for pydiflumetofen in dried potato.

Using the estimated maximum residue level of 0.4 mg/kg for the subgroup of wheat, similar grains, and pseudocereals without husks and applying the processing factor of 2.25 for wheat bran and 1.45 for wheat germs the Meeting estimated a maximum residue level of 1 mg/kg and 0.6 mg/kg for pydiflumetofen in wheat bran and wheat germ, respectively.

Using the estimated maximum residue level of 0.04 mg/kg for the subgroup of maize cereals and applying the processing factor of 1.9 for maize refined oil and 1.6 for maize flour, the Meeting estimated maximum residue levels of 0.08 mg/kg and 0.07 mg/kg for pydiflumetofen in maize oil, edible and maize flour, respectively.

Using the estimated maximum residue level of 0.05 mg/kg for peanut and applying the processing factor of 2.4, the Meeting estimated a maximum residue level of 0.15 mg/kg for pydiflumetofen in peanut oil, edible.

Residues in animal commodities

Farm animal feeding studies

Farm animal feeding studies (lactating dairy cow and laying hen) are reported in the evaluation of the 2018 JMPR.

Farm animal dietary burden

Some processed and forage commodities do not appear in the Recommendations Table (because no maximum residue level is needed), but they are used in estimating livestock dietary burdens. Those commodities are included in the list below. The input was based on the intake of pydiflumetofen.

Table 5 Potential feed items

Codex classification	Commodity	Median residue (-P) (mg/kg)	Highest residue (-P) (mg/kg)
Grape	Grape wet pomace	0.87	
Brassica vegetables	Head cabbage leaves	0.02	0.09
Fruiting vegetables, other than Cucurbits	Tomato wet pomace	0.43	
Brassica leafy vegetables	Kale leaves	0.02	0.09
Leaves of root and tuber vegetables	Turnip tops	0.02	0.02
	Sugar beet tops	0.02	0.02
Pulses	Beans (dry) seed, Cowpea seed, Lupin seed, Field pea (dry) seed, Soya bean (dry) seed, Vetch seed	0.028	
	Soya bean aspirated grain fractions	3.9	
	Soya bean meal	0.002	
	Soya bean hulls	0.092	
	Soya bean pollard	0.009	
Root vegetables	Carrot culls, Swede roots, Turnip roots	0.02	0.07
	Potato dried pulp	0.13	
	Potato process waste (wet peel)	0.063	
Tuberous and corn vegetables	Cassava roots, Potato culls	0.03	0.084
Wheat, similar grains, and pseudocereals without husks	Rye grain, Triticale grain, Wheat grain	0.063	
	Wheat aspirated grain fractions	23	
	Wheat gluten meal	0.12	
	Wheat milled by-product	0.38	
Barley, similar grains, and pseudocereals with husks	Barley grain, Oats grain	0.23	
	Barley bran fractions	0.083	
Maize Cereals	Maize grain, Popcorn grain,	0.03	
	Maize aspirated grain fractions	2.1	
	Maize milled by-product	0.066	
	Maize meal	0.028	
	Maize gluten	0.039	
	Maize gluten meal	0.096	
Small seed oilseeds	Rape seed meal	0.009	
Peanut	Peanut meal	< 0.012	
Legume animal feeds	Forage of legume animal feeds	0.88 (as received)	2.8 (as received)
	Fodder of legume animal feeds	9.2 (dry weight)	15 (dry weight)
Straw and fodder of cereal grains	Straw and fodder of barley, oats, rye triticale, and wheat	9.2 (dry weight)	40 (dry weight)
	Maize fodder	3.1 (as received)	13 (as received)
	Straw and fodder of cereal grains, except barley, oats, rye, triticale, wheat and maize	0.08 (as received)	0.28 (as received)
Forage of cereal grains ^a	Forage of barley and oats	1.95	7.0
	Forage of rye, triticale and wheat	2.7	11
	Maize forage	1.15	4.9
	Sweet corn forage	0.775	3.9
	Forage of cereal grains, except barley, oats, rye, triticale, wheat, maize and sweet corn	0.03	0.03

^a levels for cereal forage are presented on as received basis.

The dietary burdens, estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 Edition of the FAO manual^p, are presented in Annex 6 and summarized below.

Table 6 Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: Pydiflumetofen, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	7.9	3.3	22	7.3	44 ^a	11 ^c	0.38	0.36
Dairy cattle	21	5.9	22	7.3	42 ^b	10 ^d	7.7	2.0
Poultry – broiler	0.35	0.35	0.34	0.29	0.17	0.17	0.077	0.077
Poultry – layer	0.35	0.35	6.2 ^{e g}	2.2 ^{f h}	0.17	0.17	0.15	0.15

^a Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues

^b Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

^c Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.

^d Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

^e Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues.

^f Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues.

^g Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs.

^h Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs.

Animal commodity maximum residue levels

Cattle

Residues in tissues and milk at the expected dietary burden for dairy cattle are shown in the Table below.

Table 7 Maximum residue level, STMR and HR in mammalian animal commodities

	Feed Level (ppm) for milk residues	Total residues (mg eq/kg) in milk	Feed Level (ppm) for tissue residues	Total residues (mg eq/kg)			
				Muscle	Liver	Kidney	Fat
MRL Determination (beef or dairy cattle)							
Feeding Study	15	< 0.01	15	< 0.01	0.02	< 0.01	0.01
	45	< 0.01	45	< 0.01	0.05	< 0.01	0.05
Dietary burden and estimate of highest residue	42	< 0.01	44	< 0.01	0.05	< 0.01	0.05
HR Determination (beef or dairy cattle)							
Feeding Study			15	< 0.02	0.08	0.08	0.03
			45	< 0.02	0.44	0.30	0.07
Dietary burden and estimate of highest residue			44	< 0.02	0.43	0.29	0.069
STMR Determination (beef or dairy cattle)							
Feeding Study	15	< 0.02	15	< 0.02	0.06	0.07	0.02
Dietary burden and estimate of highest residue	10	< 0.02	11	< 0.02	0.044	0.051	0.015

^p <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

Based on pydiflumetofen residues in milk and cattle tissues, the Meeting estimated a maximum residue level of 0.01 (*) mg/kg in milk, 0.1 mg/kg in mammalian meat (in the fat), mammalian edible offal and mammalian fat.

Based on the highest estimated total residues of pydiflumetofen and 2,4,6-TCP expressed as pydiflumetofen in muscle and fat, the Meeting estimated HR values of 0.02 mg/kg in mammalian meat and 0.069 mg/kg in mammalian fat.

Based on the highest estimated total residues of pydiflumetofen, 2,4,6-TCP and SYN547897 expressed as pydiflumetofen in liver and kidney, the Meeting estimated an HR value of 0.43 mg/kg in mammalian edible offal.

Based on the mean estimated total residues of pydiflumetofen and 2,4,6-TCP expressed as pydiflumetofen in milk, muscle and fat, the Meeting estimated STMR values of 0.02 mg/kg in milk, 0.02 mg/kg in mammalian meat and 0.015 mg/kg in mammalian fat.

Based on the mean estimated total residues of pydiflumetofen, 2,4,6-TCP and SYN547897 expressed as pydiflumetofen in liver and kidney, the Meeting estimated an STMR value of 0.051 mg/kg in mammalian edible offal.

Poultry

Residues in tissues and eggs at the expected dietary burden for laying hen are shown in the Table below.

Table 8 Maximum residue level, STMR and HR in poultry commodities

	Feed Level (ppm) for egg residues	Total residues (mg eq/kg) in egg	Feed Level (ppm) for tissue residues	Total residues (mg eq/kg)		
				Muscle	Liver	Fat
MRL Determination (poultry broiler or layer)						
Feeding Study	3	< 0.01	3	< 0.01	< 0.01	< 0.01
	9	0.011	9	< 0.01	< 0.01	< 0.01
Dietary burden and estimate of highest residue	6.2	0.011	6.2	< 0.01	< 0.01	< 0.01
HR Determination (poultry broiler or layer)						
Feeding Study	3	< 0.02	3	< 0.02	< 0.02	< 0.02
	9	0.023	9	< 0.02	< 0.02	< 0.02
Dietary burden and estimate of highest residue	6.2	0.022	6.2	< 0.02	< 0.02	< 0.02
STMR Determination (poultry broiler or layer)						
Feeding Study	3	< 0.02	3	< 0.02	< 0.02	< 0.02
Dietary burden and estimate of highest residue	2.2	< 0.02	2.2	< 0.02	< 0.02	< 0.02

Based on pydiflumetofen residues in eggs and poultry tissues, the Meeting estimated a maximum residue level of 0.02 mg/kg in eggs, 0.01 (*) mg/kg in poultry meat, poultry edible offal and poultry fat.

Based on the highest estimated total residues of pydiflumetofen and 2,4,6-TCP expressed as pydiflumetofen in eggs, muscle, liver and fat, the Meeting estimated HR values of 0.03 mg/kg in eggs, 0.02 mg/kg in poultry meat, 0.02 mg/kg in poultry, edible offal of and 0.02 mg/kg in poultry fat.

Based on the mean estimated total residues of pydiflumetofen and 2,4,6-TCP expressed as pydiflumetofen in eggs, muscle, liver and fat, the Meeting estimated STMR values of 0.02 mg/kg in eggs, poultry meat, poultry, edible offal of and poultry fat.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels

listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and IESTI assessments.

Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: *Pydiflumetofen*

Definition of the residue for compliance with the MRL for animal commodities: *Pydiflumetofen*

Definition of the residue for estimation of dietary exposure for animal commodities other than mammalian liver and kidney: *Sum of pydiflumetofen and 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates, expressed as pydiflumetofen*

Definition of the residue for estimation of dietary exposure for mammalian liver and kidney: *Sum of pydiflumetofen, 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates, and 3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichloro-3-hydroxy-phenyl) ethyl]pyrazole-4-carboxamide (SYN547897) and its conjugates, expressed as pydiflumetofen*

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for pydiflumetofen is 0–0.1 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for pydiflumetofen were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2019 JMPR Report.

The IEDIs ranged from 1–20% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of pydiflumetofen from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for pydiflumetofen is 0.3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for pydiflumetofen were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2019 JMPR Report.

The IESTIs were less than 100% of the ARfD, except for spinach (up to 140% for toddlers in the Netherlands), lettuce (up to 350% for children in China) and endive (up to 230% for children in the Netherlands). The Meeting concluded that acute dietary exposure to residues of pydiflumetofen from uses considered by the present Meeting may present a health concern for these commodities.

