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Modification of the existing maximum residue levels and setting of import tolerances for flupyradifurone and DFA in various crops and animal commodities

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer CropScience SA-NV submitted a request to the competent national authority in the Netherlands to modify the existing maximum residue levels (MRLs) and to set import tolerances for the active substance flupyradifurone and its metabolite difluoroacetic acid (DFA) in various plant and animal commodities. The data submitted in support of the requests were found sufficient to derive MRL proposals for flupyradifurone and/or DFA in the crops under consideration. The calculated EU livestock dietary burden indicated that for several animal matrices the EU MRLs for flupyradifurone and/or DFA would need to be modified. Adequate analytical methods for enforcement are available to control the residues of both compounds in the plant and animal commodities under consideration, and in honey. Based on the risk assessment results, EFSA concluded that the proposed and authorised uses of flupyradifurone on various crops and subsequent residues of flupyradifurone and DFA in plant and animal commodities will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

Keywords: flupyradifurone, difluoroacetic acid (DFA), various crops, animal commodities, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience SA-NV submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) and to set import tolerances for flupyradifurone and its metabolite difluoroacetic acid (DFA) in various plant and animal commodities, as well as in honey.

The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 5 May 2022. To accommodate for the intended uses of flupyradifurone in Europe and the authorised uses in Australia and United States, the EMS proposed to raise the existing MRLs for flupyradifurone and/or DFA in various plant commodities (citrus fruits, macadamias, stone fruits, cane fruits, other small fruits and berries, leafy brassica, herbs and edible flowers, sunflower seeds, corn/maize, millet, oat and rye). The EMS identified a need to raise the existing EU MRLs for flupyradifurone in honey and liver, kidney and edible offal of swine and for the DFA in fat of swine, sheep and poultry and sheep milk and poultry eggs.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification, which were requested from the EMS. On 22 December 2022 the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of flupyradifurone was investigated following foliar applications in fruit crops, pulses/oilseeds and cereals, by soil granule/drench applications in fruit crops, root crops and cereals and by seed dressing in root crops. The EU pesticides peer review concluded that in primary crops flupyradifurone was expected to be the major component. Following the soil application, significant proportions of DFA were observed; the data from residue trials confirmed that DFA is the relevant plant metabolite of flupyradifurone.

In rotational crops, the major residues identified were flupyradifurone, its metabolites flupyradifurone-hydroxy, 6-CNA and their conjugates and DFA. The presence of DFA is mostly the result of its uptake from soil, where DFA is formed as the major metabolite of flupyradifurone.

Studies investigating the effect of processing on the nature of flupyradifurone (hydrolysis studies) demonstrated that the active substance is stable. Studies investigating the effect of processing on the nature of DFA are not available. However, considering the structural similarity of DFA with trifluoroacetic acid (TFA), which is very stable under hydrolysis conditions, it is concluded that DFA is unlikely to degrade under standard hydrolytic conditions.

Based on the metabolic pattern identified in primary and rotational crop metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were agreed by the EU pesticides peer review:

- Residue definition for risk assessment: Sum of flupyradifurone and DFA, expressed as flupyradifurone.
- Residue definitions for enforcement: (1) Flupyradifurone; (2) DFA, expressed as DFA.

The same residue definitions are applicable to primary crops, rotational crops, processed products and honey. The two residue definitions for enforcement in Regulation (EC) No 396/2005 are identical with the above-mentioned residue definitions. In the United States and Australia the established enforcement residue definition is only parent flupyradifurone.

EFSA concluded that for the crops assessed in this application, metabolism of flupyradifurone in primary and in rotational crops, and the possible degradation in processed products has been addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) are available to quantify residues of flupyradifurone and of DFA in the crops assessed in this application and in honey according to the enforcement residue definitions. The methods enable quantification of residues at or above the limits of quantification (LOQs) of 0.01 mg/kg for flupyradifurone and of 0.007 mg/kg for DFA in the crops assessed and in honey. According to the MRL legislation, the LOQs currently in place for flupyradifurone and DFA in

plant commodities are 0.01 and 0.02 mg/kg, respectively; the LOQ currently in place for both flupyradifurone and DFA in honey is 0.05 mg/kg. Extraction efficiency is sufficiently demonstrated in high water content, high oil content and dry commodities for flupyradifurone and in high water content commodities for DFA.

The residue data submitted in support of intended European and authorised third country uses under assessment were found to be sufficient to derive MRL proposals for flupyradifurone and/or DFA in all commodities under consideration and honey. However, the intended SEU use on large citrus fruits, the authorised use on cherries in the USA, the intended SEU use of flupyradifurone on barley, oat, maize and millet were not supported by a sufficient number of residue trials; for these commodities the MRL proposals were derived from alternative uses or no modifications of the existing MRLs were proposed.

Flupyradifurone exhibits high soil persistence, forming DFA as its soil metabolite. The gradual formation of DFA results in its uptake in rotational crops. The occurrence of flupyradifurone and DFA residues in rotational crops was investigated in the framework of the EU pesticides peer review and in the previous EFSA assessments. Since the critical primary crop uses reported for the present assessment refer to the same application patterns as assessed previously, the estimated residues of DFA in rotational crops remain valid and were not revised.

For leafy brassica, sunflower seed, maize grain, oat grain and rye grain, the expected soil uptake of DFA residues in rotational crops was identified to be significant and thus, it may affect the MRL values for DFA. For these crops, in order to quantify the contribution of soil residues to the overall residue levels in the harvested commodities, two MRL proposals for DFA were derived: an MRL proposal accounting for residues expected only from primary crop treatment and a combined MRL proposal, which reflects residues in a crop from the primary crop treatment and from the soil uptake in rotational crops. A risk management consideration is required on whether to support the setting of MRLs on the basis of residue soil uptake or to propose implementation of risk mitigation measures to avoid residues in rotational crops.

The provided residue trials with *Phacelia tanacetifolia* to investigate residue transfer from plants to honey were considered sufficient to assess the expected residues in honey. A new MRL proposal could be derived for flupyradifurone in honey, whereas no need to modify the existing MRL for DFA in honey was identified.

New studies investigating the effect of processing on the magnitude of flupyradifurone and DFA residues were submitted in cherries and peaches. Peeling factors were derived for citrus fruits.

Sufficiently validated analytical methods based on HPLC–MS/MS are available to quantify residues of flupyradifurone and of DFA in food of animal origin according to the enforcement residue definitions. The methods enable quantification of residues at or above the limits of quantification (LOQs) of 0.01 and of 0.02 mg/kg for flupyradifurone and for DFA, respectively. Extraction efficiency of flupyradifurone is sufficiently demonstrated in mammal and poultry tissues (except poultry fat), milk and eggs; extraction efficiency of flupyradifurone in poultry fat is partially demonstrated. Due to the lack of DFA radiolabelled material in animal commodities, the extraction efficiency of the method for enforcement of DFA in animal commodities could not be investigated according to the extraction efficiency Technical Guideline.

An assessment of residues in livestock was performed since several of the crops on which EU uses are intended can be fed to livestock. Moreover, cereal grains, treated according to the authorised uses in the United States, can be imported in Europe and can also enter feed chain directly or as feed derived from food by-products. Livestock exposure to flupyradifurone and DFA residues which was calculated in previous EFSA assessments (also considering the potential intake from rotational crops) was now updated for the EU livestock diet. The results indicate that the trigger value of 0.004 mg/kg body weight (bw) per day is exceeded for all livestock species, both for flupyradifurone and DFA and the main contributing commodities are kale leaves and swede roots. The contribution of residues in the crops under consideration to the overall dietary burden is marginal, but due to a more detailed data available for fat matrix from feeding studies, the need to raise the existing EU MRLs in animal commodities was further investigated.

The nature of flupyradifurone residues in livestock has been assessed during the EU pesticides peer review of flupyradifurone and the two following residue definitions for enforcement were proposed (1) 'flupyradifurone' and (2) 'DFA, expressed as DFA'; for risk assessment, the residue definition is the 'sum of flupyradifurone and DFA, expressed as flupyradifurone'. The available livestock feeding studies with flupyradifurone and DFA, respectively, for poultry and ruminants were used to derive MRL proposals for flupyradifurone and for DFA reflecting the expected dietary burden estimated for EU livestock. Results indicate that the existing EU MRL for DFA would need to be raised for sheep, goat, swine and poultry fat. The modification of MRLs in fats is based on the corrected input values for bovine fat (mean value vs individual matrix value) used in the previous assessment and the present assessment. The intake of flupyradifurone residues indicate that the existing MRL for flupyradifurone would need to be raised in swine liver, fat and kidney (including edible offal). The recalculation of these MRLs also resulted in higher risk assessment values for several commodities of animal origin, further used in the consumer exposure assessment. It is noted that estimated MRLs in animal commodities take into consideration livestock intake of both the treated primary crops and rotational crops.

The toxicological profile of flupyradifurone was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.064 mg/kg bw per day and an acute reference dose (ARfD) of 0.15 mg/kg bw. The toxicological reference values are also applicable to metabolite DFA.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo) according to the internationally agreed methodology. EFSA performed two separate consumer exposure calculations in order to estimate the intake from primary crops (including also animal products) (intake 1) and rotational crops (intake 2). This approach was chosen to provide risk managers additional information to decide on risk management options as regards residues in rotational crops, e.g. whether MRLs should be established to cover residues in rotational crops or whether other restrictions would be appropriate to avoid residues in untreated crops. The exposure was calculated for the risk assessment residue definition and compared with the toxicological reference values as derived for flupyradifurone.

The input values in intake 1 were as derived from the submitted residue trials for plant commodities and risk assessment values derived for animal commodities as described above; for several crops the risk assessment values were available from previous EFSA and JMPR assessments. The crops for which no uses have been reported since the EU pesticides peer review were excluded from the exposure calculation. In intake 2, the input values were as derived from rotational crop studies in the previous EFSA assessments.

The estimated long-term dietary exposure in intake 1 accounted for a maximum of 54% of the ADI for NL toddler diet. For intake 2, the exposure accounted for up to 17% of the ADI for GEMS/Food G06 diet and 15% of the NL toddler diet. The highest combined exposure from the intake 1 and intake 2 was identified for the Dutch toddler diet, accounting for a maximum of **69% of the ADI**. The overall exposure to flupyradifurone and DFA is unlikely to pose a chronic consumer intake concern.

In the short-term dietary exposure according to intake 1 and intake 2, no exceedances of the ARfD were identified for the crops under consideration. Based on the combined acute intake, consumer exposure concerns were not identified. The highest combined acute exposure for the annual crops under consideration was identified for kale (77% of the ARfD) and Chinese cabbage/pe-tsai (56% of ARfD).

EFSA notes that although according to the internationally agreed methodology for acute risk assessment, which is based on the highest residue found in the supervised field trials, no acute consumer intake concerns were identified, for the uses on oranges and kales, if residues of flupyradifurone occur in kales at the derived MRL value and in oranges at the existing EU MRL, the dietary exposure of certain consumers may exceed the ARfD (117.3% and 106.1% of the ARfD, respectively) under certain conditions (i.e. consumption of a large portion of the product without washing/peeling/processing which would lead to a reduction of the residues in the product, some commodity units contain more residues than the average in the lot due to inhomogeneous distribution). Risk managers should decide whether the safety margin of the exposure assessment based on the highest residue is sufficient, considering that in reality residues in individual units/lot consumed may occur at or above the proposed MRL.

EFSA concluded that the proposed and authorised uses of flupyradifurone on various crops and subsequent residues of flupyradifurone and DFA in plant and animal commodities will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

It must be noted that the investigation of possible risk to bees related to the use of flupyradifurone is outside the scope of this reasoned opinion. The evaluation of the risk to bees was recently re-assessed at EU level in a statement, following concerns raised by France and the Netherlands. An appropriate specific risk assessment for solitary bees following the intended uses of flupyradifurone was recommended by EFSA. The European Commission has recently started a procedure according to

Article 21 of Regulation (EC) No 1107/2009 to address the risk for wild bees from the use of flupyradifurone due to the afore-mentioned adverse information. National competent authorities at Member State level should pay attention to the bee health and bee protection when granting authorisations for plant protection products according to the provisions laid out in the Regulation (EU) 2015/1295.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Flupyradifurone				
0110010	Grapefruits	3	No new proposal	The intended SEU use not sufficiently supported by data. The lowering of the existing EU MRL is not proposed. The existing EU MRL is based on previously assessed import tolerance for which no consumer intake concerns were identified.
0110020	Oranges	3	No new proposal	
0110030	Lemons	1.5	No new proposal	The submitted data are sufficient to derive an MRL proposal of 0.2 mg/kg in support of the intended SEU use. The lowering of the existing EU MRL is not proposed. The existing EU MRL is based on previously assessed import tolerance for which no consumer intake concerns were identified.
0110040	Limes	1.5	No new proposal	
0110050	Mandarins	1.5	No new proposal	
0110990	Other citrus fruits	0.01*	3	The applicant proposes to increase the existing EU MRL based on a previously assessed import tolerance data set in oranges and grapefruits. Risk for consumers unlikely.
0120070	Macadamias	0.02	No new proposal	The submitted data are sufficient to derive an MRL proposal of 0.01* mg/kg in support of the authorised use in Australia. The lowering of the existing EU MRL is not proposed. Risk for consumer unlikely.
0140010	Apricots	0.01*	1	The submitted data are sufficient to support the import tolerance request from the authorised US GAP. Risk for consumers unlikely.
0140020	Cherries (sweet)	0.01*	2	The submitted data are sufficient to support the intended NEU and SEU uses. The MRL proposal is based on the critical use (SEU). The data submitted in support of the import tolerance from the USA are insufficient to derive an MRL proposal. Risk for consumers unlikely.
0140030	Peaches	0.01*	1.5	The submitted data are sufficient to support the import tolerance request from the USA. Risk for consumers unlikely.
0140040	Plums	0.01*	0.4	The submitted data are sufficient to support the intended NEU, SEU uses and import tolerance request. The MRL proposal is based on the critical use (USA). Risk for consumers unlikely.
0140990	Other stone fruits	0.01*	1.5	The applicant proposes to extrapolate MRL proposal as derived for peaches to the group of 'other stone fruit'. Risk for consumers unlikely.
0153000	Cane fruits	6	No new proposal	The submitted residue data are sufficient to support the intended EU indoor use and to derive an MRL proposal of 1.5 mg/kg. The lowering of the existing EU MRL is not proposed. Risk for consumers unlikely.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0154010	Blueberries	4	No new proposal	The residue data submitted in support of the intended EU indoor use result in a lower MRL proposal of 0.7 mg/kg. The lowering of the existing EU MRL is not proposed. Risk for consumers unlikely.
0154020	Cranberries	0.01*	0.7	The submitted residue data are sufficient to support the intended EU indoor use. Risk for consumers unlikely.
0154030	Currants	0.01*	0.7	
0154040	Gooseberries	0.01*	0.7	
0154050	Rose hips	0.01*	0.7	
0154060	Mulberries	0.01*	0.7	
0154070	Azaroles	0.01*	0.7	
0154080	Elderberries	0.01*	0.7	
0154990	Other small fruits and berries	0.01*	0.7	
0243010	Chinese cabbages/pe-tsai	0.01*	4	The submitted residue data are sufficient to support the intended NEU and SEU uses. Risk for consumers unlikely.
0243020	Kales	5	5 or 4 Further risk management consideration required	The submitted residue data are sufficient to support the intended NEU and SEU uses. The lowering of the existing EU MRL in kales is proposed by the applicant and is supported by data. Risk for consumers unlikely.
0243990	Others (leafy brassica)	0.01*	4	The submitted residue data are sufficient to support the intended NEU and SEU uses. Risk for consumers unlikely.
0256000	Herbs and edible flowers	6	40	The submitted residue data are sufficient to support the intended EU indoor use. Risk for consumers unlikely.
0401050	Sunflower seeds	0.01*	0.07	The submitted residue data are sufficient to support the intended SEU use. The intended NEU use is not sufficiently supported by data. Risk for consumers unlikely.
0500010	Barley	3	No new proposal	The submitted residue data are sufficient to support the intended NEU use and import tolerance from the USA. The intended SEU use not sufficiently supported by data. The existing EU MRL is confirmed for the critical authorised use (USA). Risk for consumers unlikely.
0500030	Maize/corn	0.02	No new proposal	The submitted residue data are sufficient to support the intended NEU use and import tolerance from the USA. The intended SEU use not sufficiently supported by data. The existing EU MRL is confirmed for the critical authorised use (USA). Risk for consumers unlikely.
0500040	Common millet/ proso millet	0.01*	0.02	The submitted residue data are sufficient to support the intended NEU use and import tolerance from the USA. The intended SEU use is not sufficiently supported by data. The MRL proposal is based on the critical authorised use (USA). Risk for consumers unlikely.
0500050	Oat	0.01*	3	The submitted residue data are sufficient to support the intended NEU use and import tolerance from the USA. The intended SEU use not sufficiently supported by data. The MRL proposal is based on the critical authorised use (USA). Risk for consumers unlikely.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0500070	Rye	0.01*	1	The submitted residue data are sufficient to support the intended NEU and SEU uses and import tolerance from the USA. The MRL proposal is based on the critical authorised use (USA). Risk for consumers unlikely.
050090	Wheat	1	No new proposal	The submitted residue data are sufficient to support the intended NEU and SEU uses and import tolerance from the USA. The existing EU MRL is confirmed for the critical authorised use (USA). Risk for consumers unlikely.
1011020	Swine, fat	0.015	0.02	The MRL proposal is based on an updated calculation considering the EU livestock exposure. Risk for consumers unlikely.
1011030	Swine, liver	0.08	0.10	The MRL proposal is based on an updated calculation considering the EU livestock exposure. Risk for consumers unlikely.
1011040	Swine, kidney	0.09	0.15	The MRL proposal is based on an updated calculation considering the EU livestock exposure. Risk for consumers unlikely.
1011050	Swine, edible offal	0.09	0.15	
1040000	Honey and other apiculture products	0.05*	2	The submitted residue data are sufficient to derive an MRL in honey. Risk for consumers unlikely.
Enforcement residue definition: difluoroacetic acid (DFA), expressed as DFA				
0110010	Grapefruit	0.05	No new proposal	The submitted residue data are not sufficient to derive a new MRL proposal.
0110020	Oranges	0.05	No new proposal	
0110030	Lemons	0.05	0.09	The submitted residue data are sufficient to support the intended SEU use of flupyradifurone. Risk for consumers unlikely.
0110040	Limes	0.05	0.09	
0110050	Mandarins	0.05	0.09	
0110990	Other citrus fruits	0.02*	0.09	The applicant proposes to extrapolate the MRL proposal from small citrus fruits to 'other citrus fruits'. Risk for consumers unlikely.
0120070	Macadamias	0.04	0.3	The submitted residue data are sufficient to support the authorised use of flupyradifurone in Australia. Risk for consumers unlikely.
0140010	Apricots	0.02*	0.3	The submitted data are sufficient to support the use of flupyradifurone in the USA. Risk for consumers unlikely.
0140020	Cherries (sweet)	0.02*	0.15	The submitted data are sufficient to support the intended NEU and SEU uses of flupyradifurone. The MRL proposal is based on the critical use (SEU). The data submitted in support of the import tolerance from the USA are not sufficient to derive an MRL proposal. Risk for consumers unlikely.
0140030	Peaches	0.02*	0.3	The submitted data are sufficient to support the use of flupyradifurone in the USA. Risk for consumers unlikely.
0140040	Plums	0.02*	0.3	The submitted data are sufficient to support the intended NEU, SEU uses and the use of flupyradifurone in the USA. The MRL proposal based on the critical use (USA). Risk for consumers unlikely.
0140990	Other stone fruits	0.02*	0.3	Proposal to extrapolate the highest MRL proposal in stone fruits to 'other stone fruits'.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0153010	Blackberries	0.07	No new proposal	The data submitted in support of the intended EU indoor use of flupyradifurone confirm the existing EU MRL.
0153020	Dewberries	0.02*	0.07	The submitted residue data are sufficient to support the intended EU indoor use of flupyradifurone. Risk for consumers unlikely.
0153030	Raspberries	0.07	No new proposal	The data submitted in support of the intended EU indoor use of flupyradifurone confirm the existing EU MRL.
0153990	Other cane fruits	0.02*	0.07	The applicant proposes to extrapolate MRL proposal to 'other cane fruits'.
0154010	Blueberries	0.05	No new proposal	The submitted residue data are sufficient to support the intended EU indoor use of flupyradifurone and to derive an MRL proposal of 0.01* mg/kg. The lowering of existing EU MRLs is not proposed.
0154020	Cranberries	0.02*	No new proposal	
0154030	Currants	0.02*	No new proposal	
0154040	Gooseberries	0.02*	No new proposal	
0154050	Rose hips	0.02*	No new proposal	
0154060	Mulberries	0.02*	No new proposal	
0154070	Azaroles	0.02*	No new proposal	
0154080	Elderberries	0.02*	No new proposal	
0154990	Other small fruits and berries	0.02*	No new proposal	
0243010	Chinese cabbages/pe-tsai	0.02*	0.5 or 0.7 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.5 mg/kg. The MRL proposal for EU uses reflecting direct treatment and residues taken up via roots would require an MRL of 0.7 mg/kg. Risk for consumers unlikely in both scenarios.
0243020	Kales	0.6	0.5 or 0.7 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.5 mg/kg (lower than the existing MRL). The MRL proposal for EU uses reflecting direct treatment and residues taken up via roots would require an MRL of 0.7 mg/kg. Risk for consumers unlikely in both scenarios.
0243990	Others (leafy brassica)	0.02*	0.5 or 0.7 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.5 mg/kg. The MRL proposal for EU uses reflecting direct treatment and residues taken up via roots would require an MRL of 0.7 mg/kg. Risk for consumers unlikely in both scenarios.
0256000	Herbs and edible flowers	0.3	No new proposal	The submitted data considering residues from the primary crop treatment and residues taken up via roots indicate no need to modify the existing EU MRL. Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.03 mg/kg.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0401050	Sunflower seeds	0.05	0.09 or 0.15 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.09 mg/kg. The MRL proposal for EU uses reflecting direct treatment and residues taken up via roots would require an MRL of 0.15 mg/kg. Risk for consumers unlikely in both scenarios.
0500010	Barley	0.8	No new proposal	The submitted data considering residues from the primary crop treatment and residues taken up via roots indicate no need to modify the existing EU MRL. Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.6 mg/kg.
0500030	Maize/corn	0.1	No new proposal or 0.15 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would result in an MRL of 0.05 mg/kg (lower than the existing MRL). The MRL proposal for EU uses reflecting direct treatment and residues taken up via roots would require an MRL of 0.15 mg/kg. Risk for consumers unlikely in both scenarios.
0500040	Common millet/ proso millet	0.3	No new proposal	The submitted data considering residues from the primary crop treatment and residues taken up via roots indicate no need to modify the existing EU MRL. Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.05 mg/kg.
0500050	Oat	0.3	0.6 or 0.8 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require a MRL of 0.6 mg/kg. The MRL proposal for US use reflecting direct treatment and residues taken up via roots would require an MRL of 0.8 mg/kg. Risk for consumers unlikely in both scenarios.
0500070	Rye	0.3	1 or 1.5 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 1 mg/kg. The MRL proposal for US use reflecting direct treatment and residues taken up via roots would require an MRL of 1.5 mg/kg. Risk for consumers unlikely in both scenarios.
0500090	Wheat	1.5	No new proposal	The submitted data considering residues from the primary crop treatment and residues taken up via roots indicate no need to modify the existing EU MRL. Direct treatment of the crop with flupyradifurone (primary crop treatment) would require a MRL of 1 mg/kg.
1011020	Swine, fat	0.1	0.2	MRL proposal based on an updated calculation considering the EU livestock exposure. The MRL proposal considers livestock exposure to residues from the intake of primary and rotational crops. Risk for consumers unlikely.
1013020	Sheep, fat	0.15	0.3	MRL proposal based on an updated calculation considering the EU livestock exposure. The MRL proposal considers livestock exposure to residues from the intake of primary and rotational crops. Risk for consumers unlikely.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
1014020	Goat, fat	0.15	0.3	MRL proposal based on an updated calculation considering the EU livestock exposure. The MRL proposal considers livestock exposure to residues from the intake of primary and rotational crops. Risk for consumers unlikely.
1016020	Poultry, fat	0.03	0.04	MRL proposal based on an updated calculation considering the EU livestock exposure. The MRL proposal considers livestock exposure to residues from the intake of primary and rotational crops. Risk for consumers unlikely.
1040000	Honey and other apiculture products	0.05*	No change proposed	The submitted residue data indicate that an MRL of 0.02 m/kg would be sufficient to cover the DFA residues in honey resulting from the use of flupyradifurone on primary crops. Additional (underdosed) trials indicated that the soil uptake of DFA in rotational crops may result in DFA residues at the range of < 0.007–0.012 mg/kg in honey; despite the possible underestimation, these data indicate the existing MRL value does not need to be changed. An analytical enforcement method validated at the LOQ of 0.007 mg/kg is available. The lowering of the current MRL value of 0.05 mg/kg is not proposed, but removal of the asterisk (*) could be considered. Further risk management consideration is required.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for flupyradifurone and its metabolite difluoroacetic acid (DFA) in various plant and animal commodities on the basis of intended flupyradifurone uses in the EU and authorised uses in Australia and United States. In addition, for flupyradifurone an MRL in honey is proposed.

The detailed description of the intended and authorised uses, which are the basis for the current MRL application, is reported in Appendix A. Flupyradifurone is the ISO common name for 4-{[(6-chloro-3-pyridyl)methyl](2,2-difluoroethyl)amino}furan-2(5*H*)-one (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Flupyradifurone was evaluated in the framework of Directive Regulation (EC) No 1107/2009[1] with the Netherlands designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on hops and lettuce. The draft assessment report (DAR) also included a proposal to set maximum residue levels (MRL application), in accordance with Article 11 (2) of the Regulation (EC) 1107/2009. The DAR prepared by the RMS has been peer reviewed by EFSA (2015a), where some information was identified as unavailable (data gaps) and tentative MRLs were derived for those uses which were not fully supported by data. Furthermore, the conclusion also addressed the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005. Flupyradifurone was approved[2] for the use as insecticide on 19 December 2015.

The data gaps identified by the EU pesticides peer review as well new EU uses and authorised uses of flupyradifurone in third countries were assessed in an EFSA reasoned opinion (EFSA, 2020a).

EFSA has recently assessed uses of flupyradifurone on rape seeds, mustard seeds and okra/lady's finger (EFSA, 2020b, 2021). The proposals from these reasoned opinions have been considered in recent MRL regulations.[3] In addition, certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation according to Commission Regulation (EU) 2022/1324.

Furthermore, EFSA has issued a statement on the active substance flupyradifurone in the context of concerns that this substance may pose high risks to humans and the environment raised by the French authorities (EFSA, 2021). With regard to human health the PPR Panel (EFSA PPR Panel, 2022) concluded that the additional information did not modify the conclusions reached in the evaluation by EFSA (2015a). It must be noted that the investigation of possible risk to bees related to the use of flupyradifurone is outside the scope of this reasoned opinion. The evaluation of the risk to bees was recently re-assessed at EU level in a statement, following concerns raised by France and the Netherlands. An appropriate specific risk assessment for solitary bees following the intended uses of flupyradifurone was recommended by EFSA. The European Commission has recently started a procedure according to Article 21 of Regulation (EC) No 1107/2009 to address the risk for wild bees from the use of flupyradifurone due to the afore-mentioned adverse information. National competent authorities at Member State level should pay attention to the bee health and bee protection when granting authorisations for plant protection products according to the provisions laid out in the Regulation (EU) 2015/1295.

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience SA-NV submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing MRLs for the active substance flupyradifurone and its metabolite DFA in various plant and animal commodities, and to set import tolerances.

The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 5 May 2022.

To accommodate for the intended uses of flupyradifurone in Europe and the authorised uses in Australia and United States, the EMS proposed to raise the existing MRLs for flupyradifurone and/or DFA in various plant commodities (citrus fruits, macadamias, stone fruits, cane fruits, other small fruits and berries, leafy brassica, herbs and edible flowers, sunflower seeds, corn/maize, millet, oat and rye).

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[2] Commission Implementing Regulation (EU) 2015/2084 of 18 November 2015 approving the active substance flupyradifurone, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 OJ L 302, 19.11.2015, p. 89–92.

[3] For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

The EMS identified a need to raise the existing EU MRLs for flupyradifurone in honey and liver, kidney and edible offal of swine and for the DFA in fat of swine, sheep and poultry and sheep milk and poultry eggs.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification, which were requested from the EMS. On 22 December 2022 the EMS submitted a revised evaluation report (Netherlands, 2022), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Netherlands, 2022), the DAR and its addenda (Netherlands, 2014, 2015) prepared under Regulation (EC) 1107/2009, the Commission review report on flupyradifurone (European Commission, 2015), the conclusion on the peer review of the pesticide risk assessment of the active substance flupyradifurone (EFSA, 2015a), as well as the conclusions from previous EFSA opinions on flupyradifurone (EFSA, 2016, 2020a,b, 2021).

For this application, the data requirements established in Regulation (EU) No 283/2013[4] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 2010, 2017, 2018, 2020, 2021; OECD, 2007a–g, 2008a,b, 2009a,b, 2011, 2013, 2016, 2018). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[5].

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, is presented in Appendix B.

The evaluation report submitted by the EMS (Netherlands, 2022) and the exposure calculations using the EFSA PRIMo are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.[6]

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

Flupyradifurone metabolism in primary crops was investigated in the framework of the EU pesticides peer review (EFSA, 2015a) in four crop groups either by foliar applications (apple, cotton, rice), by soil granule/drench applications (tomato, potato, rice) and by seed treatment (potato).

Studies were conducted using ^{14}C-flupyradifurone labelled on the pyridinyl and furanone moiety. One study on tomato using soil drench application and a ^{14}C-labelling on the ethyl group was also submitted. The metabolism in primary crops was seen to be similar in all plant groups investigated.

In tomato fruits, following the soil drench application, significant proportions (87% total radioactive residue (TRR)) and levels (0.17 mg/kg) of DFA were observed. Reanalysing samples from radiolabelled studies for non-radiolabelled DFA residues, the measured DFA residues (expressed as DFA equivalent) were in the range of 0.04–0.23 mg/kg in apple fruits, potato tuber, cotton seed and rice grain, irrespective of the mode of application (EFSA, 2015a).

The peer review concluded that in primary crops, flupyradifurone is not extensively degraded and the metabolism in plants proceed via the hydroxylation of the furanone ring leading to the flupyradifurone-hydroxy metabolite (M8 metabolite) and its glycoside conjugates and via the cleavage of the parent molecule at the ethylamine bond resulting in the formation of metabolites containing the pyridinyl moiety (CHMP-diglycoside, 6-CNA free and conjugated, see Appendix F). The furanone counterpart is incorporated in natural glycoside or carbohydrate components. The EU pesticides peer review considered parent flupyradifurone and its metabolite DFA to be the main residues in the crops investigated.

[4] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, p. 1–84.

[5] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

[6] Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00304

For the intended and authorised uses under consideration, it is concluded that the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Flupyradifurone is proposed to be used or is authorised on several crops that can be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the EU pesticides peer review, flupyradifurone exhibits moderate to high persistence in the soil with the maximum $DT_{90,field}$ value of more than 1,000 days. The relevant soil metabolites of flupyradifurone – 6-CNA and DFA – exhibited very low to moderate and moderate to medium persistence with maximum $DT_{90,lab}$ values of 121 days and 244 days, respectively (EFSA, 2015a). The 6-CNA metabolite was not identified by the peer review experts as relevant residue in rotational crops and was thus not further considered in this assessment.

The nature of flupyradifurone in rotational crops (turnips, Swiss chards and wheat) was investigated in the framework of the EU pesticides peer review (EFSA, 2015a). Flupyradifurone, ^{14}C-labelled at pyridinyl and furanone moiety was applied on bare soil at an application rate of 436 g/ha. Rotational crops were planted 29, 135 and 296 days after the soil treatment. In rotational crops flupyradifurone and its metabolites flupyradifurone-hydroxy (M8 metabolite), 6-CNA and their conjugates were found to be the major components of the radioactive residues. These radiolabelled studies did not include labelling on the difluoroethyl amino group, but this was not considered as a data gap by the peer review considering that rotational crop field trials confirmed that DFA is the main component in rotational crops. The presence of DFA is mostly due to the direct uptake of DFA residue formed in the soil from parent flupyradifurone (EFSA, 2015a).

EFSA concludes that for the intended and authorised uses under consideration the metabolism of flupyradifurone in rotational crops is addressed and further studies are not required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of flupyradifurone was investigated in the framework of the EU pesticides peer review (EFSA, 2015a).

Standard hydrolysis studies showed that flupyradifurone is hydrolytically stable under standard processing conditions of pasteurisation, baking/brewing/boiling and sterilisation. The effect of processing on the nature of DFA has not been investigated. Considering the similarity of the structures between trifluoroacetic acid (TFA) and DFA, the applicant proposed a read-across for both acids. The TFA has been widely studied due to its wide use in the organic chemistry and is, due to its structure (complete fluoride ion substitution), very stable and thus has no potential for hydrolytic degradation (EFSA, 2020a). EFSA agrees with the EMS that there is sufficient evidence that DFA is stable under standard hydrolysis conditions.

1.1.4. Analytical methods for enforcement purposes in plant commodities

The availability of analytical enforcement methods for the determination of flupyradifurone and DFA in plant matrices was investigated in the framework of the EU pesticides peer review (EFSA, 2015a).

It was concluded that a method using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) is sufficiently validated for the determination of flupyradifurone and DFA residues; LOQs achievable with the method were 0.01 mg/kg and 0.007 mg/kg for flupyradifurone and for DFA (expressed as DFA), respectively, in plant matrices with high water (lettuces), high starch (wheat, potatoes), high acid (oranges) and high oil content (rapeseeds). In hops, the validated LOQs for the determination of flupyradifurone and of DFA (expressed as DFA) were 0.05 mg/kg and 0.03 mg/kg, respectively.

EFSA concludes that a sufficiently validated analytical method is available for the enforcement of flupyradifurone and DFA residues in the crops under consideration.

The efficiency of the extraction procedures used in the analytical method for enforcement of flupyradifurone in high water content, high oil content and dry commodities was demonstrated by radio-cross-validation using radiolabelled sample material (^{14}C-flupyradifurone labelled either on the pyridinyl or furanone moiety) from the flupyradifurone metabolism studies in tomato, potato, cotton seed and wheat straw, in line with the extraction efficiency Technical Guideline (European Commission, 2017).

Similarly, the efficiency of the extraction procedures used in the analytical method for enforcement of DFA in high water content commodities was demonstrated by radio-cross-validation using radiolabelled sample material (^{14}C-flupyradifurone labelled on the difluoroethyl amino group) from the flupyradifurone metabolism study in tomato.

However, due to the lack of flupyradifurone-radiolabelled material in high acid content commodities and the lack of DFA-radiolabelled material in matrices other than high water content matrices, the extraction efficiency of the method for enforcement of flupyradifurone in high acid content commodities and of DFA in high acid content, high oil content and dry commodities could not be investigated according to the extraction efficiency Technical Guideline (European Commission, 2017). Further investigation on this matter would be required. Therefore, EFSA recommends to reconsider this point in the context of the peer review for the renewal of the approval of flupyradifurone.

1.1.5. Storage stability of residues in plants

The storage stability of flupyradifurone and DFA has been investigated in the EU pesticides peer review (EFSA, 2015a) as well as in the previously issued EFSA reasoned opinion (EFSA, 2020a). The freezer storage stability of flupyradifurone and DFA residues is confirmed at −18°C for 52 months in matrices with high water content, high acid content, high oil content, high protein content and high starch content (EFSA, 2020a). Therefore, it was demonstrated that in crops assessed in the framework of this application, residues are stable for at least 52 months when stored at −18°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation products, the capabilities of enforcement analytical methods, the following residue definitions were proposed by the EU pesticides peer review (EFSA, 2015a):

- residue definition for risk assessment: sum of flupyradifurone and DFA, expressed as flupyradifurone.
- residue definition for enforcement: (1) flupyradifurone; (2) difluoroacetic acid (DFA), expressed as DFA.

The same residue definitions are applicable to rotational crops and processed products. The residue definitions for enforcement set in Regulation (EC) No 396/2005 are identical with the above-mentioned residue definitions.

Taking into account the proposed uses assessed in this application, EFSA concludes that these residue definitions are appropriate and no modification/no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted residue trials performed in oranges, lemons, macadamias, cherries, plums, peaches, apricots, nectarines, raspberries, currants (black and red), curly kale, herbs (celery leaves, basil, chervil and parsley), open leaf lettuce, sunflower seeds, barley, maize and wheat. The samples were analysed for the parent compound and DFA separately, in accordance with the residue definitions for enforcement (RD-Mo 1 and RD-Mo 2). The sum of flupyradifurone and DFA (expressed as flupyradifurone) was calculated by the EMS, in accordance to the residue definition for risk assessment. When necessary, the residue data of metabolite DFA were converted as parent compound by applying the molecular weight conversion factor of 3. In order to derive the risk assessment values, the highest calculated sum of flupyradifurone and DFA residues from the decline trials was selected.

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated (Netherlands, 2022). According to the assessment of the EMS, the methods used to analyse residue trial samples (coded 01212, 01304, 01330, L 00.00–115 and ATM-0048), based on liquid chromatography with tandem mass spectrometry (LC–MS/MS), were sufficiently validated and fit for purpose (Netherlands, 2022).

It is noted that the extraction efficiency of the analytical methods 01212 and 01304 used for the quantification of flupyradifurone in samples collected from the residue trials performed on cherries, plums, apricots, peaches, nectarines, curly kale and lettuces (high water content commodities), sunflowers (high oil content commodities), maize, barley and wheat (dry commodities) is demonstrated by radio-cross-validation using radiolabelled sample material (^{14}C-flupyradifurone labelled either on the pyridinyl or furanone moiety) from the flupyradifurone metabolism studies in tomato, potato, cotton seed and wheat straw, in line with the extraction efficiency Technical Guidelines (European Commission, 2017). Similarly, extraction efficiency of the analytical methods 01212, 01304 and 01330 used for the quantification of DFA in cherries, plums, apricots, peaches, nectarines, curly kale, lettuces and herbs and edible flowers (high water content commodities) is demonstrated by radio-cross-validation using radiolabelled sample material (^{14}C-flupyradifurone labelled on the difluoroethyl amino group) from the flupyradifurone metabolism study in tomato.

On the other hand, extraction efficiency of flupyradifurone could not be considered demonstrated in the following commodities based on the considerations below:

- Herbs and edible flowers (high water content commodities): the extraction procedures of the analytical method L 00.00-115 are different compared to the ones used in the metabolism studies in tomato, potato, apple (high water content commodities) (i.e. pure acetonitrile was used as a solvent in the analytical method for data generation in herbs and edible flowers, while acetonitrile/water mixtures were used for the metabolism studies (four extraction steps with acetonitrile/water 80/20 for tomato; three extraction steps with acetonitrile:water 80:20 and one extraction step with acetonitrile:water 50:50 for potatoes and apples)) and no cross-validation study comparing the extraction efficiency of the two solvent systems was provided;
- Macadamias (high oil content commodities): no detailed information on the number of extraction steps performed in the ATM-0048 analytical method used for flupyradifurone data generation were available and no conclusion on extraction efficiency could be reached;
- Oranges, lemons, raspberries, currants (high acid content commodities): extraction efficiency of the analytical methods 01212 and 01304 used for the quantification of flupyradifurone in high acid content commodities could not be investigated according to the Technical Guideline (European Commission, 2017), considering that metabolism studies and radiolabelled material in high acid content commodities are not available to date.

Due to the lack of DFA radiolabelled material in matrices other than high water content matrices, the extraction efficiency of the method for quantification of DFA in high acid content, high oil content and dry matrices could not be investigated according to the extraction efficiency Technical Guideline (European Commission, 2017).

Therefore, uncertainties on the validity of measurements of flupyradifurone in oranges, lemons, raspberries, currants, herbs and edible flowers, macadamias and of DFA in oranges, lemons, raspberries, currants, macadamias, sunflower seeds, maize, barley and wheat cannot be excluded to the present.

Large citrus fruit (grapefruits, oranges)

SEU GAP: 1 × 150 g/ha, BBCH 55–75, PHI 30 days

A total of seven independent and GAP-compliant field trials on oranges were submitted in support of the intended GAP. The trials were conducted in Italy, Portugal and Spain in 2017 and 2018 growing seasons. The trials consisted of one foliar treatment of a nominal application rate of 150 g a.s./ha (125–165 g a.s./ha), performed at BBCH 81 at last application and were designed as decline trials (samples were collected 0, 28–31 and 34–35 (corresponding to the intended preharvest interval, PHI), 37–38, 41–43 and 44–46 days after the treatment).

The available results indicate residue concentrations ranging between 0.013 and 0.17 mg/kg for flupyradifurone and between < 0.007 and 0.013 mg/kg for DFA. The submitted data (seven trials) are not sufficient to derive new MRL proposals for flupyradifurone and DFA for the intended SEU use on large citrus fruits (major crop). A modification of the existing MRL of 3 mg/kg for flupyradifurone and 0.05 mg/kg for DFA in grapefruits and oranges, as derived based on a recent EFSA assessment on a US GAP (EFSA, 2020a), is therefore not justified. This is in line with the assessment performed by the EMS (Netherlands, 2022). The EMS also proposes that for citrus fruits belonging to the group of 'others', the EU MRL is established on the basis of a previously assessed import tolerance data set in oranges and grapefruits.

Small citrus fruits (lemons, limes, mandarins)

SEU GAP: 1 × 150 g/ha, BBCH 55–75, PHI 30 days

A total of eight independent and GAP-compliant field trials on lemons were submitted in support of the intended GAP. The trials were conducted in Italy, Portugal and Spain in 2017 and 2018 growing seasons. The trials consisted of one foliar treatment at a nominal application rate of 150 g a.s./ha, performed at BBCH 77–89 at last application and were designed as decline trials (samples were collected 0, 29–34 (corresponding to the intended PHI), 37–38, 41–43 and 44–46 days after the treatment).

The submitted data are sufficient to derive MRL proposals of 0.2 mg/kg for flupyradifurone and 0.09 mg/kg for DFA for the intended SEU use on small citrus fruits. It is noted that the MRL proposal for flupyradifurone in small citrus fruits is covered by the MRL currently in place (i.e. 1.5 mg/kg); therefore, an MRL modification for flupyradifurone in small citrus fruits is not necessary. On the contrary, an MRL modification for DFA in small citrus fruits is justified, based on the available data.

Macadamias

AU GAP: 1 × 400 g a.s./ha, BBCH ≥ 50, PHI 20 days

In support of the import tolerance the applicant provided numerous residue trials performed at seven different sites in Australia during the growing seasons of 2012/2013 and 2013/2014. Residue trials were performed under different treatment regimens and designed as either decline studies or harvest trials. The appropriate trials were selected in support of the authorised use on macadamias to derive MRLs for flupyradifurone and DFA. Kernels without the shell were analysed for residues, in line with Annex I of the Regulation (EC) 396/2005.

For flupyradifurone, five trials were selected by the EMS to support the authorised use. In one trial sampling was conducted at 34 days (significantly longer than the intended PHI), thus this trial was disregarded by EFSA. In the rest four trials, macadamia trees were treated three times with a dose of 310–420 g a.s./ha. Therefore, these trials are overdosed regarding the total number of applications while the single application rates are within the acceptable range of ±25% compared to one of the authorised use. Flupyradifurone levels were below the LOQ of 0.01 mg/kg in all samples, at PHIs ranging between, 18 and 20 days.

DFA was found in higher concentrations when an early treatment was performed on the trees. Therefore, five trials with a PHI of 83–136 days were selected by the EMS to simulate a more critical situation and estimate a DFA MRL for macadamias. These trials were performed with an application rate complying with the intended use (within the acceptable range of ±25% of the authorised use). It is noted that in two trials, trees were treated three times with the third treatment performed 1 year after the initials. In these trials, DFA levels were within the range of trials conducted in line with the authorised use (single application) and therefore these trials were not disregarded.

The MRL derived in support of the import tolerance is at the LOQ of 0.01 mg/kg for flupyradifurone and 0.3 mg/kg for DFA. It is noted that the existing EU MRL for flupyradifurone is 0.02 mg/kg, as derived in a previous EFSA reasoned opinion (EFSA, 2020a). The applicant did not request to lower the existing EU-MRL for flupyradifurone. For DFA, however, the setting of a new MRL, higher than the existing one, is justified.

Cherries

NEU/SEU GAP: 1 × 180 g/ha (1 × 60 g a.s./ha × m CH, max CH 3 m), BBCH 69–85, PHI 7 days
US GAP: 2 × 205 g a.s./ha, 10-day interval, BBCH unknown, PHI 14 days

A total of eight independent and GAP-compliant NEU field trials on cherries were submitted in support of the intended NEU GAP. The trials were conducted in northern France, Germany, Hungary, Poland and the United Kingdom in 2015 and 2016 growing seasons. The trials consisted of one foliar treatment at a nominal application rate of 180 g a.s./ha (180–198 g a.s./ha), performed at BBCH 81–87 at last application and were designed as decline trials (samples were collected 0, 7 (corresponding to the intended PHI), 13–15, 19–23 and 26–30 days after the treatment).

A total of four independent and GAP-compliant SEU field trials on cherries were submitted in support of the intended SEU GAP. The trials were conducted in Italy and Spain in 2015 and 2016 growing seasons. The trials consisted of one foliar treatment at a nominal application rate of 180 g a.s./ha (162–180 g a.s./ha), performed at BBCH 81–85 at last application and were designed as decline trials (samples were collected 0, 6–7 (corresponding to the intended PHI), 13–14, 20–21 and 27–28 days after the treatment).

A total of seven independent and GAP-compliant field trials on cherries were submitted in support of the authorised US GAP. The trials were conducted in the USA and Canada in 2012 and 2014 growing seasons. The trials consisted of two foliar treatments at a nominal application rate of 205 g a.s./ha (200–215 g a.s./ha), performed at BBCH 75–87 at last application and were designed as decline trials (samples were collected 0, 5–7, 12–14 (corresponding to the intended PHI), 19–21 and 26–28 and 33–35 days after the treatment). Duplicate plots were conducted in each trial. For each residue definition, the highest residue value observed in the duplicates was selected.

The submitted NEU data are sufficient to derive MRL proposals of 1 mg/kg for flupyradifurone and 0.15 mg/kg for DFA for the intended NEU use on cherries.

As regards to the SEU data set, a sufficient number of SEU trials is available for flupyradifurone MRL setting. As for DFA, it is noted that the residue level measured in the untreated control samples of one of the four available SEU trials was above the LOQ. However, this trial was not disregarded by the EMS, based on the following arguments:

- DFA residues in the untreated sample of the afore-mentioned SEU trial were only slightly above or at the LOQ of 0.007 mg/kg for DFA (i.e. 0.009 and 0.007 mg/kg in cherry samples collected 0 and 7 days after the treatment (corresponding to the intended PHI), respectively).
- The uncorrected DFA level (i.e. DFA, expressed as DFA) measured in the treated plot of the afore-mentioned trial (i.e. 0.43 mg/kg) may be slightly overestimated, however, the residue level is still within the range of the SEU data set for DFA (0.032–0.079 mg/kg) and also within the range of the NEU data set (0.007–0.070 mg/kg).
- Inclusion or omission of this uncorrected DFA level in the SEU data set does not affect the calculation of MRL for DFA.
- The residue level measured according to the risk assessment residue definition (i.e. 0.96 mg/kg for the sum of flupyradifurone and DFA, expressed as flupyradifurone) is driven by the residue level of flupyradifurone (i.e. 0.92 mg/kg for flupyradifurone + 0.044 mg/kg for DFA, expressed as flupyradifurone). The uncertainty related to the DFA level has no significant impact on the consumer risk assessment.

EFSA considered the afore-mentioned arguments as acceptable and considered the submitted SEU data as sufficient to derive an MRL proposal of 2 mg/kg for flupyradifurone and 0.15 mg/kg for DFA.

As regards to the NAFTA data set, with seven trials only, the submitted data are not sufficient to support the US GAP on cherries (major crop worldwide).

It is noted that the EMS proposed to derive MRLs of 1.5 mg/kg for flupyradifurone and 0.15 mg/kg for DFA in cherries, based on the combined NEU and SEU data sets. It must be noted that residue trials from NEU and SEU should in principle not be combined, unless the criteria for combining NEU and SEU trial data sets, described in the Technical Guidelines on MRL setting (European Commission, 2020) are all met. Despite the three criteria are all met for DFA, they are not for flupyradifurone (i.e. the MRL proposals derived for the individual data sets do not fall into the same or neighbouring MRL classes). Therefore, EFSA is not in favour of combining the two data sets.

Overall, EFSA proposes MRLs of 2 mg/kg for flupyradifurone, based on the critical SEU data set, and 0.15 mg/kg for DFA, based on both the NEU and SEU data sets assessed separately. These MRLs are not expected to accommodate the US GAP on cherries.

Peaches

US GAP: 2 × 205 g a.s./ha, 10-day interval, BBCH unknown, PHI 14 days

A total of 11 independent and GAP-compliant field trials on peaches were submitted in support of the authorised US GAP. The trials were conducted in the USA in 2012 and 2014 growing seasons. The trials consisted of two foliar treatments at a nominal application rate of 205 g a.s./ha (199–215 g a.s./ha), performed at BBCH 79–87 at last application. Among these, seven trials were designed as decline trials (samples were collected 0, 6–7, 13–15 (corresponding to the intended PHI), 20–21, 27–28 and, in some trials, 30–35 days after the treatment). Duplicate plots were conducted in each trial. For each residue definition, the highest residue value observed in the duplicates was selected.

In addition, four independent and GAP-compliant field trials on nectarines were submitted. These were added to the residue data set of peaches considering that for nectarines according to Annex I of Regulation (EC) No 396/2005 the MRL for peaches apply. The trials were conducted in the USA in 2014 and 2015 growing seasons. The trials consisted of two foliar treatments at a nominal application rate of 205 g a.s./ha (202–210 g a.s./ha), performed at BBCH 79–85 at last application. Among these, two trials were designed as decline trials (samples were collected 7, 14 (corresponding to the intended PHI), 21, 27–28, 34–35 and 41–42 days after the treatment). Duplicate plots were conducted in each trial. For each residue definition, the highest residue value observed in the duplicates was selected. Residues were measured in nectarines without stone since fruit samples were pitted (stone removed) prior to extraction and analysis. According to Reg. (EU) 2018/62 replacing Annex I to Reg. (EC) 396/2006, the MRL on peaches applies to the 'whole product after removal of stems'. For the purpose of MRL setting and enforcement in peaches, residues should therefore be expressed as a concentration in the whole fruit, including the stone, to avoid overestimation of residues for MRL calculations. Considering stone weights were not recorded in the studies, the EMS proposed to recalculate the residue values by applying an approximate stone weight of 14% as a generic correction factor, as done in a previous reasoned opinion on flubendiamid (EFSA, 2018a). The proposed application of a generic correction factor for stone weight was considered acceptable by EFSA. Corrected residue values were used for calculations of MRL and risk assessment values.

The submitted data are sufficient to derive MRL proposals of 1.5 mg/kg for flupyradifurone and 0.3 mg/kg for DFA in peaches. The EMS proposes that the MRL proposal as derived for peaches is extrapolated to the group of 'other stone fruits'.

Apricots

US GAP: 2 × 205 g a.s./ha, 10-day interval, BBCH unknown, PHI 14 days

A total of 19 independent and GAP-compliant field trials on apricots (4), peaches (11) and nectarines (4) were submitted in support of the authorised US GAP on apricots. The trials on peaches and nectarines are described in the section above. The trials on apricots were conducted in USA in 2012 and 2014 growing seasons. The trials consisted of two foliar treatments at a nominal application rate of 205 g a.s./ha (203–216 g a.s./ha), performed at BBCH 78–85 at last application. Half of the trials (2) were designed as decline trials (samples were collected 7–8, 11–14 (corresponding to the intended PHI), 21, 26–28 and, in one trial, 32 and 37 days after the treatment). Duplicate plots were conducted in each trial. For each residue definition, the highest residue value observed in the duplicates was selected.

Residues were measured in apricots without stone since fruit samples were pitted (stone removed) prior to extraction and analysis. According to Annex I of Regulation (EC) 396/2006, the MRL on apricots applies to the 'whole product after removal of stems'. For the purpose of MRL setting and enforcement in apricots, residues should therefore be expressed as a concentration in the whole fruit, including the stone, to avoid overestimation of residues for MRL calculations. Considering stone weights were not recorded in the studies, the EMS proposed to recalculate the residue values by applying an approximate stone weight of 14% as a generic correction factor, as done in a previous reasoned opinion on flubendiamid (EFSA, 2018a). The proposed application of a generic correction factor for stone weight was considered acceptable by EFSA.

It is noted that the EMS proposed to derive the highest residue (HR) and the supervised trials median residue (STMR) values based on uncorrected residue levels measured in pitted fruits. However, for consistency with the residue levels measured in the trials on peaches (whole commodity) and considering that consumption data used in the exposure calculations are expressed as whole fruits, corrected residue values estimated for the whole commodity were used for calculations of both MRL and risk assessment values.

The submitted data on apricots (4), peaches (11) and nectarines (4) are sufficient to derive MRL proposals of 1 mg/kg for flupyradifurone and 0.3 mg/kg for DFA in apricots. It is noted that the higher MRL proposal of 1.5 mg/kg was derived by the EMS for flupyradifurone in apricots, based on the reduced set of trials on apricots (4) and peaches (11).

Plums

NEU/SEU GAP: 1 × 180 g/ha (1 × 60 g a.s./ha × m CH, max CH 3 m), BBCH 69–85, PHI 14 days
US GAP: 2 × 205 g a.s./ha, 10-day interval, BBCH unknown, PHI 14 days

A total of eight independent and GAP-compliant NEU field trials on plums were submitted in support of the intended NEU GAP. The trials were conducted in Germany, the Netherlands and the United Kingdom in 2015 and 2016 growing seasons. The trials consisted of one foliar treatment at a nominal application rate of 180 g a.s./ha (168–180 g a.s./ha), performed at BBCH 81–87 at last application and were designed as decline trials (samples were collected 0, 7, 14 (corresponding to the intended PHI), 21 and, in some trials, 27–28 and 35–36 days after the treatment).

A total of eight independent and GAP-compliant SEU field trials on cherries were submitted in support of the intended SEU GAP. The trials were conducted in Italy, Greece, southern France and Spain in 2015 and 2016 growing seasons. The trials consisted of one foliar treatment at a nominal application rate of 180 g a.s./ha (168–198 g a.s./ha), performed at BBCH 81–85 at last application and were designed as decline trials (samples were collected 0, 7–8, 14 (corresponding to the intended PHI), 21–22 and, in some trials, 28–29 and 35 days after the treatment).

A total of eight independent and GAP-compliant field trials on plums were submitted in support of the intended US GAP. The trials were conducted in USA and Canada in 2012 and 2013 growing seasons. The trials consisted of two foliar treatments at a nominal application rate of 205 g a.s./ha (193–211 g a.s./ha), performed at BBCH 79–85 at last application and were designed as decline trials (samples were collected 0, 6–7, 13–14 (corresponding to the intended PHI), 20–21 and 27–28 and 33–35 days after the treatment). Duplicate plots were conducted in each trial. For each residue definition, the highest residue value observed in the duplicates was selected.

The submitted data are sufficient to derive the following MRLs in plums:

- 0.3 mg/kg for flupyradifurone and 0.10 mg/kg for DFA, based on the NEU use;
- 0.3 mg/kg for flupyradifurone and 0.20 mg/kg for DFA, based on the SEU use;
- 0.4 mg/kg for flupyradifurone and 0.3 mg/kg for DFA, based on the US use.

Overall, EFSA proposes MRLs of 0.4 mg/kg for flupyradifurone and 0.3 mg/kg for DFA, based on the critical US GAP.

Cane fruit

EU GAP (indoor): 1 × 200 g a.s./ha (2 × 100 g a.s./ha per m crown height (CH), max CH 2 m), 10-day interval, BBCH 15–89, PHI 3 days

It was noted that four residue trials on raspberries have been already assessed by EFSA in 2016 in support of identical GAP. Based on these data, MRLs of 1.5 mg/kg for flupyradifurone and 0.07 mg/kg for DFA were derived for raspberries and blackberries (EFSA, 2016).

In addition, the applicant provided two new GAP-compliant residue trials on raspberries. Residue trials have been performed in 2017 in the Netherlands and Italy.

The applicant proposes to merge the six available raspberry residue trials. The MRL of 1.5 mg/kg for flupyradifurone and of 0.07 mg/kg for DFA, previously derived for raspberries and blackberries are not modified when considering the two new trials. The applicant proposes to extrapolate these data to the whole group of cane fruit. Such an extrapolation is applicable according to the EU Technical Guidelines (European Commission, 2020). Thus, the MRL of 1.5 mg/kg for flupyradifurone and of 0.07 mg/kg for DFA can be derived for all cane fruit.

It is noted that following the JMPR evaluation, in 2019, a higher MRL of 6 mg/kg for flupyradifurone has been implemented for cane fruit according to Regulation (EU) 2022/1324. It is concluded that there is a need to raise the existing EU MRL only for the DFA in dewberries and other cane fruits from the LOQ of 0.02 to 0.7 mg/kg.

Other small fruits and berries: blueberries, cranberries, currants (red, black, white), gooseberries (green, red and yellow), rose hips, mulberries (black and white), azaroles/ Mediterranean medlars, elderberries

EU GAP (indoor): 1 × 60 g a.s./ha (40 g a.s./ha per m CH, max CH 1.5 m), BBCH 11–89, PHI 3 days

In support of the intended indoor GAP, the applicant provided six GAP-compliant residue trials on red and black currant. All trials were from 2016, performed in France, Spain and Italy. All trials were decline trials, providing information of residues on the day of the treatment and 3, 5, 7, 10 and 14 days after the treatment.

The applicant proposes to extrapolate the residue data on currants to the whole group of other small fruits and berries (154000), comprising blueberries, cranberries, gooseberries, rose hips, mulberries, azaroles and currants. Such an extrapolation is acceptable according to the EU Technical Guidelines (European Commission, 2020). From the available residue data set an MRL of 0.7 mg/kg is derived for flupyradifurone and of 0.01 mg/kg (at the LOQ) for DFA.

Regarding blueberries where existing MRLs are already sufficient to cover the GAP under assessment (4 mg/kg for flupyradifurone and 0.05 mg/kg for DFA), the applicant did not propose any MRL modifications. For the remaining small fruits and berries, the applicant's proposal of raising the existing flupyradifurone MRL to 0.7 mg/kg is sufficiently supported; for DFA the modification of the existing EU MRL of 0.02 mg/kg (at the LOQ) is not necessary.

Leafy brassica

NEU GAP: 2 × 125 g/ha, 10-day interval, BBCH 12–49, PHI 3 days
SEU GAP: 1 × 125 g/ha, 10-day interval, BBCH 12–49, PHI 3 days

In support of the NEU use the applicant submitted two GAP-compliant residue trials on curly kale, which were performed in Germany in 2018. These trials were submitted to complement the residue trials on kale which have been previously assessed by EFSA in 2020 to propose an MRL of 5 mg/kg for flupyradifurone and of 0.4 mg/kg for DFA in kale from primary crop use. It is noted that the MRL for kale as implemented by Regulation (EU) 2021/1842 is 0.6 mg/kg, considering also the soil uptake of DFA (EFSA, 2020).

In support of the SEU use, the applicant submitted six GAP-compliant residue trials on curly kale, which were performed in 2017 and 2018 in France, Spain and Italy. All trials were designed as decline trials, analysing samples on days 3, 7, 10, 13–14, 16–17 and 20 after the application.

The applicant proposes to extrapolate the residue data on kale to the whole group of leafy brassica (243000), comprising Chinese cabbage and other leafy brassica. Such an extrapolation is applicable according to the EU Technical Guidelines (European Commission, 2020). The MRL proposal derived in support of either NEU or SEU use is 4 mg/kg for flupyradifurone. The lowering of the existing EU MRL in kale of 5 mg/kg for flupyradifurone is proposed by the applicant. For DFA, the MRL proposal derived from the use on primary crops (NEU use more critical) would be 0.5 mg/kg. However, the MRL of 0.7 mg/kg as proposed for DFA by the applicant and the EMS also considers the uptake of residues by leafy brassica when grown as rotational crops (Section 1.2.2).

Herbs and edible flowers

EU GAP (indoor): 1 × 125 g/ha, BBCH 41–46, PHI 3 days

In support of the indoor EU GAP the applicant provided five GAP-compliant residue trials on herbs: leaf celery, basil, chervil and parsley. The trials were performed in Germany in 2017. Two trials were performed in the same location on the same date, but on a different crop (chervil and parsley) and were considered therefore independent. In addition, the applicant submitted nine GAP-compliant residue trials on open leaf varieties of lettuce, which were performed in 2017 in various locations of the Netherlands, France, Italy, Portugal, Greece. All trials were designed as decline trials.

The applicant proposes to extrapolate the residue trial data on either herbs, leafy lettuce or combined, to the whole group of edible herbs and flowers. According to the EU Technical Guidelines (European Commission, 2020) either of these approaches is applicable. However, the EMS and EFSA are of the opinion that the residue data on herbs is more representative of the residue situation in herbs and edible flowers and therefore derived an MRL proposal of 40 mg/kg for flupyradifurone on the basis of available residue trials on basil, chervil, parsley and celery leaves. Based on the same trials, an MRL of 0.03 mg/kg would be derived for DFA from the use on primary crops. It is noted, that when residue data on herbs and lettuce are combined, a lower MRL proposal of 30 mg/kg would be derived for flupyradifurone while the same MRL proposal of 0.03 mg/kg would be derived for DFA.

Sunflower seed

NEU GAP: 2 × 56.25 g/ha, 14-day interval, BBCH 31–69, no PHI

In support of the intended NEU GAP the applicant submitted eight GAP-compliant residue trials performed in 2016 in France, Hungary, the United Kingdom and Poland. Seed samples were taken at two different PHI interval ranges, first sampling occasion occurring 29 to 56 days (covering BBCH 89) after the last application and second – 36–63 days (covering BBCH 89–92) after the last application. Considering that on both sampling points crop had reached the maturity (fully ripe BBCH 89 and overripe (at BBCH 92)), the highest values among these sampling occasions were selected for the residue data set. In two residue trials, control samples contained residues of DFA (70–125% of residues in treated samples). Moreover, in one of these trials, the control sample contained also residues of flupyradifurone (50% of residues in treated sample). One trial for flupyradifurone data and two trials for DFA data were therefore disregarded. The available number of trials is not sufficient to support the use of flupyradifurone on a major crop sunflower. No MRL proposal was derived.

SEU GAP: 2 × 56.25 g/ha, 14-day interval, BBCH 31–69, no PHI

In support of the intended SEU GAP the applicant submitted eight GAP-compliant residue trials performed in 2016 in France, Italy, Spain, Greece. In all trials, samples of both seed (kernel with shell) and kernels were analysed. Seed samples were taken at two different PHI interval ranges, first sampling occasion occurring 36 to 66 days (covering BBCH 87–89) after the last application and second – 43-73 days (covering BBCH 89–92) after the last application. Considering that on both sampling points crop had reached the maturity (physiological ripeness BBCH 87, fully ripe BBCH 89 and overripe (at BBCH 92)), the highest values among these sampling occasions were selected for the residue data set. In none of the trials the control samples contained residues, the number of trials is sufficient to support the intended SEU use. The data indicate that an MRL of 0.07 mg/kg would be derived for flupyradifurone and of 0.09 mg/kg for DFA.

Barley

Existing EU MRL for barley (3 mg/kg for flupyradifurone and 0.8 mg/kg for DFA) have been established based on an import tolerance (EFSA, 2020a). The applicant now submitted new residue trials conducted in the EU in support of the intended NEU and SEU uses. The EU residue trials also provide information on residues of flupyradifurone and DFA in straw, which is relevant to update the EU livestock dietary burden calculations (see Section 2).

NEU GAP: 2 × 56.25 g a.s./ha, 14-day interval, BBCH 41–83, PHI 30 days

In support of the intended use on barley applicant submitted 8 NEU GAP-compliant residue trials on barley, performed in Germany, Belgium, the UK and the Netherlands in 2015 and 2016. In all trials grain and straw samples were collected in two or three sampling points (21–22, 27–33 and 31–37 days) after the last treatment. In each trial highest residue value was considered for calculations. EFSA does not consider these trials as decline studies in line with the extrapolation guidelines (European Commission, 2020), as all samples were collected within the ±25% range of the intended PHI. This deviation, however, is considered minor, since a residue decline is generally shown in the whole plant samples collected at earlier stages, and overall data on seeds are sufficient to derive a robust MRL. From the respective residue data an MRL of 0.3 mg/kg is calculated for flupyradifurone and of 0.15 mg/kg for DFA; these values are lower than the existing MRLs on barley grain.

SEU GAP: 2 × 56.25 g a.s./ha, 14-day interval, BBCH 41–83, PHI 30 days

In support of the intended use applicant submitted eight SEU residue trials on barley, performed in France, Italy, Spain and Greece in 2015 and 2016. Plots were treated with an application rate of 75 g a.s./ha, which is overdosed compared to the intended GAP. The applicant proposed to apply the proportionality principle to scale the available residue trials to match the intended GAP. It is noted that in trial 15–2130-01 sampling of the grain and straw was not performed at the intended PHI. Finally, seven trials are not sufficient to support the proposed use. However, the submitted data give an indication that the SEU GAP is not expected to lead to higher residues in grain compared to the existing MRL which is based on the previously assessed import tolerance. The residue data on straw are more critical when compared to NEU use. Since the existing EU MRL for flupyradifurone in barley is more critical than the MRL estimated for European uses, it is possible that Member States may grant authorisations of flupyradifurone which are more critical than intended SEU/NEU uses. Therefore, to account for a worst-case situation of residues in barley straw, the risk assessment values from SEU data set were not excluded from the dietary burden calculation. It is noted that SEU data set on straw is not fully supported by residue data and additional one trial would be required. The MRL proposal and risk assessment values for grain were not derived in support of the SEU GAP.

Oat

NEU GAP: 2 × 56.25 g a.s./ha, 14-day interval, BBCH 41–83, PHI 30 days

In support of the intended use on oat, the applicant proposes to extrapolate residue data on barley (see above) to oat. Such an extrapolation is acceptable according to the EU Technical Guidelines SANTE/2019/12752 (European Commission, 2020). From the available data, an MRL of 0.3 mg/kg is calculated for flupyradifurone and of 0.15 mg/kg for DFA.

US GAP: 2 × 205 g a.s./ha, 7-day interval, PHI 21 days

In support of the import tolerance on oat the applicant relied upon residue data on barley evaluated previously by EFSA (2020a). A sufficient number of residue trials (20 trials) on barley were submitted to derive an import tolerance for barley. The applicant proposes to extrapolate the residue data from barley to oat. Such an extrapolation is appropriate according to the EU Technical Guidelines (European Commission, 2020). For oat grain an MRL of 3 mg/kg for flupyradifurone and of 0.6 mg/kg for the DFA is proposed in support of the authorised use in the USA.

Maize

Existing EU MRLs for maize (0.02 mg/kg for flupyradifurone and 0.1 mg/kg for DFA) have been already established based on an import tolerance (EFSA, 2020a). Applicant submitted new residue trials conducted in the EU (8 NEU and 8 SEU) in order to support the intended NEU and SEU uses.

NEU GAP: 1 × 56.25 g a.s./ha, BBCH 51–75, no PHI

In support of the intended NEU use applicant submitted eight residue trials performed in 2015 and 2016 in Germany, Belgium and the Netherlands. Foliar applications were made at BBCH 75. Application rates were overdosed, ranging from 87.75 to 93.75 g a.s./ha. The EMS proposed to scale down the residue values in accordance to the EFSA technical report (EFSA, 2018c) to derive data supporting the intended GAP. Besides maize grain, stover and silage (both feed items) were analysed for residues. Data from stover were further considered for the EU livestock dietary burden, while data from silage were not considered since the intended use does not refer to treatment of maize for feed purposes. EFSA notes that grains and stover were only sampled once at normal commercial harvesting date (BBCH 89). Lack of decline studies on the commodities under consideration is considered a minor deviation to the guidelines (European Commission, 2020) since residues in the whole plants in cereals tend to generally decline with time.

For maize grain, the derived MRL is at the LOQ of 0.01 mg/kg for flupyradifurone and at 0.03 mg/kg for DFA.

SEU GAP: 1 × 93.75 g a.s./ha, BBCH 59–75, no PHI

In support of the intended SEU use the applicant submitted eight GAP-compliant residue trials performed in Spain, France and Italy during growth seasons of 2015 and 2016. In a single trial sampling of the grain and stover was not performed at normal commercial harvest date. Flupyradifurone concentrations were below the LOQ of 0.01 mg/kg in grains in seven trials, thus, as for the NEU GAP, significant levels of flupyradifurone are not expected in grain. However, for DFA, the seven available data are not sufficient to support an MRL proposal. The residue data on stover are slightly more critical when compared to the NEU use. Since the existing EU MRL for flupyradifurone maize (based on import tolerance) is more critical than the MRL estimated for European uses, it is possible that Member States may grant authorisations of flupyradifurone which are more critical than intended SEU/NEU uses. Therefore, to account for a worst-case situation of residues in maize (and millet) stover, the risk assessment values from the SEU data set were not excluded from the dietary burden calculation. It is noted that SEU data set on stover is not fully supported by residue data and additional one trial would be required.

Common millet

NEU GAP: 1 × 56.25 g a.s./ha, BBCH 51–75, no PHI

The applicant proposes to extrapolate the residue data on maize (see above) to common millet. Such an extrapolation is appropriate according to the EU Technical Guidelines SANTE/2019/12752 (European Commission, 2020). Based on maize data, MRLs at the LOQ of 0.01 mg/kg for flupyradifurone and at 0.03 mg/kg for DFA can be derived.

SEU GAP: 1 × 93.75 g a.s./ha, BBCH 59–75, no PHI

The applicant proposes to extrapolate the residue data on maize (see above) to common millet. With only seven trials in grain and straw, a sufficient number of trials is not available to fully support the SEU use on millet, also noting that residues levels of DFA in grain were above the LOQ. Flupyradifurone was below the LOQ of 0.01 mg/kg in maize grains in seven trials, thus, significant residues are also not expected in millet grain. The considerations for straw are reported in the section above.

US GAP: 2 × 205 g a.s./ha, 7-day interval, PHI 21 days

In support of the import tolerance, the applicant proposes to extrapolate the residue data on maize to millet from a sufficiently supported residue data set (20 trials) on maize as assessed previously by EFSA (EFSA, 2020a). Such an extrapolation is appropriate according to the EU Technical Guidelines (European Commission, 2020). For millet grain an MRL of 0.02 mg/kg for flupyradifurone and of 0.05 mg/kg for the DFA can be derived in support of the authorised use in the USA.

Wheat

Existing MRLs for wheat (1 mg/kg for flupyradifurone and 1.5 mg/kg for DFA) have been already established on the basis of an import tolerance (EFSA, 2020a). Applicant submitted new residue trials conducted in the EU in support of the intended NEU and SEU uses. The EU residue trials provided also information on residues of flupyradifurone and DFA in straw, which is relevant to update the EU livestock dietary burden calculations (see Section 2).

NEU GAP: 2 × 56.25 g a.s./ha, 14-day interval, BBCH 41–83, PHI 30 days

In support of the intended use on wheat applicant submitted 8 NEU GAP-compliant residue trials on wheat, performed in Germany, Belgium and the Netherlands in 2015 and 2016. In all trials, grain and straw samples were collected in two or three sampling points (21, 28–30 and 34–36 days) after the second treatment. In each trial the highest residue value of the three samples was considered for calculations. EFSA does not consider these trials as decline studies in line with the extrapolation guidelines (European Commission, 2020), as all samples were within the ±25% range of the intended PHI. This deviation however is considered minor, since a decline is generally shown in the whole plant samples collected at earlier stages, and overall data on seeds are sufficient to derive a robust MRL. From the available residue data an MRL of 0.1 mg/kg would be derived for flupyradifurone and of 0.6 mg/kg for DFA; these values are lower than the existing MRLs on wheat grain.

SEU GAP: 2 × 56.25 g a.s./ha, 14-day interval, BBCH 41–83, PHI 30 days

In support of the intended use on wheat applicant submitted 8 SEU residue trials on wheat, performed in Italy, Spain, Portugal and France in 2015 and 2016. In all trials grain and straw samples were collected in two or three sampling points (21, 28–30 and 35–36 days) after the second treatment. In each trial highest residue value of the three samples was considered for calculations. EFSA does not consider these trials as decline studies in line with the extrapolation guidelines (European Commission, 2020), as all samples were within the ±25% range of the intended PHI. This deviation however is considered minor, since a decline is generally shown in the whole plant samples collected at earlier stages, and overall data on seeds are sufficient to derive a robust MRL. Application rate was higher in the residues trials (75 instead of 56.25 g a.s./ha) and, based on EMS proposal, residue values were scaled down according to the technical report (EFSA, 2018c). From the available residue data, an MRL of 0.09 mg/kg would be derived for flupyradifurone and of 0.4 mg/kg for DFA; these values are lower than the existing MRLs on wheat grain.

Rye

SEU GAP: 2 × 56.25 g a.s./ha, 14-day interval, BBCH 41–83, PHI 30 days

The applicant proposes to extrapolate the residue data on wheat (see above) to rye. Such an extrapolation is acceptable according to the EU Technical Guidelines (European Commission, 2020). From the available SEU residue data an MRL of 0.09 mg/kg would be derived for flupyradifurone and of 0.4 mg/kg for DFA.

US GAP: 2 × 205 g a.s./ha, 7-day interval, PHI 21 days

In support of the import tolerance on rye, the applicant proposes to extrapolate residue data on wheat which were assessed previously by EFSA in support of identical authorised use (EFSA, 2020a). A sufficient number of residue trials (29 trials) on wheat are available. Such an extrapolation is acceptable according to the EU Technical Guidelines (European Commission, 2020). For rye grain, an MRL of 1 mg/kg for flupyradifurone and of 1 mg/kg for the DFA is proposed in support of the authorised use in the USA.

Feed items

For wheat, barley, oat, rye, maize and millet, that can be used as feed items, residue data were also provided on straw (wheat and barley) and stover (maize and millet). The data were used to derive risk assessment values, as reported in Table B.1.2.1. It is noted that SEU uses on barley, maize and millet grain are not supported by a sufficient number of residue trials. However, since the existing EU MRL for flupyradifurone in maize and barley and the proposed MRL in millet (all based on import tolerances) are more critical than the MRL required for the SEU/NEU uses, it is possible that Member States may grant authorisations of flupyradifurone which are more critical than SEU/NEU use. Therefore, to account for a worst-case situation of residues in cereal straws, the risk assessment values from not fully supported SEU data sets were not excluded from the dietary burden calculation. Additional uncertainty is therefore introduced in the livestock exposure assessment.

Cereal straw, forage, hay and silage are not expected to be imported in the EU. Therefore, non-EU data on such feed items were not considered for livestock dietary burden.

1.2.2. Magnitude of residues in rotational crops

Flupyradifurone is highly persistent in soil and can be taken up by plants directly or in a form of its degradation product DFA, in addition to residues that result from the primary crop treatment. Moreover, the accumulation of residues in the soil with a subsequent uptake of residues by rotational crops from multi-annual use of flupyradifurone cannot be excluded. Thus, the magnitude of residue uptake in rotational crops via soil has to be investigated for the EU uses considered in this application and for the imported crops for which import tolerances have been requested.

A wide range of rotational crop field studies were submitted for the EU pesticides peer review and in the framework of the previous EFSA assessments (EFSA, 2015a, 2020a). Flupyradifurone was either applied on a bare soil or on lettuce as a primary crop at application rates ranging from 125 to 300 g/ha. Studies indicate a significant uptake of metabolite DFA in rotational crops. Consequently, the EU pesticide peer review derived provisional MRLs for DFA in rotational crops and identified the need for further data (data gaps) (EFSA, 2015a). These provisional MRLs were further assessed by EFSA in the light of rotational crop studies which were submitted by the EMS Netherlands for the assessment of Article 12 confirmatory data and for the setting of MRLs for flupyradifurone and DFA (EFSA, 2020a). In rotational crops, parent flupyradifurone was below the LOQ of 0.01 mg/kg in all edible plant matrices at all plant-back intervals (PBI) (except one barley grain sample containing residues at the LOQ of 0.01 mg/kg and lettuce at 0.03 mg/kg). DFA residues were present in all edible plant matrices at all plant back intervals, indicating that DFA is gradually formed in the soil from flupyradifurone and taken up by the crops.

In the previous EFSA assessments the occurrence of DFA residues in rotational crops has been investigated, considering the estimated long-term plateau soil concentrations of flupyradifurone from the critical primary crop uses and comparing these values with the residue soil concentrations of flupyradifurone in the available rotational crop studies. The critical primary crop GAPs for Europe and the critical authorised GAPs in the third countries assessed in the previous EFSA output are identical to the critical primary crop GAPs submitted for the present assessment and therefore revision of residues in rotational crops was not performed:

- for EU use the GAP on leafy brassica (2 × 125 g/ha, BBCH 12–49, PHI 3 days).
- for the import tolerance uses the GAP on cereals (2 × 205 g/ha, 7–10 days interval, PHI 21 day).

According to the OECD guidance document on residues in rotational crops, the application rate in the rotational crop field studies should be the maximum seasonal application rate (on the primary crop) plus the application rate corresponding to residues in the soil from the long-term use of the active substance (soil plateau levels) (OECD, 2018). In order to investigate whether the available rotational crop studies are sufficiently representative for the critical intended and authorised flupyradifurone GAPs on primary crops, the approaches reported in detail below have been followed in the previous EFSA assessments and in the present one.

a) Primary crop EU uses (leafy brassica, 2 × 125 g/ha, 10-day interval, BBCH 12–49, PHI 3 days)

According to previous EFSA output (EFSA, 2020a), the worst-case long-term flupyradifurone soil plateau concentration (Cmin) reflecting the critical EU application rates (2 × 125 g/ha) was estimated in the framework of the EU pesticides peer review (EFSA, 2015a) as 0.062 mg/kg (DT_{50} 462 days, indoor application on lettuce at 2 × 0.125 kg a.s./ha, crop interception 25%, 10-day interval, residue distribution over 20 cm soil). This value was compared with the determined geometrical mean soil concentrations of flupyradifurone in soil from the rotational crop residue trials (0.029 mg/kg, highest value at the PBI of 107–204 days, after application of 300 g flupyradifurone/ha) (EFSA, 2020a). EFSA concluded that the available rotational crop residue trials are considered underdosed. The available residue data from rotational crop field trials were scaled up by a factor of 2.06 to derive risk assessment values for DFA in rotational crops reflecting the rotational crop uptake of DFA following the use of flupyradifurone on primary crops in Europe according to the critical use pattern.

b) Primary crop import tolerance uses (cereals, 2 × 205 g/ha, 7-day interval, PHI 21 days)

According to previous EFSA output (EFSA, 2020a), the worst-case long-term flupyradifurone soil plateau concentration (C_{min}) from critical authorised uses in North America (2 × 205 g/ha) was estimated using the EU soil dissipation data. The following input parameters were used: DT_{50} 462 days, application of 2 × 205 g/ha, interval between applications 7 days, crop interception 70%, residue distribution over 20 cm soil; the method of the calculation: Double First Order in Parallel (DFOP). The C_{min} was calculated at 0.0416 mg/kg. This value was compared to the geometrical mean soil concentration of flupyradifurone in soil from the rotational crop residue trials (0.029 mg/kg 20 cm soil). The available residue data from rotational crop field trials were scaled up by a factor of 1.4 to derive risk assessment values for DFA in rotational crops reflecting the rotational crop uptake of DFA following the use of flupyradifurone on primary crops in USA according to the critical use pattern. The risk assessment values for certain representative rotational crops from USA uses are compiled in Table E.1, Appendix E to this reasoned opinion.

The risk assessment values for certain representative rotational crops which have been derived by scaling from the available rotational crop field studies reflecting the critical EU and import tolerance primary crop uses are compiled in Table E.1, Appendix E to this reasoned opinion and are as derived in the previous EFSA assessment (EFSA, 2020a). In order to estimate an MRL proposal for crops that can be both treated as a primary crop and take up DFA residues from the soil, the HR value in the respective rotational crop/rotational crop group was summed with the MRL proposal derived for the primary crop belonging to the same crop group as respective rotational crop. The MRL proposals for DFA residues in crops that can be treated as primary crops and simultaneously rotated in soil containing potential residues of DFA, are summarised in Table E.2 of the Appendix E.

1.2.3. Magnitude of residues in processed commodities

Processing factors on various commodities have been calculated in the previous outputs by EFSA (EFSA, 2015a, 2020a) and can be applied on commodities under consideration.

In eight new residue trials on citrus fruits (four on oranges and four on mandarins) peel and pulp were analysed for residues at various PHIs ranging from 29 to 45 days. EMS calculated peeling factors for all PHIs and the highest values per trial were selected. When residues in the raw agricultural commodity (RAC) were below the LOQ, no processing factor was derived (Netherlands, 2022). These data were combined with peeling factors derived from previous assessment on citrus fruits and are summarised in Appendix B.1.2.3. These results indicate that flupyradifurone concentration is generally lower in pulp compared to whole fruit; however, this is not the case for DFA for which peeling factors of 1 were derived for both large and small citrus fruits.

In addition, the residue trials on cherries and peaches provided information on the effect of cooking on the magnitude of flupyradifurone and DFA in cooked cherries and cooked peaches. The data on the peeling of peaches were also provided. The derived processing factors are included in Appendix B.1.2.3 and indicate that cooking and peeling reduces residues.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive new MRL proposals for flupyradifurone in stone fruits, small fruits and berries, except blueberries, leafy brassica, herbs and edible flowers, sunflower seeds, millet grain, oat grain, rye grain. For citrus fruits, macadamia nuts, cane fruits, blueberries, barley grain, maize/corn grain and wheat grain the submitted residue data indicated that the existing flupyradifurone EU MRL does not need to be modified (see Appendix B.5). The EMS proposes that for citrus fruits belonging to the group of 'others', the EU MRL is established on the basis of a previously assessed import tolerance data set in oranges and grapefruits. Similarly, the EMS proposes that the MRL proposal as derived for peaches and kales is extrapolated to the group of 'other stone fruits' and 'other leafy brassica', respectively.

The available data are considered sufficient to derive new MRL proposals for DFA on the basis of submitted residue trials for lemons, limes and mandarins, macadamias, stone fruits and dewberries. No need to modify the existing EU MRL was identified for grapefruits, oranges, blackberries, raspberries, small fruits and berries, herbs and edible flowers, barley grain, millet grain and wheat grain.

For leafy brassica, sunflower seed, maize/corn grain, oat grain and rye grain, two MRL proposals were derived: an MRL proposal accounting for residues expected from primary crop treatment and a combined MRL proposal, which reflects residues in a crop from the primary crop treatment and from the soil uptake. The combined MRL proposal for these crops was derived by adding the estimated highest residue value (HR) in the respective rotational crop/rotational crop group from the field trials (see Table E.1 in Appendix E) to the MRL proposal derived for the crops from primary treatment (Appendix B.1.2.1); the summed value was then rounded to the nearest MRL class to derive final MRL proposal (Table E.2 in Appendix E). It is to note, that residues in rotational crops had been estimated already in the previous EFSA assessment (EFSA, 2020a) both for the crops grown in European soils as well as for the crops grown in soils in the US and were not further revised under the present assessment. For primary annual crops under consideration which can be both grown in EU or imported from the US – millet, oat and rye – the highest residue value estimated in rotational crops among these soils was added to the MRL value in the respective primary crop (see Appendix B.5).

2. Residues in livestock

Several of the crops on which EU uses are intended (citrus fruits, kale, sunflower, cereals) or their by-products can be fed to livestock. Moreover, some food crops imported to Europe can also enter livestock feed chain directly as feed or their by-products. However, the import of bulked feed commodities like straw, forage, hay, silage in Europe is unlikely (EFSA, 2015b) and therefore the data on these feed commodities of rye, millet and oat from import tolerances were not considered in livestock dietary exposure calculation. The EU livestock can be exposed to residues of flupyradifurone (mainly via primary crops) and to DFA residues (mainly from residues in rotational crops but also from primary crops as metabolite of flupyradifurone).

The livestock exposure which was calculated in the previous EFSA output separately for flupyradifurone and the DFA considering the livestock intake of primary and rotational crops grown in the EU as well as from the import tolerances (EFSA, 2020a) was now updated with the residue data from the new intended EU uses and from the authorised uses of flupyradifurone in the United States. The exposure was calculated according to the OECD methodology using the Animal model 2017.

The dietary burden for flupyradifurone was updated considering the new input values derived from the GAPs under assessment, for example in case risk assessment (RA) values were higher than in the previous assessment (kale) or if a new use on a crop has been reported resulting in residues in feed items not considered previously (e.g. cereal straws from EU uses, millet and rye grain, sunflower meal). Thus, for citrus dried pulp, maize, wheat and barley grain and their by-products the input values were as derived in the previous EFSA assessments (EFSA, 2020a). For rape seed meal the input value was as derived from previous EFSA assessment (EFSA, 2020b). The summary of the input values is presented in Appendix D.1. The results of the dietary burden calculation are presented in Appendix B.3 and demonstrated that the trigger value of 0.004 mg/kg bw per day is exceeded for all livestock species and main contributing commodities are kale leaves and swede roots. However, significant changes in the dietary burden from the previous calculation are not observed.

To calculate the livestock exposure to DFA residues, only the commodities which can reasonably enter EU livestock feed chain were considered and for the choice of input values, the following approaches were taken:

- For feed crops under the present assessment on which the use of flupyradifurone is intended only in Europe (kale, sunflower, maize, wheat, barley), DFA residues in primary crop (reflecting the EU intended use, see Appendix B.1.2.1) were added to residue levels of DFA estimated in the respective rotational crop when grown in the soil with flupyradifurone residues at EU plateau level (see Table E.1, Appendix E). For barley, kale and wheat the derived risk assessment value was compared to the value derived in the previous assessment (EFSA, 2020a) and the highest value was used in the calculation of the livestock dietary burden. For processed feed commodities of wheat and barley grain the processing factors applied were as derived in the previous EFSA assessment (2020a).
- For millet, oat and rye, for which an import tolerance was requested for USA uses and for which also EU uses are intended, the DFA residues in grain as primary crop (EU and USA use,

respectively) were added to residue levels of DFA estimated in the respective rotational crop (barley grain or maize grain) when grown in the soil with flupyradifurone residues at EU or USA plateau levels (Table E.1, Appendix E). The highest STMR and HR value (either EU or USA) was selected as input value.
- For imported rye, oat and barley the data on straw and stover from authorised US uses were not considered in the dietary burden as it is not expected that these bulky commodities will be imported in the EU.
- In the remaining feed commodities the input values were as reported in the previous EFSA outputs, considering also feed crops on which primary crop uses are not known, but residues might occur from the soil uptake only (EFSA, 2020a,b).

The input values for the EU dietary burden calculation are summarised in Appendix D.1. The results of the dietary burden calculation are presented in Appendix B.3 and demonstrated that the trigger value of 0.004 mg/kg bw per day is exceeded for all livestock species and main contributing commodities are kale leaves and swede roots. However, the contribution of residues in the crops under consideration to the overall dietary burden is marginal.

2.1. Nature of residues and methods of analysis in livestock

The nature of flupyradifurone residues in livestock was investigated in the framework of the EU pesticides peer review (EFSA, 2015a). ^{14}C-flupyradifurone labelled on pyridinyl or furanone moiety was administered to goats or hens at the dose rate of *ca*. 1 mg/kg bw. Metabolism studies with DFA are not available, parent flupyradifurone has also not been labelled in the ethyl group (EFSA, 2015a). The absence of such studies was not considered as a data gap by the EU pesticides peer review noting that the available feeding studies demonstrate that DFA is a major metabolite in livestock.

In goats, parent flupyradifurone accounted for 24–35% in milk and kidney and up to 81–99% in fat. The metabolism was more extensive in hens; low amounts of flupyradifurone were detected in any poultry matrices in the ^{14}C-furanone study (< 3% TRR) and was in the range of 1% (liver) to 20% TRR (eggs) in the ^{14}C-pyridinyl study. The main components identified in hens were the flupyradifurone-hydroxy metabolites (18% TRR in eggs) and its sulphate conjugate in fat and liver (16–23% TRR) and the acetyl-AMCP metabolite in egg, fat and muscle (23–40% TRR) (EFSA, 2015a).

The animal feeding studies with flupyradifurone alone revealed that DFA is a major marker of the residues in poultry matrices and to a lesser extent, in ruminant matrices.

Based on these studies the residue definitions were proposed as 'Sum of flupyradifurone and DFA, expressed as flupyradifurone' for risk assessment. For enforcement, to align with the residue definition set for plants, two separate residue definitions were established: (1) flupyradifurone and (2) DFA, expressed as DFA (EFSA, 2015a).

The metabolic pathway of flupyradifurone in rats and ruminants proceeds in a similar pathway and therefore the metabolism study in swine is not necessary. Flupyradifurone is not considered fat soluble (EFSA, 2015a). The fat-solubility of DFA has been investigated in studies submitted to European Chemicals Agency (ECHA) (log P_{ow} 0.60097 at 37°C and pH of 2.03)[7], confirming that DFA is hydrophilic in nature.

The availability of analytical enforcement methods for the determination of flupyradifurone and DFA in animal commodities was investigated in the framework of the EU pesticides peer review (EFSA, 2015a). Residues of flupyradifurone and DFA in food of animal origin can be monitored with single HPLC–MS/MS method with LOQs of 0.01 and 0.02 mg/kg for flupyradifurone and DFA (expressed as DFA), respectively, in all animal commodities.

The extraction efficiency of the analytical method for enforcement of flupyradifurone in mammal and poultry tissues (except poultry fat), milk and eggs is demonstrated considering that the extraction procedures are comparable to those of the analytical methods used in the metabolism studies in the respective commodities. This is in accordance with the EU Technical Guideline SANTE 2017/10632 on the extraction efficiency (European Commission, 2017).

As regards to poultry fat, it is noted that extraction procedure of the analytical method for enforcement of flupyradifurone (i.e. three extraction steps with acetonitrile/water (4/1, v/v) with the addition of *n*-heptane) is different from the one of the analytical methods used in the metabolism studies (i.e. two extraction steps with pure acetonitrile with the addition of n-heptane). An extraction efficiency study was submitted in the context of the peer review, as part of the poultry feeding studies. The study

[7] https://echa.europa.eu/registration-dossier/-/registered-dossier/11679/4/8

consists of a radio-cross-validation of the procedures of the analytical method for enforcement using radiolabelled sample material from the flupyradifurone metabolism studies in poultry fat. EFSA acknowledges that the incurred residues extracted from poultry fat with the enforcement method and the analytical method used in the metabolism studies are comparable (amounts of extracted residues in the two systems differ by no more than 30%). However, the following drawbacks are highlighted:

- the specific % TRR of flupyradifurone in the two solvent systems was not reported;
- levels of flupyradifurone incurred residues in poultry fat were close to the LOQ of 0.01 mg/kg (from 0.016 to 0.022 mg/kg). Higher quantification levels would have been desirable;
- the extraction efficiency was investigated in a limited number of samples (only three replicates available). A higher number of replicates would have been desirable;

Considering the above-mentioned sources of uncertainty, the extraction efficiency of the analytical method for enforcement of flupyradifurone in poultry fat is only partially demonstrated.

Due to the lack of DFA radiolabelled material in animal commodities, the extraction efficiency of the method for enforcement of DFA in animal commodities could not be investigated according to the extraction efficiency Technical Guideline (European Commission, 2017). Further investigation on this matter would be required. Therefore, EFSA recommends to reconsider this point in the context of the peer review for the renewal of the approval of flupyradifurone.

2.2. Magnitude of residues in livestock

The magnitude of flupyradifurone residues (flupyradifurone and DFA, separately) in livestock was investigated in the framework of the EU pesticides peer review (EFSA, 2015a) and in the studies submitted in the previous EFSA assessment (EFSA, 2020a).

Lactating cows were dosed with flupyradifurone alone for 29 consecutive days at dose rates of 0.18, 0.9, 1.84 and 4.9 mg/kg bw per day. Laying hens were dosed with flupyradifurone alone at 0.1, 0.45, 1.31 and 4.5 mg/kg bw per day. Animal matrices were analysed for flupyradifurone and DFA individually.

Laying hens were administered DFA at an actual average dose rates corresponding to 0.018, 0.054 and 0.181 mg DFA/kg bw per day. Dairy cows were administered DFA at an actual average dose rates corresponding to 0.032, 0.17 and 0.33 mg DFA/kg bw per day.

The calculated dietary burdens for flupyradifurone and DFA were then compared to the results of the livestock feeding studies with flupyradifurone and DFA, respectively, to estimate the magnitude of residues expected in animal matrices. The magnitude of flupyradifurone in animal matrices was estimated from the feeding studies with flupyradifurone. The magnitude of DFA in animal matrices was estimated from the feeding studies with DFA as well from the feeding studies with flupyradifurone where DFA is formed as a metabolite of flupyradifurone. The final levels of DFA in animal matrices were derived from the sum of DFA formed from flupyradifurone intake and from the animal intake of DFA. It is noted that livestock exposure to DFA residues also take into account the intake of DFA from rotational crops.

The data indicate that the existing EU MRLs as estimated by the previous EFSA assessment in 2020 (EFSA, 2020a) would need to be raised for the DFA in sheep and goat fat to 0.3 mg/kg, in swine fat to 0.2 mg/kg and in poultry fat to 0.04 mg/kg. Acknowledging that the dietary burdens calculated under present assessment and previously are not significantly different, the modification of MRLs in fats is based on the corrected input values for bovine fat used in the previous assessment (mean value for fat used as reported in the DAR (Netherlands, 2014)) and the individual fat sample values as available and reported by the EMS for the present assessment (Netherlands, 2022). The previous MRL proposals for flupyradifurone (EFSA, 2020a) would need to be raised for swine fat to 0.02 mg/kg, swine liver to 0.1 mg/kg, swine kidney and edible offal to 0.15 mg/kg.

3. Residues in honey

3.1. Nature of residues in honey

In the framework of the present assessment, the applicant has applied for the MRLs in honey from the uses of flupyradifurone. Honey is a product produced by bees from sugary secretions of plants (floral nectar mainly) through regurgitation, enzymatic conversion and water evaporation and followed by storage in the bee hives for a certain time period.

In the absence of specific metabolism studies with honey bees, studies investigating the nature of residues in primary crops and rotational crops and studies investigating the degradation during pasteurisation should be considered to determine the nature of residues in honey (European Commission, 2018). It is likely that the nature of residues in pollen and nectar collected from primary and rotational crops, as well as in honey (resulting from the residues in floral nectar), is the same as in primary and rotational crops.

Considering that sufficient data investigating the metabolic profile in primary and rotational crops and the degradation of the active substance under standard hydrolysis conditions are available, no further information is required for the current application according to the guidelines. However, it would be desirable to further investigate whether enzymatic processes involved in the production of honey occurring in the bee gut or during the storage in the bee hive have an impact on the nature of residues in honey.

3.1.1. Analytical methods for enforcement purposes in honey

In the framework of the present assessment the applicant submitted a new method for enforcement of flupyradifurone and DFA residues in honey (Netherlands, 2022). The method, based on HPLC–MS/MS is sufficiently validated for the quantification of residues of flupyradifurone and DFA at or above their respective LOQs of 0.01 mg/kg and 0.007 mg/kg in honey, including confirmation and independent laboratory validation (ILV). Confirmation of the method was achieved by use of a second mass transition for flupyradifurone (simultaneous confirmation of the primary detection method) and by use of an Hillic column via HILIC-DMS-MS (confirmation by an independent analytical technique) for DFA. Information on extraction efficiency of the analytical methods applied for enforcement of residues in honey is not available. However, since the existing guidance document on extraction efficiency (European Commission, 2017) cannot be applied for the honey matrix and since no other guidance on how to investigate extraction efficiency in honey is available, the lack of evidence of extraction efficiency is not considered to be a major data gap for the present assessment.

3.1.2. Storage stability of residues in honey

Information on the stability of residues in frozen samples of honey was submitted with the current application (Netherlands, 2022). It was demonstrated that in honey, residues of flupyradifurone and DFA are stable for at least 171 and 162 days, respectively, when stored at −18°C.

3.1.3. Proposed residue definitions

In the absence of specific metabolism studies on honey, the studies investigating the nature of residues in primary and rotational crops and studies investigating the degradation of the active substance during pasteurisation are considered to derive the residue definitions for honey; the same residue definitions as mentioned for plant commodities are therefore proposed.

3.2. Magnitude of residues in honey

In support of the MRL application in honey, the Applicant submitted eight semi-field tunnel trials conducted with a surrogate crop (i.e. *Phacelia tanacetifolia*) with high melliferous capacity.

Four trials to investigate flupyradifurone and DFA residues were performed in Germany (two), southern France (one) and Spain (one) in 2019. Each trial consisted of two plots, one treated and one untreated. Crop was treated twice with foliar applications during flowering at a nominal rate of 180 g a.s./ha per application with an interval of 12–15 days. The residue trials are compliant with the EU critical GAP on pome fruits selected by the applicant, consisting of two foliar applications at a nominal application rate of 180 g a.s./ha and at BBCH 60–79. Tunnels were set on the treated and untreated plots and a beehive was introduced in each tunnel. Honey was sampled 7–15 days after last application. The amount of honey collected from the trials ranged from 10.1 to 128 g. It is noted that, in some trials, this was below the recommended honey amount of at least 100 g (European Commission, 2018). However, it is commonly acknowledged that this sample size is difficult to obtain under semi-field conditions. This is therefore considered only as a minor deviation not affecting the validity of the trials. Residues were measured in mature or dried honey.

According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

Based on the tunnel trials an MRL of 2 mg/kg was derived for flupyradifurone and an MRL of 0.02 mg/kg was estimated for DFA.

To estimate residues that might occur from rotational crops, another set of four residue tunnel trials were conducted in Germany (two), southern France (one) and Spain (one) during the growing seasons 2019–2020. Flupyradifurone was applied to bare soil once with a nominal application rate of 300 g a.s./ha and *Phacelia* was sown at three different plant back intervals (22–25 days, 136–196 days, 297–358 days). A tunnel was set on each treated plot to confine bees, and a beehive was set up per tunnel at the beginning of flowering. Honey was collected when mature. In cases where water content in honey was above 20%, samples were artificially dried to achieve the appropriate humidity.

According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

Residues of flupyradifurone in honey ranged between < 0.01 and0.02 mg/kg, with residues measured above the LOQ of 0.01 mg/kg from a single trial where *Phacelia* was sown at a PBI of 22 days. Residues of DFA ranged between < 0.007 and 0.012 mg/kg, with residues measured above the LOQ of 0.007 mg/kg in honey samples from trials where *Phacelia* was sown at PBIs of 22 (one trial) and 136–149 days (two trials).

Overall, based on the available data, an MRL of 2 mg/kg is proposed for flupyradifurone in honey.

As regards to DFA, the submitted residue data indicate that an MRL of 0.02 m/kg would be sufficient to account for residues in honey from the use of flupyradifurone on primary crops. It is noted that residues measured in both the primary and the rotational semi-field trials are above the new LOQ of 0.007 mg/kg (as validated for the method for enforcement of DFA in honey submitted in the context of the current application), but below the existing default MRL of 0.05* mg/kg for DFA in honey. It is also noted that the rotational semi-field trials are underdosed as regards to the rotational crop uptake of DFA following the critical EU use of flupyradifurone on primary crops (see Section 1.2.2), thus potentially leading to an underestimation of DFA residue levels in honey. Based on these considerations and the uncertainties linked to the potential residue transfer to honey from rotational crops, EFSA proposes to maintain the current MRL of 0.05 mg/kg, without asterisk. Further risk management considerations are required.

4. Consumer risk assessment

The consumer risk assessment as performed in the latest EFSA output (EFSA, 2021) was updated with revision 3.1 of the EFSA PRIMo taking into consideration MRLs as implemented by the Commission Regulation (EU) 2022/1324[8]. This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population and is developed according to the internationally agree methodology (EFSA, 2018b, 2019).

The toxicological reference values for flupyradifurone used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2015). The peer review also assessed toxicological studies submitted for metabolite DFA and concluded that the reference values of parent are applicable to DFA (EFSA, 2015a). The risk assessment residue definition in plant and livestock commodities is the sum of flupyradifurone and the DFA, expressed as flupyradifurone.

In line with the methodology applied in the previous assessments, EFSA performed two separate consumer intake calculations in order to estimate separately the intake resulting from primary crops (including also animal products derived from livestock which have been subject to residue intake from both the primary and rotational crops) and the intake resulting from rotational crops. This approach was chosen to provide risk managers additional information to decide on risk management options as regards residues in rotational crops, e.g. whether MRLs should be established to cover residues in rotational crops or whether other restrictions would be appropriate to avoid residues in untreated crops.

Intake 1: exposure to residues resulting from treated primary crops and animal commodities

In order to calculate chronic consumer exposure to residues of flupyradifurone and DFA, the median residue values expressed according to the residue for risk assessment (STMR-RA) as derived for the crops under consideration from the submitted supervised residue trials (Appendix B.1.2.1) were used as input values. For citrus fruits, macadamia, blueberries, cane fruit, wheat grain, barley grain

[8] Commission Regulation (EU) 2022/1324 of 28 July 2022 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzovindiflupyr, boscalid, fenazaquin, fluazifop-P, flupyradifurone, fluxapyroxad, fosetyl-Al, isofetamid, metaflumizone, pyraclostrobin, spirotetramat, thiabendazole and tolclofos-methyl in or on certain products. C/2022/5316. OJ L 200, 29.7.2022, p. 68–108.

and maize grain the existing EU MRL with the respective risk assessment value is higher or the same and therefore were maintained for the present risk assessment. For swine fat, kidney and liver the risk assessment values as derived under the present assessment for EU livestock dietary burden (Appendix B.2.2.1.4) were higher than derived in the previous EFSA assessment (EFSA, 2020a) and were therefore used as input values. For the remaining animal commodities, the risk assessment values were as derived in the framework of the previous EFSA assessment (EFSA, 2020a). For honey the STMR value as derived from the submitted residue trials was used as input value (see Appendix B.2.2.1)

For the remaining commodities the risk assessment values corresponding to the MRLs as implemented by the Commission Regulation (EU) 2022/1324 were available to refine the exposure calculation. These risk assessment values were as derived in the previous EFSA assessments (EFSA, 2015a, 2016, 2020a,b, 2021) and by the JMPR (FAO, 2019). The crops for which no uses have been reported since the EU pesticides peer review were excluded from the exposure calculation.

The acute consumer exposure to residues of flupyradifurone and DFA was calculated only for the commodities under consideration using the highest residue values expressed according to the residue for risk assessment (HR-RA) as derived for the crops under consideration from the submitted supervised residue trials (Table B.1.2.1); for bulked products (e.g. cereal grains), the STMR-RA was considered. For citrus fruits, macadamia, blueberries, cane fruit, wheat grain, barley grain and maize grain the existing EU MRL with the respective risk assessment value is higher or the same and therefore were maintained for the present risk assessment. For sheep fat, goat fat, swine muscle, swine fat, swine kidney, swine liver, poultry muscle and poultry fat the risk assessment values as derived under the present assessment for EU livestock dietary burden (Appendix B.2.2.1.4) were higher than derived in the previous EFSA assessment (EFSA, 2020a) and were therefore used as input values. For remaining animal commodities, the risk assessment values were as derived in the framework of the previous EFSA assessment (EFSA, 2020a). For honey the HR value as derived from the submitted residue trials was used as input value (see Appendix B.2.2.1).

Intake 2: exposure to residues from plant commodities that are grown as rotational crops (untreated)

The exposure assessment as calculated in the previous EFSA outputs (EFSA, 2020a,b, 2021) remains valid and was not updated since the residue estimates of the DFA and flupyradifurone in untreated rotational crops remain unchanged.

An overview of input values for consumer exposure assessment is provided in Appendix D.2.

The calculated exposures were then compared with the toxicological reference values as derived for flupyradifurone.

The estimated long-term dietary exposure in intake 1 (consumer exposure due to primary crop treatment and residues in animal commodities) accounted for a maximum of 54% of the ADI (NL toddler diet); for intake 2 (consumer exposure from the intake of DFA residues taken up by crops from the soil which was previously treated with flupyradifurone), accounted for up to 17% of the ADI for GEMS/Food G06 diet and 15% of the NL toddler diet (EFSA, 2021). The highest combined exposure (sum of intake 1 and intake 2) accounts for a maximum of **69% of the ADI** for the Dutch toddler diet. The overall exposure to flupyradifurone and DFA is unlikely to pose a chronic consumer intake concern.

In the short-term dietary exposure according to intake 1 and intake 2 no exceedances of the ARfD were identified for the crops under consideration. Based on the combined acute intake, consumer exposure concerns were not identified. The highest combined acute exposure, which was derived as the sum of individual crop exposures calculated under intake 1 and intake 2, for the annual crops under consideration was identified for kale (77% of the ARfD) and Chinese cabbage/pe-tsai (56% of ARfD).

EFSA notes that although according to the internationally agreed methodology for acute risk assessment, which is based on the highest residue found in the supervised field trials, no acute consumer intake concerns were identified, for the uses on oranges and kales, if residues of flupyradifurone occur in kales at the derived MRL value and in oranges at the existing EU MRL, the dietary exposure of certain consumers may exceed the ARfD (117.3% and 106.1% of the ARfD, respectively) under certain conditions (i.e. consumption of a large portion of the product without washing/peeling/processing which would lead to a reduction of the residues in the product, some commodity units contain more residues than the average in the lot due to inhomogeneous distribution). Risk managers should decide whether the safety margin of the exposure assessment based on the highest residue is sufficient, considering that in reality residues in individual units/lot consumed may occur at or above the proposed MRL.

The results of the consumer exposure assessment are presented in more detail in Appendix B.3.

EFSA concluded that the long-term and short-term intake of residues of flupyradifurone and DFA resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

5. Conclusion and recommendations

The available data are considered sufficient to derive new MRL proposals for flupyradifurone in stone fruits, small fruits and berries, except blueberries, leafy brassica, herbs and edible flowers, sunflower seeds, millet grain, oat grain, rye grain and honey. For citrus fruits, macadamia nuts, cane fruits, blueberries, barley grain, maize/corn grain and wheat grain the submitted residue data indicated that the existing flupyradifurone EU MRL does not need to be modified.

The available data are considered sufficient to derive new MRL proposals for DFA on the basis of submitted residue trials for lemons, limes and mandarins, macadamias, stone fruits and dewberries. No need to modify the existing EU MRL was identified for grapefruits, oranges, blackberries, raspberries, small fruits and berries, herbs and edible flowers, barley grain, millet grain, wheat grain and honey. For leafy brassica, sunflower seed, maize/corn grain, oat grain and rye grain, the expected soil uptake of DFA residues in rotational crops was identified to be significant and thus, it may affect the MRL values for DFA. For these crops, in order to quantify the contribution of soil residues to the overall residue levels in the harvested commodities, two MRL proposals were derived: an MRL proposal accounting for residues expected only from primary crop treatment and a combined MRL proposal, which reflects residues in a crop from the primary crop treatment and from the soil uptake in rotational crops. A risk management consideration is required on whether to support the setting of MRLs on the basis of residue soil uptake or to propose implementation of risk mitigation measures to avoid residues in rotational crops.

The intended SEU use of flupyradifurone on large citrus fruits, the authorised use on cherries in the USA, the intended SEU use on barley, oat, maize and millet were not supported by a sufficient number of residue trials; for these commodities the MRL proposals were derived from alternative uses.

The updated livestock dietary burden was not significantly affected by residues from the new intended uses or import tolerance uses, but due to a more detailed data available for fat matrix from feeding studies, the need to raise the existing EU MRL was identified for DFA in fat of sheep, goat, swine and poultry. For flupyradifurone the existing EU MRL would need to be raised for kidney, liver, edible offal and fat of swine.

Additionally, based on residue trials investigating residue transfer from plants to honey, a new MRL proposal could be derived for flupyradifurone in honey whereas no need to modify the existing MRL for DFA in honey was identified.

EFSA performed two consumer exposure calculations in order to estimate separately the exposure from primary crops (including also animal products) (intake 1) and rotational crops (intake 2). This approach was chosen to demonstrate the contribution of residues in rotational crops to the overall consumer exposure. The overall consumer exposure (69% of the ADI for NL toddler diet) was then estimated as the sum of intake 1 and 2 and accounts for the worst-case scenario when risk mitigation measures for restricting residues in rotational crops are not in place. Under these conditions EFSA concluded that the proposed and authorised uses of flupyradifurone on the crops under assessment will not result in an overall consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

EFSA notes that although according to the internationally agreed methodology for acute risk assessment, which is based on the highest residue found in the supervised field trials, no acute consumer intake concerns were identified, for the uses on oranges and kales, if residues of flupyradifurone occur in kales at the derived MRL value and in oranges at the existing EU MRL, the dietary exposure of certain consumers may exceed the ARfD (117.3% and 106.1% of the ARfD respectively) under certain conditions (i.e. consumption of a large portion of the product without washing/peeling/processing which would lead to a reduction of the residues in the product, some commodity units contain more residues than the average in the lot due to inhomogeneous distribution). Risk managers should decide whether the safety margin of the exposure assessment based on the highest residue is sufficient, considering that in reality residues in individual units/lot consumed may occur at or above the proposed MRL.

The MRL recommendations are summarised in Appendix B.5.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
EC	emulsifiable concentrate
EMS	evaluating Member State
GAP	Good Agricultural Practice
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SEU	southern Europe
STMR	supervised trials median residue
TRR	total radioactive residue

Appendix A – Summary of intended and authorised GAPs triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F, G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Grapefruits	SEU	F	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 55–75	1	–			150	g a.i./ha	30	
Oranges	SEU	F	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 55–75	1	–			150	g a.i./ha	30	
Lemons	SEU	F	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 55–75	1	–			150	g a.i./ha	30	
Limes	SEU	F	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 55–75	1	–			150	g a.i./ha	30	
Mandarins	SEU	F	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 55–75	1	–			150	g a.i./ha	30	
Other citrus fruit	SEU	F	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 55–75	1	–			150	g a.i./ha	30	
Cherries (sweet)	SEU, NEU	F	*Rhagoletis cerasi* (L.)	SL	200	Foliar treatment – broadcast spraying	BBCH 69–85	1	–			180	g a.i./ha	7	60 g a.s./ha × m CH, max. CH = 3 m[#]
Plums	SEU, NEU	F	*Hoplocampa* sp.	SL	200	Foliar treatment – broadcast spraying	BBCH 69–85	1	–			180	g a.i./ha	14	60 g a.s./ha × m CH, max. CH = 3 m[#]

Crop and/or situation	NEU, SEU, MS or country	F, G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Blackberries	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 15–89	1–2	10			200–100	g a.i./ha	3	200 g a.s./ha or 2 × 100 g a.s./ ha × mCH, max. CH = 2 m#
Dewberries	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 15–89	1–2	10			200–100	g a.i./ha	3	200 g a.s./ha or 2 × 100 g a.s./ ha × mCH, max. CH = 2 m#
Raspberries (red and yellow)	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 15–89	1–2	10			200–100	g a.i./ha	3	200 g a.s./ha or 2 × 100 g a.s./ ha × mCH, max. CH = 2 m#
Other cane fruit	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 15–89	1–2	10			200–100	g a.i./ha	3	200 g a.s./ha or 2 × 100 g a.s./ ha × mCH, max. CH = 2 m#
Blueberries	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 11–89	1	–			60	g a.i./ha	3	60 g a.s./ha or 40 g a.s./ ha × mCH, max. CH = 1.5 m#
Cranberries	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 11–89	1	–			60	g a.i./ha	3	60 g a.s./ha or 40 g a.s./ ha × mCH, max. CH = 1.5 m#
Currants (red, black and white)	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 11–89	1	–			60	g a.i./ha	3	60 g a.s./ha or 40 g a.s./ ha × mCH, max. CH = 1.5 m#
Gooseberries (green, red and yellow)	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 11–89	1	–			60	g a.i./ha	3	60 g a.s./ha or 40 g a.s./ ha × mCH, max. CH = 1.5 m#

Crop and/or situation	NEU, SEU, MS or country	F, G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Rose hips	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 11–89	1	–			60	g a.i./ha	3	60 g a.s./ha or 40 g a.s./ ha × mCH, max. CH = 1.5 m[#]
Mulberries (black and white)	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 11–89	1	–			60	g a.i./ha	3	60 g a.s./ha or 40 g a.s./ ha × mCH, max. CH = 1.5 m[#]
Azarole/ Mediterranean medlar	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 11–89	1	–			60	g a.i./ha	3	60 g a.s./ha or 40 g a.s./ ha × mCH, max. CH = 1.5 m[#]
Elderberries	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 11–89	1	–			60	g a.i./ha	3	60 g a.s./ha or 40 g a.s./ ha × mCH, max. CH = 1.5 m[#]
Other small fruit & berries	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 11–89	1	–			60	g a.i./ha	3	60 g a.s./ha or 40 g a.s./ ha × mCH, max. CH = 1.5 m[#]
Chinese cabbages/ pe-tsai	NEU	F	Aphids	SL	25	Foliar treatment – broadcast spraying	BBCH 12–49	2	10			125	g a.i./ha	3	
Kales	NEU	F	Aphids	SL	25	Foliar treatment – broadcast spraying	BBCH 12–49	2	10			125	g a.i./ha	3	
Other leafy brassica	NEU	F	Aphids	SL	25	Foliar treatment – broadcast spraying	BBCH 12–49	2	10			125	g a.i./ha	3	

Crop and/or situation	NEU, SEU, MS or country	F, G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Chinese cabbages/ pe-tsai	SEU	F	Aphids	SL	25	Foliar treatment – broadcast spraying	BBCH 12–49	1	–			125	g a.i./ha	3	
Kales	SEU	F	Aphids	SL	25	Foliar treatment – broadcast spraying	BBCH 12–49	1	–			125	g a.i./ha	3	
Other leafy brassica	SEU	F	Aphids	SL	25	Foliar treatment – broadcast spraying	BBCH 12–49	1	–			125	g a.i./ha	3	
Chervil	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 41–46	1	–			125	g a.i./ha	3	Minor use
Chives	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 41–46	1	–			125	g a.i./ha	3	Minor use
Celery leaves	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 41–46	1	-			125	g a.i./ha	3	Minor use
Parsley	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 41–46	1	–			125	g a.i./ha	3	Minor use
Sage	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 41–46	1	–			125	g a.i./ha	3	Minor use

Crop and/or situation	NEU, SEU, MS or country	F, G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Rosemary	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 41–46	1	–			125	g a.i./ha	3	Minor use
Thyme	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 41–46	1	–			125	g a.i./ha	3	Minor use
Basil and edible flowers	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 41–46	1	–			125	g a.i./ha	3	Minor use
Laurel/bay leaves	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 41–46	1	–			125	g a.i./ha	3	Minor use
Tarragon	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 41–46	1	–			125	g a.i./ha	3	Minor use
Other herbs and edible flowers	EU	G	Aphids	SL	200	Foliar treatment – broadcast spraying	BBCH 41–46	1	–			125	g a.i./ha	3	Minor use
Sunflower seeds	SEU, NEU	F	*Bradychaudus helichrysi*, *Lygus* sp.	EC	10 g/L deltamethrin and 75 g/L flupyradifurone[##]	Foliar treatment – broadcast spraying	BBCH 31–69	2	14	9.375–28.125	200–600	56.25	g a.i./ha		As per growth stage
Barley	SEU, NEU	F	Aphids	EC	10 g/L deltamethrin and 75 g/L flupyradifurone[##]	Foliar treatment – broadcast spraying	BBCH 41–83	2	14	9.375–28.125	200–600	56.25	g a.i./ha	30	

Crop and/or situation	NEU, SEU, MS or country	F, G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Maize/corn	NEU	F	Aphids	EC	10 g/L deltamethrin and 75 g/L flupyradifurone##	Foliar treatment – broadcast spraying	BBCH 51–75	1	–	5.625–28.125	200–1,000	56.25	g a.i./ha		As per growth stage
Maize/corn	SEU	F	Aphids	EC	10 g/L deltamethrin and 75 g/L flupyradifurone##	Foliar treatment – broadcast spraying	BBCH 59–75	1	–	9.375–46,875	200–1,000	93.75	g a.i./ha		As per growth stage
Common millet/proso millet	NEU	F	*Rhopalosiphum padi*, *Sitobion avenae* (F.), *Ostrinia nubilalis*, *Helicoverpa armigera*	EC	10 g/L deltamethrin and 75 g/L flupyradifurone##	Foliar treatment – broadcast spraying	BBCH 51–75	1	–	5.625–28.125	200–1,000	56.25	g a.i./ha		As per growth stage
Common millet/proso millet	SEU	F	*Ostrinia nubilalis*, *Helicoverpa armigera*	EC	10 g/L deltamethrin and 75 g/L flupyradifurone##	Foliar treatment – broadcast spraying	BBCH 51–75	1	–	11.72–23.44	400–800	93.75	g a.i./ha		As per growth stage
Oat	NEU	F	*Eurygaster* sp.	EC	10 g/L deltamethrin and 75 g/L flupyradifurone##	Foliar treatment – broadcast spraying	BBCH 41–83	2	14	9.375–28.125	200–600	56.25	g a.i./ha	30	
Rye	SEU	F	*Sitobion avenae* (F.), *Eurygaster* sp., *Cnephasia pumicana*	EC	10 g/L deltamethrin and 75 g/L flupyradifurone##	Foliar treatment – broadcast spraying	BBCH 41–83	2	14	9.375–28.125	200–600	56.25	g a.i./ha	30	
Wheat	SEU, NEU	F	Aphids	EC	10 g/L deltamethrin and 75 g/L flupyradifurone##	Foliar treatment – broadcast spraying	BBCH 41–83	2	14	9.375–28.125	200–600	56.25	g a.i./ha	30	

Crop and/or situation	NEU, SEU, MS or country	F, G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Macadamias	Australia	F	Macadamia lace bug, banana spotting bug, fruit spotting bug, Scirtothrips	SL	200	Foliar treatment – broadcast spraying	BBCH ≥ 50	1	–	20		400	g a.i./ha	20	
Apricots	USA	F	Aphids, San Jose Scale	SL	200	Foliar treatment – broadcast spraying		2	10		Min. 234 L/ha (25 gal/ Acre)	205	g a.i./ha	14	Do not apply more than 410 g a.s./ha (0.365 lb/Acre) per calendar year. Use of adjuvant.
Cherries (sweet)	USA	F	Aphids, San Jose Scale	SL	200	Foliar treatment – broadcast spraying		2	10		Min. 234 L/ha (25 gal/ Acre)	205	g a.i./ha	14	Do not apply more than 410 g a.s./ha (0.365 lb/Acre) per calendar year. Use of adjuvant.
Peaches	USA	F	Aphids, San Jose Scale	SL	200	Foliar treatment – broadcast spraying		2	10		Min. 234 L/ha (25 gal/ Acre)	205	g a.i./ha	14	Do not apply more than 410 g a.s./ha (0.365 lb/Acre) per calendar year. Use of adjuvant.
Plums	USA	F	Aphids, San Jose Scale	SL	200	Foliar treatment – broadcast spraying		2	10		Min. 234 L/ha (25 gal/ Acre)	205	g a.i./ha	14	Do not apply more than 410 g a.s./ha (0.365 lb/Acre) per calendar year. Use of adjuvant.
Other stone fruit	USA	F	Aphids, San Jose Scale	SL	200	Foliar treatment – broadcast spraying		2	10		Min. 234 L/ha (25 gal/ Acre)	205	g a.i./ha	14	Do not apply more than 410 g a.s./ha (0.365 lb/Acre) per calendar year. Use of adjuvant.

Crop and/or situation	NEU, SEU, MS or country	F, G or I[(a)]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[(d)]	Remarks
				Type[(b)]	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season[(c)]	Number min–max	Interval between application (days) min–max	g a.s./hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Common millet/proso millet (extrapolation via Maize (field corn))	USA	F	Aphids, leafhoppers, white-flies	SL	200	Foliar treatment – broadcast spraying		2	7		Min. 93.5 L/ ha (25 gal/ Acre)	205	g a.i./ha	21	Do not apply more than 410 g a.s./ha (0.365 lb/Acre) per calendar year
Oat (extrapolation via Barley)	USA	F	Aphids, leafhoppers, white-flies	SL	200	Foliar treatment – broadcast spraying		2	7		Min. 93.5 L/ ha (25 gal/ Acre)	205	g a.i./ha	21	Do not apply more than 410 g a.s./ha (0.365 lb/Acre) per calendar year
Rye (extrapolation via Wheat)	USA	F	Aphids, leafhoppers, white-flies	SL	200	Foliar treatment – broadcast spraying		2	7		Min. 93.5 L/ ha (25 gal/ Acre)	205	g a.i./ha	21	Do not apply more than 410 g a.s./ha (0.365 lb/Acre) per calendar year

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; EC: emulsifiable concentrate; SL: soluble (liquid) concentrate; CH: crown (canopy) height.

#: The application rate reported as 'g a.s./ha × m CH' indicates that the application rate depends on the crown height (CH) expressed in metres, where a maximum crown height is indicated to determine the critical GAP.

##: The formulation of Sivanto Energy is 10 g/L deltamethrin +75 g/L flupyradifurone.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI – minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and analytical methods for enforcement purposes in plant commodities

B.1.1.1. Metabolism studies, analytical methods and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Apple	Foliar a) 1 × 86 g/ha per m canopy height (CH); BBCH 69 b) 2 × 86 g/ha per m CH; BBCH 69	a) 89 DAT b) 14 DALA	Radiolabelled active substance: [furanone-4-^{14}C], [pyridinylmethyl-^{14}C] flupyradifurone (Netherlands, 2014; EFSA, 2015a)
		Tomato	Soil drench, 2 × 300 g/ha, BBCH 14–15, interval 14 days	56–73 DALA	Radiolabelled active substance: [furanone-4-^{14}C], [pyridinylmethyl-^{14}C] and [ethyl-1-^{14}C] flupyradifurone (Netherlands, 2014; EFSA, 2015a)
	Root crops	Potato	In furrow (soil spraying), 1 × 626 g/ha, BBCH 03	97 DAT	Radiolabelled active substance: [furanone-4-^{14}C] and [pyridinylmethyl-^{14}C] flupyradifurone (Netherlands, 2014; EFSA, 2015a)
			Seed treatment, 1 × 254 g/ha, BBCH 03	97 DAT	
	Cereals/ grass	Rice	Foliar, 175 g/ha, BBCH 13/ 15 + 240 g/ha, BBCH 87–89	29 DALA	Radiolabelled active substance: [furanone-4-^{14}C] and [pyridinylmethyl-^{14}C] flupyradifurone (Netherlands, 2014; EFSA, 2015a)
			Soil (granules) at planting, 1 × 409–434 g/ha, BBCH 13/15	127 DAT	Radiolabelled active substance: [furanone-4-^{14}C] and [pyridinylmethyl-^{14}C] flupyradifurone (Netherlands, 2014; EFSA, 2015a)
	Pulses/ oilseeds	Cotton	Foliar a) 1 × 210 g/ha, BBCH 15–18 b) 210 + 175 g/ha, BBCH 15–18	a) 169 DAT b) 14–15 DALA	Radiolabelled active substance: [furanone-4-^{14}C] and [pyridinylmethyl-^{14}C] flupyradifurone (Netherlands, 2014; EFSA, 2015a)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Turnips	Soil, 436 g/ha	29, 135 and 296	Radiolabelled active substance: [furanone-4-^{14}C] and [pyridinylmethyl-^{14}C] flupyradifurone (Netherlands, 2014; EFSA, 2015a)
	Leafy crops	Swiss chard			
	Cereal (small grain)	Wheat			

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	Flupyradifurone: yes DFA: not investigated, but considered stable	EFSA (2015a,b) Considering the similarity of the structures between trifluoroacetic acid (TFA) and DFA, a read-across for both acids was applied. The TFA, due to its stability in environment, has been widely studied and is, due to its structure, very stable and thus has no potential for hydrolytic degradation. The same was concluded for DFA (EFSA, 2020a)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Flupyradifurone: yes DFA: not investigated, but considered stable	
	Sterilisation (20 min, 120°C, pH 6)	Flupyradifurone: yes DFA: not investigated, but considered stable	
	Other processing conditions		

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2015)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2015)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2015)
Plant residue definition for monitoring (RD-Mo)	Two separate residue definitions (EFSA, 2015a): 1) Flupyradifurone 2) Difluoroacetic acid (DFA), expressed as DFA	
Plant residue definition for risk assessment (RD-RA)	Sum of flupyradifurone and DFA, expressed as flupyradifurone (EFSA, 2015a)	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	<u>Matrices with high water content (lettuce), high starch content (wheat, potato), high acid content (oranges), high oil content (rapeseed):</u> HPLC–MS/MS method 01330 with acetonitrile/water (4/1, v/v) with 2.2 mL/L formic acid extraction. LOQ 0.01 mg/kg (flupyradifurone); LOQ 0.007 mg/kg (DFA, expressed as DFA). <u>Hops:</u> HPLC–MS/MS method 01330 with acetonitrile/water (4/1, v/v) with 2.2 mL/L formic acid extraction. LOQ 0.05 mg/kg (flupyradifurone); LOQ 0.03 mg/kg (DFA, expressed as DFA). (EFSA, 2015a) Extraction efficiency proven for enforcement of flupyradifurone in high water content, high oil content and dry commodities; extraction efficiency proven for enforcement of DFA in high water content commodities.	

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.

B.1.1.2. Storage stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ Source**
				Value	**Unit**		
	High water content	Spinach, sugar cane, tomato	–18	52	Months	Flupyradifurone, DFA	EFSA (2020a)
	High oil content	Soybean seed	–18	52	Months	Flupyradifurone, DFA	
	High protein content	Bean seed	–18	52	Months	Flupyradifurone, DFA	
	Dry/High starch	Wheat grain	–18	52	Months	Flupyradifurone, DFA	
	High acid content	Oranges	–18	52	Months	Flupyradifurone, DFA	
	Others	Coffee bean	–18	52	Months	Flupyradifurone, DFA	

B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

Commodity	Region[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
Large citrus fruits (grapefruits and oranges)	SEU	**Mo (FPF):** 0.013; 0.026; 0.038; 0.046; 0.052; 0.15[(e)]; 0.17 **Mo (DFA):** 4 × < 0.007; 0.008[(e)]; 0.010[(e)]; 0.013 **RA:** 0.033; 0.046; 0.058; 0.066; 0.072; 0.17[(e)]; 0.20	Residue trials on orange compliant with GAP (Netherlands, 2022). The submitted data are not sufficient to derive MRL and risk assessment values.	–	–	–	n.r.
Small citrus fruits (lemons, limes and mandarins)	SEU	**Mo (FPF):** 0.024; 2 × 0.028[(e)]; 0.042[(e)]; 0.053; 0.066; 0.084; 0.11 **Mo (DFA):** < 0.007; 0.007[(e)]; 0.013[(e)]; 0.016; 0.016[(e)]; 0.021[(e)]; 0.034[(e)]; 0.057[(e)] **RA:** 2 × 0.048[(e)]; 0.067[(e)]; 0.078[(e)]; 2 × 0.11; 0.17; 0.27	Residue trials on lemon compliant with GAP (Netherlands, 2022). The submitted data are sufficient to derive MRL proposals for the SEU use. Extrapolation to lime and mandarins is possible.	**Mo (FPF):** 0.2 **Mo (DFA):** 0.09	**Mo (FPF):** 0.11 **Mo (DFA):** 0.06 **RA:** 0.27	**Mo (FPF):** 0.05 **Mo (DFA):** 0.02 **RA:** 0.09	n.r.
Macadamias	AU	**Mo (FPF):** 4 × < 0.01[(f)] **Mo (DFA):** < 0.02; 0.03; 0.06[(g)]; 0.07[(g)]; 0.12 **RA:** < 0.07; 0.10; 0.19[(g)]; 0.22[(g)]; 0.37	Residue trials on macadamias. (Netherlands, 2022). Set of four residue trials selected, measuring flupyradifurone were performed at a more critical GAP (3 × 400 g a.s./ha (nominal rate)), where residues were < LOQ. Another set of trials was selected to support the use and investigate DFA residues. In two of these trials, two additional applications were conducted in the preceding year. The submitted data are sufficient to derive IT proposals for the authorised use in Australia.	**Mo (FPF):** 0.01* **Mo (DFA):** 0.3	**Mo (FPF):** 0.01 **Mo (DFA):** 0.12 **RA:** 0.37	**Mo (FPF):** 0.01 **Mo (DFA):** 0.06 **RA:** 0.19	n.r.

Commodity	Region[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Apricots	NAFTA (USA)	**Mo (FPF):** Apricots, corrected for stone weight (14% generic correction factor)[i]: 0.17; 0.28; 0.36; 0.38 Peaches: 0.134; 0.135; 0.217; 0.253; 0.281; 0.308; 0.313; 0.329; 0.618; 0.722; 0.729 Nectarines, corrected for stone weight (14% generic correction factor)[i]: 0.19; 0.23; 0.26; 0.28 **Mo (DFA):** Apricots, corrected for stone weight (14% generic correction factor)[i]: 0.008; 0.032[e]; 0.033; 0.112[e] Peaches: < 0.008; 0.015[e]; 0.021; 0.031; 0.036; 0.057[e]; 0.059[e]; 0.079[e]; 0.126; 0.138[e]; 0.179[e] Nectarines, corrected for stone weight (14% generic correction factor)[i]: 0.022; 0.041; 0.074[e]; 0.077[e] **RA:** Apricots, corrected for stone weight (14% generic correction factor): 0.31; 0.39; 0.43[e]; 0.44 Peaches: 0.16; 0.25; 0.34; 0.35[e]; 0.37; 0.39; 0.43; 0.61[e]; 0.71; 0.94; 1.1 Nectarines, corrected for stone weight (14% generic correction factor)[i]: 0.25; 0.33; 2 × 0.34	Residue trials on apricots (4), peaches (11) and nectarines (4) compliant with US GAP (Netherlands, 2022). Residue trials were conducted in duplicates. For each residue definition, the highest residue value observed in the duplicates was selected for the calculations of MRL and risk assessment values. The submitted data are sufficient to derive IT proposals for the US use.	**Mo (FPF):** 1.0 **Mo (DFA):** 0.3	**Mo (FPF):** 0.73 **Mo (DFA):** 0.18 **RA:** 1.10[j]	**Mo (FPF):** 0.28 **Mo (DFA):** 0.04 **RA:** 0.37[j]	n.r.
Cherries	NEU	**Mo (FPF):** 0.067; 0.11; 0.21; 0.24; 0.26[e]; 0.41; 0.44; 0.55 **Mo (DFA):** 0.007[e]; 0.011[e]; 0.013[e]; 0.017[e]; 0.25[e]; 0.027[e]; 0.055[e]; 0.07[e] **RA:** 0.092; 0.13; 0.23; 0.27; 0.28[e]; 0.43; 0.47; 0.61	Residue trials on cherries compliant with GAP (Netherlands, 2022). The submitted data are sufficient to derive MRL proposals for the NEU use.	**Mo (FPF):** 1 **Mo (DFA):** 0.15	**Mo (FPF):** 0.55 **Mo (DFA):** 0.07 **RA:** 0.61	**Mo (FPF):** 0.25 **Mo (DFA):** 0.02 **RA:** 0.28	n.r.

Commodity	Region[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
	SEU	**Mo (FPF):** 0.41; 0.42; 0.81; 0.92 **Mo (DFA):** 0.032[(e)]; 0.037[(e)]; 0.043[(h)]; 0.079[(e)] **RA:** 0.43; 0.44; 0.86; 0.96[(h)]	Residue trials on cherries compliant with GAP (Netherlands, 2022). The submitted data are sufficient to derive an MRL proposal.	**Mo (FPF): 2** **Mo (DFA): 0.15**	**Mo (FPF):** 0.92 **Mo (DFA):** 0.08 **RA:** 0.96	**Mo (FPF):** 0.62 **Mo (DFA):** 0.04 **RA:** 0.65	n.r.
	USA	**Mo (FPF):** 0.014; 0.168; 0.254; 0.356[(e)]; 0.360[(e)]; 0.624; 0.936[(e)] **Mo (DFA):** 0.061[(e)]; 0.063[(e)]; 0.096; 0.124[(e)]; 0.139[(e)]; 0.169[(e)]; 0.19[(e)] **RA:** 0.38[(e)]; 0.43; 0.44; 0.51; 0.54[(e)]; 0.86; 1.1[(e)]	Residue data on cherries compliant with GAP (Netherlands, 2022). No proposal due to an insufficient number of independent trials. No sufficient data are available in support of the NAFTA GAP on cherries. Residue trials were conducted in duplicates. For each residue definition, the highest residue value observed in the duplicates was selected.	–	–	–	n.r.
Peaches	USA	**Mo (FPF):** Peaches: 0.134; 0.135; 0.217; 0.253; 0.281; 0.308; 0.313; 0.329; 0.618; 0.722; 0.729 Nectarines, corrected for stone weight (14% generic correction factor)[(i)]: 0.19; 0.23; 0.26; 0.28 **Mo (DFA):** Peaches: < 0.008; 0.015[(e)]; 0.021; 0.031; 0.036; 0.057[(e)]; 0.059[(e)]; 0.079[(e)]; 0.126; 0.138[(e)]; 0.179[(e)] Nectarines, corrected for stone weight (14% generic correction factor)[(i)]: 0.022; 0.041; 0.074[(e)]; 0.077[(e)] **RA:** Peaches: 0.16; 0.25; 0.34; 0.35[(e)]; 0.37; 0.39; 0.43; 0.61[(e)]; 0.71; 0.94; 1.1 Nectarines, corrected for stone weight (14% generic correction factor)[(i)]: 0.25; 0.33; 2 × 0.34	Residue trials on peaches and nectarines compliant with US GAP (Netherlands, 2022). Residue trials were conducted in duplicates. For each residue definition, the highest residue value observed in the duplicates was selected for the calculations of MRL and risk assessment. The submitted data are sufficient to derive IT proposals for the US use.	**Mo (FPF):** 1.5 **Mo (DFA):** 0.3	**Mo (FPF):** 0.73 **Mo (DFA):** 0.18 **RA:** 1.10[(j)]	**Mo (FPF):** 0.28 **Mo (DFA):** 0.06 **RA:** 0.35[(j)]	n.r.

Commodity	Region[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
Plums	NEU	**Mo (FPF):** 0.017; 0.030[(e)]; 0.033; 0.047[(e)]; 0.096[(e)]; 0.098[(e)]; 0.12; 0.12[(e)] **Mo (DFA):** 3 × < 0.007; 0.009[(e)]; 0.020[(e)]; 0.031[(e)]; 0.044[(e)]; 0.052[(e)] **RA:** 0.038[(e)]; 0.053; 0.089[(e)]; 0.11[(e)]; 0.12[(e)]; 0.14; 2 × 0.25[(e)]	Residue trials on plums compliant with GAP (Netherlands, 2022). The submitted data are sufficient to derive MRL proposals for the NEU use.	**Mo (FPF):** 0.3 **Mo (DFA):** 0.1	**Mo (FPF):** 0.12 **Mo (DFA):** 0.05 **RA:** 0.25	**Mo (FPF):** 0.07 **Mo (DFA):** 0.01 **RA:** 0.12	n.r.
	SEU	**Mo (FPF):** 2 × < 0.01; 0.013; 0.014; 0.021; 0.061; 0.068[(e)]; 0.14 **Mo (DFA):** 0.013[(e)]; 0.017[(e)]; 0.018[(e)]; 0.02[(e)]; 0.03[(e)]; 0.034[(e)]; 0.59[(e)]; 0.11[(e)] **RA:** 0.048[(e)]; 0.07[(e)]; 0.088[(e)]; 0.1[(e)]; 0.11[(e)]; 0.17[(e)]; 0.19[(e)]; 0.35[(e)]	Residue trials on plums compliant with GAP (Netherlands, 2022). The submitted data are sufficient to derive MRL proposals for the SEU use.	**Mo (FPF):** 0.3 **Mo (DFA):** 0.2	**Mo (FPF):** 0.14 **Mo (DFA):** 0.11 **RA:** 0.35	**Mo (FPF):** 0.02 **Mo (DFA):** 0.03 **RA:** 0.11	n.r.
	USA	**Mo (FPF):** 0.037; 0.046; 0.068; 0.089[(e)]; 0.098; 0.14[(e)]; 0.151; 0.263[(e)] **Mo (DFA):** < 0.017; 0.027[(e)]; 0.037; 2 × 0.044[(e)]; 0.065[(e)]; 0.129[(e)]; 0.15[(e)] **RA:** 0.087; 0.14[(e)]; 0.16[(e)]; 0.20; 0.24[(e)]; 0.27[(e)]; 0.4[(e)]; 0.59[(e)]	Residue trials on plums compliant with US GAP (Netherlands, 2022). Residue trials were conducted in duplicates. For each residue definition, the highest residue value observed in the duplicates was selected for the calculations of MRL and risk assessment values. The submitted data are sufficient to derive IT proposals for the US use.	**Mo (FPF):** **0.4** **Mo (DFA):** **0.3**	**Mo (FPF):** 0.26 **Mo (DFA):** 0.15 **RA:** 0.59	**Mo (FPF):** 0.09 **Mo (DFA):** 0.04 **RA:** 0.22	n.r.
Cane fruits	EU (indoor)	**Mo (FPF):** 0.56; 0.62 **Mo (DFA):** 0.018[(e)]; 0.023[(e)] **RA:** 0.58; 0.64 EFSA (2016): **Mo (FDF):** 0.24; 0.31; 0.4; 0.64 **Mo (DFA):** 0.02; 0.028; 0.029; 0.01 **RA:** 0.3; 0.34; 0.43; 0.66	Residue trials on raspberries compliant with the intended GAP (Netherlands, 2022, EFSA 2016). Extrapolation to the whole group of cane fruits acceptable.	**Mo (FPF):** 1.5 **Mo (DFA):** 0.07	**Mo (FPF):** 0.64 **Mo (DFA):** 0.029 **RA:** 0.66	**Mo (FPF):** 0.48 **Mo (DFA):** 0.022 **RA:** 0.51	n.r.

Commodity	Region[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
Other small fruits and berries: blueberries, cranberries, currants (red, black and white), gooseberries (green, red and yellow), rose hips, mulberries (black and white), azaroles/Mediterranean medlars, elderberries	EU (indoor)	**Mo (FPF):** 0.029; 0.057; 0.12; 0.15[(e)]; 0.24[(e)]; 0.37 **Mo (DFA):** 5 × < 0.0067; 0.008[(e)] **RA:** 0.049; 0.077; 0.14; 0.17[(e)]; 0.26[(e)]; 0.39	Residue trials on red and black currant compliant with the intended GAP (Netherlands, 2022). Extrapolation to the whole group of other small fruits and berries (blueberries, cranberries, gooseberries, rose hips, mulberries, azaroles) is acceptable.	**Mo (FPF):** 0.7 **Mo (DFA):** 0.01*	**Mo (FPF):** 0.37 **Mo (DFA):** 0.008 **RA:** 0.39	**Mo (FPF):** 0.14 **Mo (DFA):** 0.007 **RA:** 0.16	n.r.
Leafy brassica: kales, Chinese cabbages/pe-tsai and others	NEU	**Mo (FPF):** 0.87; 0.76 **Mo (DFA):** 0.15[(e)]; 0.3[(e)] **RA:** 1.2; 1.5 EFSA (2020): **Mo (FDF):** 0.09; 0.22; 1.10; 1.90 **Mo (DFA):** 0.058[(e)]; 0.11[(e)]; 0.14[(e)]; 0.20[(e)] **RA:** 0.20[(e)]; 0.54; 1.4; 2.20	Residue trials on curly kale compliant with the intended GAP (Netherlands, 2022, EFSA 2002a). Extrapolation to the remaining crops of the leafy brassica crop group-Chinese cabbage and others-acceptable.	**Mo (FPF): 4.0** **Mo (DFA): 0.5**	**Mo (FPF):** 1.9 **Mo (DFA):** 0.30 **RA:** 2.20	**Mo (FPF):** 0.82 **Mo (DFA):** 0.15 **RA:** 1.30	
	SEU	**Mo (FPF):** 0.3; 0.77; 0.81; 0.89; 0.91; 2.1 **Mo (DFA):** 0.027[(e)]; 0.058[(e)]; 0.092[(e)]; 0.11[(e)]; 0.12[(e)]; 0.12[(e)] **RA:** 0.33; 0.92; 0.98; 1.1; 1.1; 2.1		**Mo (FPF): 4.0** **Mo (DFA):** 0.3	**Mo (FPF):** 2.10 **Mo (DFA):** 0.12 **RA:** 2.1	**Mo (FPF):** 0.85 **Mo (DFA):** 0.10 **RA:** 1.04	n.r.
Herbs and edible flowers	EU (indoor)	**Mo (FPF):** 8.17 (basil); 9.03 (chervil); 15.9 (parsley); 16.3 (parsley); 18.2 (celery leaves) *[Open-leaf Lettuce: 0.94; 1.2; 1.7; 1.9; 2.2; 4.1; 4.5; 4.8; 6.5]* **Mo (DFA):** 4 × < 0.01 (celery leaves, basil, parsley); 0.017 (chervil) *[Open-leaf Lettuce: 5 × < 0.007; 0.0071[(e)]; 0.0092[(e)]; 0.014[(e)]; 0.019[(e)]]*	Residue trials on basil, chervil, parsley, celery leaf compliant with the intended GAP (Netherlands, 2022). The MRL proposal derived from the residue data set on fresh herbs. [Residue trials on open leaf lettuce also compliant with GAP are not used to derive MRL because residue trials on herbs are considered more	Herbs residue data: **Mo (FPF): 40** **Mo (DFA): 0.03**	Herbs residue data: **Mo (FPF):** 18.20 **Mo (DFA):** 0.01	Herbs residue data: **Mo (FPF):** 15.90 **Mo (DFA):** 0.01	n.r.

Commodity	Region[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
		RA: 8.20 (basil); 9.07 (chervil); 15.9 (parsley); 16.3 (parsley); 18.2 (celery leaves) *[Open-leaf Lettuce: 1.0; 1.2; 1.7; 1.9; 2.2; 4.1; 4.5; 4.8; 6.5]*	representative for the residue situation expected in herbs and edible flowers.]		**RA:** 18.2	**RA:** 15.90	
Sunflower seeds	NEU	**Mo (FPF):** 3 × 0.011; 0.015; 0.024; 0.046; 0.10 **Mo (DFA):** 0.007; 0.011; 0.015; 0.016; 0.025; 0.042 **RA:** 0.04; 0.06; 0.076; 0.085; 0.09; 0.23	Residue trials on sunflower compliant with the GAP (Netherlands, 2022). In two residue trials, control samples contained residues of DFA (70–125% of residues in treated samples). In one trial, the same control sample contained residues also of flupyradifurone (50% of residues in treated sample). Insufficient number of residue trials to support the intended use.	–	–	–	
	SEU	**Mo (FPF):** 2 × < 0.01; 0.014; 0.025; 0.026; 0.027; 0.032; 0.043 **Mo (DFA):** 0.008; 0.009; 0.013; 0.023; 0.024; 0.036; 0.043; 0.049 **RA:** 0.038; 0.048; 0.061; 0.096; 0.12; 0.13; 0.14; 0.16	Residue trials data on sunflower compliant with the GAP (Netherlands, 2022).	**Mo (FPF):** 0.07 **Mo (DFA):** 0.09	**Mo (FPF):** 0.043 **Mo (DFA):** 0.049 **RA:** 0.16	**Mo (FPF):** 0.026 **Mo (DFA):** 0.024 **RA:** 0.11	n.r.
Barley grain, Oat grain	NEU	**Mo (FPF):** < 0.01; 0.022; 0.034; 0.053[(e)]; 0.081[(e)]; 0.082[(e)]; 0.099[(e)]; 0.160 **Mo (DFA):** 0.011; 0.031[(e)]; 0.036[(e)]; 0.039; 0.052; 0.059[(e)]; 0.064; 0.080 **RA:** 0.12[(e)]; 0.15[(e)]; 0.18; 0.20; 0.21[(e)]; 0.26[(e)]; 2 × 0.27	Residue trials on barley compliant with GAP (Netherlands, 2022). The submitted data are sufficient to derive MRL proposals for the NEU use. Extrapolation to oat is possible.	**Mo (FPF):** 0.3 **Mo (DFA):** 0.15	**Mo (FPF):** 0.16 **Mo (DFA):** 0.08 **RA:** 0.27	**Mo (FPF):** 0.07 **Mo (DFA):** 0.05 **RA:** 0.21	n.r.
	USA	**Mo (FPF):** 0.04; 0.07; 0.10; 0.21; 0.24; 0.25; 0.27; 0.30; 0.31[(e)]; 0.44; 0.46[(e)]; 0.48; 0.68; 0.68; 0.71; 0.81; 0.84; 1.18; 1.68; 2.26 **Mo (DFA):** 2 × < 0.017; 0.026; 0.027; 0.029; 0.033; 0.059; 0.08; 0.085; 0.10;	Residue trials on barley (grain) submitted in a previous MRL application for setting an import tolerance in barley (EFSA, 2020a). These are compliant with the intended US GAP on oat. The	**Mo (FPF): 3** **Mo (DFA): 0.6**	**Mo (FPF):** 2.26 **Mo (DFA):** 0.385	**Mo (FPF):** 0.45 **Mo (DFA):** 0.10	n.r.

Commodity	Region[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
		0.105; 0.11[(e)]; 0.12; 0.13; 0.155; 0.175; 0.18; 0.27[(e)]; 0.365; 0.385 **RA:** 0.49; 0.51; 0.56; 0.64; 0.65; 0.70; 0.74; 0.76; 0.77; 0.78[(e)]; 0.84; 0.89; 1.01; 1.13[(e)]; 1.19; 1.19; 1.21; 1.27; 1.76; 2.34	submitted data are sufficient to derive IT proposals for the US use in oat (extrapolation is possible).		**RA:** 2.34	**RA:** 0.81	
Barley	SEU	**Mo (FPF):** Unscaled: < 0.01; 0.012[(e)]; 0.016[(e)]; 0.042[(e)]; 0.044[(e)]; 0.13; 0.19 Scaled: 0.008; 0.009[(e)]; 0.012[(e)]; 0.032[(e)]; 0.033[(e)]; 0.10; 0.14 **Mo (DFA):** Unscaled: < 0.007; 0.029; 0.037[(e)]; 0.064; 0.072[(e)]; 0.09[(e)]; 0.13[(e)] Scaled: 0.005; 0.022; 0.028[(e)]; 0.048; 0.054[(e)]; 0.068[(e)]; 0.10[(e)] **RA:** Unscaled: 0.064[(e)]; 0.13[(e)]; 2 × 0.23[(e)]; 0.28; 0.39; 0.41[(e)] Scaled: 0.048[(e)]; 0.10[(e)]; 2 × 0.17[(e)]; 0.21; 0.29; 0.031[(e)]	Seven overdosed residue trials on barley were scaled to the intended GAP by a scaling factor of 0.75 (Netherlands, 2022). Insufficient number of residue trials available to support the intended GAP	–	–	–	–
Maize grain, Millet grain	NEU	**Mo (FPF):** Unscaled: 8 × < 0.01 Scaled: 8 × < 0.006 **Mo (DFA):** Unscaled: 2 × < 0.007; 0.008; 0.013; 0.016; 0.018; 0.021; 0.026 Scaled: 2 × < 0.004; 0.005; 0.008; 0.010; 0.011; 0.013; 0.016 **RA:** Unscaled: 2 × < 0.03; 0.035; 0.050; 0.057; 0.064; 0.072; 0.088 Scaled: 2 × < 0.018; 0.021; 0.030; 0.034; 0.038; 0.043; 0.053	Overdosed residue trials on maize (Netherlands, 2022). Residues were scaled down by applying a scaling factor of 0.6 to predict the residue concentrations expected at the intended GAP. MRLs and risk assessment values were derived based on the scaled residues. The submitted data are sufficient to derive MRL proposals for the NEU use. Extrapolation to millet is possible.	**Mo (FPF):** 0.01* **Mo (DFA):** 0.03 mg/kg	**Mo (FPF):** 0.01* **Mo (DFA):** 0.02 **RA:** 0.05	**Mo (FPF):** 0.01* **Mo (DFA):** 0.01 **RA:** 0.03	n.r.

Commodity	Region(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR(b) (mg/kg)	STMR(c) (mg/kg)	CF(d)
	SEU	**Mo (FPF):** 7 × < 0.01 **Mo (DFA):** 0.009; 0.012; 0.013; 0.017; 0.018; 0.020; 0.026 **RA:** 0.037; 0.045; 0.048; 0.062; 0.063; 0.069; 0.089	Residue trials on maize compliant with GAP (Netherlands, 2022). SEU GAP on maize is not supported by sufficient number of residue trials.	–	–	–	n.r.
	USA	**Mo (FPF):** 19 × < 0.01; 0.011 **Mo (DFA):** 19 × < 0.017; 0.041 **RA:** 18 × < 0.06; 0.061; 0.140	Residue trials on maize (kernel) submitted in a previous MRL application for setting an import tolerance in maize (EFSA, 2020a). These are compliant with the intended US GAP on millet. The submitted data are sufficient to derive IT proposals for the US use on millet (extrapolation is possible).	**Mo (FPF):** 0.02 **Mo (DFA):** 0.05	**Mo (FPF):** 0.01 **Mo (DFA):** 0.04 **RA:** 0.14	**Mo (FPF):** 0.01 **Mo (DFA):** 0.02 **RA:** 0.06	n.r.
Wheat grain, Rye grain	SEU	**Mo (FPF):** Unscaled: 5 × < 0.01; 0.014; 0.028(e); 0.078 Scaled: 5 × < 0.008; 0.011; 0.021(e); 0.059 **Mo (DFA):** Unscaled: 0.07(e); 0.082; 0.098; 0.12: 0.14; 0.17(e); 0.19; 0.24(e) Scaled: 0.053(e); 0.062; 0.074; 0.090; 0.105; 0.128(e); 0.143; 0.180(e) **RA:** Unscaled: 0.22(e); 0.3; 0.33; 0.36; 0.45(e); 0.53(e); 0.58; 0.74(e) Scaled: 0.165(e); 0.225; 0.248; 0.270; 0.338(e); 0.398(e); 0.435; 0.555(e)	Overdosed residue trials on wheat (Netherlands, 2022). Residues in grains were scaled down by applying a scaling factor of 0.75 to estimate the residue levels expected at the intended GAP. MRLs and risk assessment values were derived based on scaled residues. The submitted data are sufficient to derive MRL proposals for the SEU use. Extrapolation to rye is possible.	**Mo (FPF):** 0.09 **Mo (DFA):** 0.4	**Mo (FPF):** 0.06 **Mo (DFA):** 0.18 **RA:** 0.56	**Mo (FPF):** 0.01 **Mo (DFA):** 0.10 **RA:** 0.30	n.r.
	USA	**Mo (FPF):** 3 × 0.02; 3 × 0.03; 0.04; 0.05; 0.06; 0.07; 2 × 0.09; 2 × 0.10; 0.15; 0.15(e); 0.16; 0.16(e); 0.17; 0.18; 0.21(e); 0.22; 0.23; 0.26; 0.34; 0.37; 0.58; 0.61; 0.73	Residue trials on wheat submitted in a previous MRL application for setting an import tolerance in wheat (EFSA, 2020a). These are compliant with the intended US GAP on rye.	**Mo (FPF):** 1	**Mo (FPF):** 0.73	**Mo (FPF):** 0.15	n.r.

Commodity	Region[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
		Mo (DFA): 4 × < 0.017; 0.02; 0.02; 2 × 0.04; 0.06; 3 × 0.09; 0.11; 0.14; 2 9 0.16; 0.17[(e)]; 2 × 0.18[(e)]; 0.20; 0.22; 0.24; 0.28; 2 × 0.33; 0.47; 0.55[(e)]; 0.65; 0.72 **RA:** 0.07; 0.08; 0.09; 0.10; 0.21; 0.24; 0.26; 0.29; 0.30; 0.37; 0.56; 0.59; 3 × 0.65[(e)]; 0.67; 0.74; 0.75[(e)]; 0.76; 0.77; 0.81; 0.87; 0.90; 1.08; 1.20; 1.46; 1.83[(e)]; 2.54; 2.69	The submitted data are sufficient to derive IT proposals for the authorised US use on rye (extrapolation is possible).	**Mo (DFA):** 1	**Mo (DFA):** 0.72 **RA:** 2.69	**Mo (DFA):** 0.16 **RA:** 0.65	
Wheat grain	NEU	**Mo (FPF):** 2 × < 0.01; 0.01; 0.011; 0.012[(e)]; 0.015[(e)]; 0.032[(e)]; 0.061 **Mo (DFA):** 0.018; 0.067; 0.074; 0.10; 0.14[(e)]; 0.16; 0.20; 0.34 **RA:** 0.12; 2 × 0.23; 0.32; 0.42[(e)]; 0.48; 0.62; 1	Residue trials on wheat compliant with GAP (Netherlands, 2022). The submitted data are sufficient to derive MRL proposals for the NEU use.	**Mo (FPF):** 0.1 **Mo (DFA):** 0.6	**Mo (FPF):** 0.06 **Mo (DFA):** 0.34 **RA:** 1	**Mo (FPF):** 0.01 **Mo (DFA):** 0.12 **RA:** 0.37	n.r.
Barley straw, oat straw	NEU	**Mo (FPF):** 0.087[(e)]; 2 × 0.11; 2 × 0.17; 0.28; 0.41[(e)]; 0.69 **Mo (DFA):** 0.016[(e)]; 2 × < 0.017; 0.017[(e)]; 0.025; 0.027; 0.027[(e)]; 0.040[(e)] **RA:** 0.13[(e)]; 2 × 0.19; 2 × 0.22; 0.37; 0.46[(e)]; 0.75	Straw samples collected from GAP compliant trials on barley (Netherlands, 2022). Residue data can be extrapolated to oat.	–	**Mo (FPF):** 0.69 **Mo (DFA):** 0.04	**Mo (FPF):** 0.11 **Mo (DFA):** 0.02	n.r.
	USA	–	Straw is not expected to be imported in the EU, therefore data on straw from the authorised US use were not considered.	–	–	–	n.r.
Barley straw	SEU	**Mo (FPF):** Unscaled: 0.020[(e)]; 0.096; 0.18; 0.66; 0.72; 4.5; 6.4 Scaled: 0.015[(e)]; 0.072; 0.14; 0.5; 0.54; 3.4; 4.8 **Mo (DFA):** Unscaled: 2 × 0.018; 0.022; 0.024[(e)]; 0.036; 0.046[(e)]; 0.77 Scaled: 2 × 0.014; 0.017; 0.018[(e)]; 0.027; 0.035[(e)]; 0.58	Straw samples collected from GAP compliant trials on barley and scaled to the intended GAP by a factor of 0.75 (Netherlands, 2022). Although the number of trials is not sufficient (one more GAP compliant residue trial would be required), tentative risk assessment values were derived based on scaled residues.	–	**Mo (FPF):** 4.8 **Mo (DFA):** 0.58	**Mo (FPF):** 0.5 **Mo (DFA):** 0.02	n.r.

Commodity	Region[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
		RA: 0.075[(e)]; 0.21[(e)]; 0.25; 0.77; 0.79; 6.4; 6.8 Scaled: 0.056[(e)]; 0.16[(e)]; 0.19; 0.58; 0.59; 4.8; 5.1					
Maize stover, millet stover	NEU	**Mo (FPF):** Unscaled: 0.057; 0.059; 0.084; 0.16; 0.36; 0.39; 0.53; 0.75 Scaled: 0.0342; 0.0354; 0.0504; 0.096; 0.216; 0.234; 0.318; 0.45 **Mo (DFA):** Unscaled: 2x < 0.0067; 0.0069; 0.0073; 0.0077; 0.0093; 0.012; 0.015 Scaled: 2 × < 0.004; 2 × 0.004; 0.005; 0.006; 0.0072; 0.009 **RA:** Unscaled: 0.077; 0.10; 0.12; 0.18; 0.38; 0.41; 0.55; 0.77 Scaled: 0.0462; 0.06; 0.072; 0.108; 0.228; 0.246; 0.33; 0.462	Stover samples collected from overdosed residue trials on maize (Netherlands, 2022). Residues were scaled down by applying a scaling factor of 0.6 to predict the residue concentrations expected at the intended GAP. Risk assessment values were derived based on the scaled residues. Extrapolation to millet is possible.	–	**Mo (FPF):** 0.45 **Mo (DFA):** 0.01	**Mo (FPF):** 0.16 **Mo (DFA):** 0.01	n.r.
	SEU	**Mo (FPF):** 0.035; 0.067; 0.15; 0.18; 0.21; 0.30; 0.46 **Mo (DFA):** 2 × 0.007; 0.008; 0.011; 0.013; 0.014; 0.022 **RA:** 0.056; 0.091; 0.22; 0.23; 0.33; 0.19; 0.53	Residue trials on maize compliant with GAP (Netherlands, 2022). SEU GAP on maize is not supported by sufficient number of residue trials. Although the number of trials is not sufficient (one more GAP compliant residue trial would be required), tentative risk assessment values were derived based on scaled residues.	–	**Mo (FPF):** 0.46 **Mo (DFA):** 0.022	**Mo (FPF):** 0.18 **Mo (DFA):** 0.011	
	USA	–	Maize stover is not expected to be imported in the EU, therefore data from the authorised US use were not considered.	–	–	–	n.r.

Commodity	Region[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
Wheat straw, rye straw	SEU	**Mo (FPF):** Unscaled: 0.066; 0.11; 0.44[(e)]; 0.71; 0.78; 1.5; 2.4[(e)]; 3.5 Scaled: 0.050; 0.083; 0.33[(e)]; 0.53; 0.59; 1.1; 1.8[(e)]; 2.6 **Mo (DFA):** Unscaled: 0.029; 0.032; 2 × 0.033; 0.070[(e)]; 0.080[(e)]; 0.089[(e)]; 0.11 Scaled: 0.022; 0.024; 2 × 0.025; 0.053[(e)]; 0.06[(e)]; 0.067[(e)]; 0.083 **RA:** Unscaled: 0.17; 0.21; 0.78[(e)]; 0.80; 0.87; 1.7[(e)]; 2.7[(e)]; 3.8 Scaled: 0.13; 0.16; 0.59[(e)]; 0.60; 0.65; 1.3[(e)]; 2.0[(e)]; 2.9	Straw samples collected from overdosed residue trials on wheat (Netherlands, 2022). Residues in straw were scaled down by applying a scaling factor of 0.75 to estimate the residue levels expected at the intended GAP. Risk assessment values were derived based on scaled residues. Extrapolation to rye is possible.	–	**Mo (FPF):** 2.6 **Mo (DFA):** 0.08	**Mo (FPF):** 0.43 **Mo (DFA):** 0.04	n.r.
	USA	–	Wheat straw is not expected to be imported in the EU, therefore data on straw from the authorised US use were not considered.	–	–	–	n.r.
Wheat straw	NEU	**Mo (FPF):** 0.12; 0.18[(e)]; 0.27; 0.31; 0.41; 0.43[(e)]; 0.81; 1.2 **Mo (DFA):** 0.022[(e)]; 0.025; 0.030; 0.039; 0.042[(e)]; 0.053; 0.11[(e)]; 0.17[(e)] **RA:** 0.21; 0.30[(e)]; 0.38; 0.49[(e)]; 0.57; 0.76; 1.1; 1.2	Straw samples collected from GAP compliant trials on wheat (Netherlands, 2022).	–	**Mo (FPF):** 1.2 **Mo (DFA):** 0.17	**Mo (FPF):** 0.36 **Mo (DFA):** 0.04	n.r.

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): Peak residue level detected after PHI.
(f): Residue levels measured in trials performed at a more critical GAP (3 × 400 g a.s./ha (nominal rate)).
(g): Residue levels measured in trials where two applications were conducted in the preceding year (interval between second and third application ≥ 347 days).

(h): Residue level measured in a trial where the untreated plot showed residue levels of uncorrected and corrected DFA (i.e. expressed as DFA and flupyradifurone, respectively) slightly above the LOQ. The trial is acceptable considering that (1) DFA residues in the untreated sample of the afore-mentioned SEU trial were only slightly above the LOQ of 0.007 mg/kg for DFA (i.e. 0.009 and 0.007 mg/kg in cherry samples collected 0 and 7 days after the treatment (corresponding to the intended PHI), respectively); (2) the uncorrected DFA level (i.e. DFA, expressed as DFA) measured in the treated plot (i.e. 0.43 mg/kg) may be slightly overestimated, however, the residue level is still within the range of the SEU data set for DFA (0.032–0.079 mg/kg) and also within the range of the NEU data set (0.007–0.070 mg/kg); (3) the residue level measured according the risk assessment residue definition (i.e. 0.96 mg/kg for the sum of flupyradifurone and DFA, expressed as flupyradifurone) is driven by the residue level of flupyradifurone.

(i): For the purpose of MRL setting and enforcement in apricots, residues were recalculated in the whole fruit by applying an approximate stone weight of 14% as a generic correction factor, as done in a previous reasoned opinion on flubendiamid (EFSA, 2018a).

(j): For reason of consistency, risk assessment values were derived based on residue levels measured in the whole commodities (i.e. residue levels measured in commodities without stone were corrected for stone weight using a 14% generic correction factor).

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	EFSA (2015a, 2020a)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Yes	Field rotational crop studies in NEU/SEU at 200 g/ha on bare soil (25–30 days PBI) or on lettuce as primary crop (61–145 and 266–329 days PBI) indicate residues of flupyradifurone in edible matrices at ≤ 0.01 mg/kg, except in lettuce head (0.03 mg/kg (one sample)) and in barley straw (two samples 0.02 and 0.04 mg/kg). Metabolite DFA was present at significant levels, requiring setting of MRLs for this compound in rotational crops (EFSA, 2015a). Field rotational crop studies, performed at 300 g/ha on bare soil (21–30, 107–204 and 273–365 days PBI) or at 175–185 g/ha on bare soil (107–204 and 273–365 days PBI) (EFSA, 2020a). Residues of flupyradifurone were < LOQ of 0.01 mg/kg in all crops at all plant back intervals, except in one sample of barley grain (0.01 mg/kg, 2nd rotation) and in barley straw (0.02 and 0.03 mg/kg 2nd rotation and 0.02 mg/kg 3rd rotation). Residues of DFA (expressed as DFA, mg/kg) were observed at significant levels and these data are in detail reported in the previous assessment by EFSA (EFSA, 2020a). The data on relevant rotational crops scaled to the application rate on primary crops are reported in Appendix E, Table E.1

B.1.2.3. Processing factors

Processing factors relevant to commodities under assessment can be found in previous EFSA opinions (EFSA, 2020a).

Processed commodity	Number of valid studies[(a)]	Processing Factor (PF)	Median PF			Comment/Source
		Individual values	FPF	DFA	RA	
Large citrus fruits, peeled	7	**FPF:** < *0.03*; < 0.04; < 0.08; 0.10; < 0.5; 0.88; 1.17 **DFA:** < 0.34; 0.3; 3 × < 1; < *1*; 1 **RA:** < *0.08*; < 0.12; < 0.75; 2 × 0.21; 0.9; 1.16	0.3	1	0.57	Data on oranges and grapefruits (in italics) (EFSA, 2020a).

Processed commodity	Number of valid studies[(a)]	Processing Factor (PF) Individual values	Median PF FPF	DFA	RA	Comment/Source
	4	**FPF:** 0.21; < 0.3; < 0.48; < 0.91 **DFA:** 0.90; < 1 **RA:** 0.37; < 0.57; < 0.73; < 0.97				Data on oranges. Highest peeling factor selected from each trial. No processing factors were derived when the residues in the RAC were < LOQ (Netherlands, 2022).
Small citrus fruits, peeled	1	**FPF:** < 0.19 **DFA:** < 1 **RA:** < 0.41	0.58	1	0.79	Data on lemons (EFSA, 2022a)
	4	**FPF:** < 0.43; 0.58; < 0.63; 0.80 **DFA:** 1; 1; 1.44 **RA:** < 0.70; 0.79; 0.91; 1.11				Data on lemons. Highest peeling factor selected from each trial. No processing factors were derived when the residues in the RAC were < LOQ (Netherlands, 2022).
Cherry, cooked	2	**FPF:** 0.26; 0.48 **DFA:** 0.29; 0.44 **RA:** 0.25; 0.47	0.37	0.37	0.36	Data from trials performed in USA (Netherlands, 2022).
Peach, cooked	3	**FPF:** 0.24; 2 × 0.32 **DFA:** 0.37; < 0.38; 0.54 **RA:** 0.29; 0.33; 0.40	0.32	0.38	0.33	Data from trials performed in USA (Netherlands, 2022).
Peach, peeled	3	**FPF:** 0.37; 0.41; 0.72 **DFA:** 0.78; 0.83; 1.18 **RA:** 0.58; 0.65; 0.73	0.41	0.83	0.65	

PF: processing factor.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

B.2. Residues in livestock

Dietary burden for EU livestock considering primary and rotational crops grown in the EU as well as imported feed items and their by-products from the US. The import of bulked feed commodities like straw, hay and stover in Europe is unlikely and therefore these feed items for import tolerance uses were not considered.

Flupyradifurone:

Dietary burden calculated for the intake of flupyradifurone residues. Dietary burden calculation according to OECD (2013).

Relevant groups (subgroups)	Dietary burden expressed in mg/kg bw per day: Median	Maximum	mg/kg DM: Median	Maximum	Most critical subgroup[(a)]	Most critical commodity[(b)]	Trigger (0.004 mg/kg bw per day) exceeded (Y/N) Max burden	DB calculated in previous assessment (mg/kg bw per day) (EFSA, 2020b)
Cattle (all)	0.073	0.180	2.04	5.87	Dairy cattle	Kale leaves	Y	0.170
Cattle (dairy only)	0.073	0.180	1.89	4.68	Dairy cattle	Kale leaves	Y	0.170

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[(a)]	Most critical commodity[(b)]	Trigger (0.004 mg/kg bw per day) exceeded (Y/N) Max burden	DB calculated in previous assessment (mg/kg bw per day) (EFSA, 2020b)
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Sheep (all)	0.052	0.221	1.49	5.20	Lamb	Swede roots	Y	0.155
Sheep (ewe only)	0.050	0.173	1.49	5.20	Ram/Ewe	Swede roots	Y	0.129
Swine (all)	0.031	0.100	1.33	4.35	Swine (breeding)	Kale leaves	Y	0.097
Poultry (all)	0.037	0.095	0.52	1.38	Poultry layer	Swede roots	Y	0.078
Poultry (layer only)	0.035	0.095	0.51	1.38	Poultry layer	Swede roots	Y	0.074

bw: body weight; DM: dry matter.
(a): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

Difluoroacetic acid (DFA), expressed as DFA

Dietary burden calculated for the intake of DFA residues expected in primary and in rotational crops. Dietary burden calculation according to OECD (2013).

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[(a)]	Most critical commodity[(b)]	Trigger exceeded (Y/N) Max burden	DB calculated in previous assessment (mg/kg bw per day) (EFSA, 2020b)
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all)	0.040	0.063	1.17	2.13	Dairy cattle	Kale leaves	Y	0.057
Cattle (dairy only)	0.040	0.063	1.03	1.63	Dairy cattle	Kale leaves	Y	0.057
Sheep (all)	0.040	0.068	1.00	1.66	Lamb	Kale leaves	Y	0.065
Sheep (ewe only)	0.033	0.055	1.00	1.66	Ram/Ewe	Swede roots	Y	0.053
Swine (all)	0.022	0.044	0.89	1.73	Swine (finishing)	Swede roots	Y	0.044
Poultry (all)	0.036	0.050	0.53	0.73	Poultry layer	Swede roots	Y	0.050
Poultry (layer only)	0.036	0.050	0.53	0.73	Poultry layer	Swede roots	Y	0.050

bw: body weight; DM: dry matter.
(a): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

Livestock (available studies)	**Animal**	**Dose (mg/kg bw/d)**	**Duration (days)**	**Comment/Source**
	Laying hen	FPF: 1.02–1.05	14	^{14}C- 4 furanone, ^{14}C-pyridiniylethyl flupyradifurone (EFSA, 2015a)
	Lactating ruminants	FPF: 0.92–1	5	Goat. ^{14}C-pyridiniylethyl flupyradifurone (EFSA, 2015a)

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: FPF: 9 days	Confirmed by cattle feeding study (EFSA, 2015a)
	Eggs: FPF: 6 days	Confirmed by feeding study (EFSA, 2015a)
Metabolism in rat and ruminant similar	Yes	EFSA (2015a)
Can a general residue definition be proposed for animals?	Yes	EFSA (2015a)
Animal residue definition for monitoring (RD-Mo)	1) Flupyradifurone 2) DFA, expressed as DFA	
Animal residue definition for risk assessment (RD-RA)	Sum of flupyradifurone and DFA, expressed as flupyradifurone	
Fat soluble residues	No	EFSA (2015a)
Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)	Milk, eggs, muscle, fat, liver, kidney: HPLC–MS/MS, acetonitrile/water (4/1, v/v) with the addition of n-heptane in the cases of fat and milk; LOQ of 0.01 mg/kg for flupyradifurone and LOQ 0.02 mg/kg for DFA (EFSA, 2015a)	

F: flupyradifurone; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.

B.2.1.2. Storage stability of residues in livestock

Animal products (available studies)	**Animal**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ Source**
				Value	**Unit**		
	Bovine	Muscle	–20	43	Days	DFA	EFSA (2015)
	Bovine	Liver					
	Bovine	Kidney					
	Bovine	Fat					

B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

Calculations performed with Animal model 2017[9]

B.2.2.1.1.

Flupyradifurone, expressed as flupyradifurone. Derived from feeding studies with flupyradifurone for the intake of feed containing residues of flupyradifurone.

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1 N level		MRL proposal (mg/kg)
	Mean	Highest	$STMR_{Mo}$[(a)] (mg/kg)	HR_{Mo}[(b)] (mg/kg)	
Cattle (all diets)					
Closest feeding level[(c)]:	0.18	mg/kg bw	1.0	N Dairy cattle (highest diet)	
Muscle	0.04	0.05	0.017	0.048	0.05
Fat	0.02	0.03	0.008	0.028	0.03
Liver	0.15	0.17	0.059	0.343	0.4
Kidney	0.16	0.22	0.064	0.222	0.3
Cattle (dairy only)					
Closest feeding level[(c)]:	0.18	mg/kg bw	1.0	N Dairy cattle	
Milk[(d)]	0.02	0.03	0.009	0.023	0.03
Sheep (all diets)[(f)]					
Closest feeding level[(c)]:	0.18	mg/kg bw	1.1	N Lamb (highest diet)	
Muscle	0.04	0.05	0.012	0.060	0.06
Fat	0.02	0.03	0.006	0.034	0.04
Liver	0.15	0.17	0.042	0.375	0.4
Kidney	0.16	0.22	0.046	0.273	0.3
Sheep (dairy only)[(f)]					
Closest feeding level[(c)]:	0.18	mg/kg bw	1.4	N Ewe	
Milk[(d)]	0.02	0.03	0.006	0.022	0.03
Swine[(f)]					
Closest feeding level[(c)]:	0.18	mg/kg bw	1.8	N Breeding (highest diet)	
Muscle	0.04	0.05	0.007	0.027	0.03
Fat	0.02	0.03	0.004	0.016	**0.02**
Liver	0.15	0.17	0.025	0.096	**0.1**
Kidney	0.16	0.22	0.027	0.124	**0.15**
Poultry (all diets)					
Closest feeding level[(c)]:	0.1	mg/kg bw	1.1	N Layer (highest diet)	
Muscle	0.004	0.004	0.004	0.004	0.01*
Fat	0.003	0.003	0.003	0.003	0.01*
Liver	0.003	0.003	0.003	0.003	0.01*
Poultry (layer only)					
Closest feeding level[(c)]:	0.1	mg/kg bw	1.1	N Layer	
Eggs[(e)]	0.004	0.004	0.004	0.004	0.01*

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): The mean residue level for milk and the mean residue levels for eggs and tissues were recalculated at the 1 N rate for the median dietary burden.
(b): The mean residue level in milk and the highest residue levels in eggs and tissues, were recalculated at the 1 N rate for the maximum dietary burden.

[9] https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en

(c): Closest feeding level and N dose rate related to the maximum dietary burden.
(d): Highest residue level from day 1 to day 28 (daily mean of 3 cows).
(e): Highest residue level from day 1 to day 28 (daily mean of 12 laying hens).
(f): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

B.2.2.1.2.

DFA, expressed as DFA. Risk assessment values calculated from the feeding studies with DFA for the intake of primary and rotational crops containing residues of the DFA.

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1 N level	
	Mean	Highest	$STMR_{Mo}$[(a)] (mg/kg)	HR_{Mo}[(b)] (mg/kg)
Cattle (all diets)				
Closest feeding level[(c)]:	0.032	mg/kg bw	0.5 N Dairy cattle (highest diet)	
Muscle	0.070	0.090	0.086	0.175
Fat	0.074	0.131	0.092	0.257
Liver	0.053	0.065	0.067	0.127
Kidney	0.106	0.119	0.131	0.233
Cattle (dairy only)				
Closest feeding level[(c)]:	0.032	mg/kg bw	0.5 N Dairy cattle	
Milk[(d)]	0.015	0.02	0.019	0.029
Sheep (all diets)[(f)]				
Closest feeding level[(c)]:	0.032	mg/kg bw	0.5 N Lamb (highest diet)	
Muscle	0.070	0.090	0.086	0.189
Fat	0.074	0.131	0.092	0.277
Liver	0.053	0.065	0.067	0.137
Kidney	0.106	0.119	0.131	0.251
Sheep (dairy only)[(f)]				
Closest feeding level[(c)]:	0.032	mg/kg bw	0.6 N Ewe	
Milk[(d)]	0.02	0.02	0.016	0.026
Swine[(f)]				
Closest feeding level[(c)]:	0.032	mg/kg bw	0.7 N Finishing (highest diet)	
Muscle	0.070	0.090	0.048	0.124
Fat	0.074	0.131	0.051	0.181
Liver	0.053	0.065	0.037	0.089
Kidney	0.106	0.119	0.073	0.164
Poultry (all diets)				
Closest feeding level[(c)]:	0.054	mg/kg bw	1.1 N Layer (highest diet)	
Muscle	0.094	0.103	0.063	0.098
Fat	0.021	0.022	0.014	0.022
Liver	0.175	0.188	0.117	0.192
Poultry (layer only)				
Closest feeding level[(c)]:	0.054	mg/kg bw	1.1 N Layer	
Eggs[(e)]	0.057	0.083	0.042	0.078

STMR: supervised trials median residue; HR: highest residue.
(a): The mean residue level for milk and the mean residue levels for eggs and tissues were recalculated at the 1 N rate for the median dietary burden.
(b): The mean residue level in milk and the highest residue levels in eggs and tissues, were recalculated at the 1 N rate for the maximum dietary burden.
(c): Closest feeding level and N dose rate related to the maximum dietary burden.
(d): Highest residue level from day 1 to day 28 (daily mean of 3 cows).
(e): Highest residue level from day 1 to day 28 (daily mean of 12 laying hens).

(f): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

B.2.2.1.3.

DFA, expressed as flupyradifurone. Risk assessment values calculated from the feeding studies with flupyradifurone, forming metabolite DFA, from the intake of primary crops containing residues of flupyradifurone.

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1 N level	
	Mean	Highest	$STMR_{Mo}$[(a)] (mg/kg)	HR_{Mo}[(b)] (mg/kg)
Cattle (all diets)				
Closest feeding level[(c)]:	0.18	mg/kg bw	1 N Dairy cattle (highest diet)	
Muscle	0.012	0.014	0.013	0.013
Fat	0.010	0.013	0.012	0.012
Liver	0.012	0.014	0.014	0.014
Kidney	0.017	0.022	0.007	0.022
Cattle (dairy only)				
Closest feeding level[(c)]:	0.18	mg/kg bw	1.0 N Dairy cattle	
Milk[(d)]	0.004	0.005	0.002	0.004
Sheep (all diets)[(f)]				
Closest feeding level[(c)]:	0.18	mg/kg bw	1.1 N Lamb (highest diet)	
Muscle	0.01	0.01	0.013	0.017
Fat	0.01	0.01	0.012	0.015
Liver	0.01	0.01	0.014	0.017
Kidney	0.02	0.02	0.005	0.027
Sheep (dairy only)[(f)]				
Closest feeding level[(c)]:	0.18	mg/kg bw	1.4 N Ewe	
Milk[(d)]	0.004	0.005	0.001	0.004
Swine[(f)]				
Closest feeding level[(c)]:	0,18	mg/kg bw	1.8 N Breeding (highest diet)	
Muscle	0.01	0.01	0.013	0.013
Fat	0.01	0.01	0.012	0.012
Liver	0.01	0.01	0.014	0.014
Kidney	0.02	0.02	0.003	0.012
Poultry (all diets)				
Closest feeding level[(c)]:	0.1	mg/kg bw	1.1 N Layer (highest diet)	
Muscle	0.083	0.096	0.030	0.091
Fat	0.029	0.035	0.011	0.033
Liver	0.104	0.112	0.038	0.106
Poultry (layer only)				
Closest feeding level[(c)]:	0.1	mg/kg bw	1.1 N Layer	
Eggs[(e)]	0.05	0.05	0.016	0.056

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): The mean residue level for milk and the mean residue levels for eggs and tissues were recalculated at the 1 N rate for the median dietary burden.
(b): The mean residue level in milk and the highest residue levels in eggs and tissues, were recalculated at the 1 N rate for the maximum dietary burden.
(c): Closest feeding level and N dose rate related to the maximum dietary burden.
(d): Highest residue level from day 1 to day 28 (daily mean of 3 cows).
(e): Highest residue level from day 1 to day 28 (daily mean of 12 laying hens).
(f): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

B.2.2.1.4. Overview of the risk assessment values and MRL proposals for DFA

Data reflect livestock feeding studies with flupyradifurone and the DFA.

Matrix	STMR (mg/kg)	HR (mg/kg)	MRL proposal DFA[(e)]	Existing EU MRL DFA (Reg. (EU) 2021/1842)	STMR (mg/kg)	HR (mg/kg)	STMR (mg/kg)	HR (mg/kg)	MRL proposal FPF (mg/kg)[(f)]	Existing EU MRL FPF (Reg.(EU) 2022/1324; EFSA, 2020a)	Risk assessment values for consumer exposure assessment from EU livestock exposure[(d)]	
	DFA, expressed as DFA[(a)]				DFA, expressed as flupyradifurone[(b)]		Flupyradifurone[(c)]				STMR (mg/kg)	HR (mg/kg)
Cattle muscle	0.090	0.179	0.2	0.4[(g)]	0.271	0.539	0.017	0.048	0.05	0.3[(g)]	0.288	0.586
Cattle fat	0.095	0.261	0.3	0.5[(g)]	0.287	0.782	0.008	0.028	0.03	0.2[(g)]	0.296	0.810
Cattle liver	0.071	0.131	0.15	0.4[(g)]	0.214	0.394	0.059	0.343	0.4	1.0[(g)]	0.273	0.737
Cattle kidney	0.133	0.240	0.3	0.5[(g)]	0.401	0.720	0.064	0.222	0.3	1.0[(g)]	0.466	0.942
Cattle milk	0.019	0.031	0.03	0.07[(g)]	0.058	0.092	0.009	0.023	0.03	0.15[(g)]	0.067	0.115
Sheep muscle	0.090	0.195	0.2	0.2[(h)]	0.271	0.585	0.0124	0.0601	0.06	0.3[(g)]	0.284	0.645
Sheep fat	0.095	0.282	**0.3**	0.15[(h)]	0.287	0.846	0.0061	0.0344	0.04	0.2[(g)]	0.294	0.881
Sheep liver	0.071	0.142	0.15	0.15[(h)]	0.215	0.428	0.0420	0.3745	0.4	1.0[(g)]	0.257	0.802
Sheep kidney	0.133	0.260	0.3	0.3[(h)]	0.400	0.781	0.0461	0.2727	0.3	1.0[(g)]	0.446	1.05
Sheep milk	0.016	0.027	0.03	0.03[(h)]	0.048	0.082	0.006	0.022	0.03	0.15[(g)]	0.055	0.104
Swine muscle	0.052	0.128	0.15	0.15[(h)]	0.157	0.383	0.007	0.027	0.03	0.03[(h)]	0.165	0.410
Swine fat	0.055	0.185	**0.2**	0.1[(h)]	0.166	0.554	0.004	0.016	**0.02**	0.015[(h)]	0.169	0.570
Swine liver	0.041	0.094	0.1	0.1[(h)]	0.125	0.282	0.025	0.096	**0.10**	0.08[(h)]	0.150	0.378
Swine kidney	0.074	0.168	0.2	0.2[(h)]	0.224	0.504	0.027	0.124	**0.15**	0.09[(h)]	0.251	0.628
Poultry muscle	0.073	0.128	0.15	0.15[(h)]	0.219	0.386	0.004	0.004	0.01*	0.01*[(h)]	0.223	0.390
Poultry fat	0.017	0.033	**0.04**	0.03[(h)]	0.052	0.099	0.003	0.003	0.01*	0.01*[(h)]	0.055	0.102
Poultry liver	0.129	0.229	0.3	0.3[(h)]	0.389	0.689	0.003	0.003	0.01*	0.01*[(h)]	0.392	0.692
Eggs	0.047	0.098	0.10	0.1[(h)]	0.142	0.295	0.004	0.004	0.01*	0.01*[(h)]	0.146	0.299

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Sum of residue values for the DFA derived the feeding studies with flupyradifurone and from the feeding studies with DFA; residues expressed as DFA.
(b): Residue values for the DFA derived the feeding studies with flupyradifurone and from the feeding studies with DFA; residues expressed as flupyradifurone.
(c): Residue values for flupyradifurone derived from the feeding studies with flupyradifurone; residues expressed as flupyradifurone.
(d): Risk assessment values derived for the residue definition 'sum of DFA and flupyradifurone, expressed as flupyradifurone' from the feeding studies with DFA and flupyradifurone. Underline values refer to risk assessment values which are higher than derived in the previous EFSA assessment in 2020a and were used in an updated consumer exposure assessment.
(e): MRL proposals derived for DFA in the present assessment. Values which are higher than estimated in the previous EFSA assessment from EU or USA/CA uses are reported in bold.
(f): MRL proposals derived for flupyradifurone in the present assessment. Values which are higher than estimated in the previous EFSA assessment from EU or USA/CA uses are reported in bold
(g): MRL proposals derived on the basis of USA livestock dietary burden.
(h): MRL proposals derived on the basis of EU livestock dietary burden.

B.3. Residues in honey

B.3.1. Nature of residues and analytical methods for enforcement purposes in honey

B.3.1.1. Metabolism studies, analytical methods and residue definitions in honey

Metabolism studies in honey	The nature of the residues in honey is based on the major components of the residue detected in primary crops, rotational crops and processed commodities.
Honey residue definition for monitoring (RD-Mo)	Two separate residue definitions: 1) Flupyradifurone 2) Difluoroacetic acid (DFA), expressed as DFA
Honey residue definition for risk assessment (RD-RA)	Sum of flupyradifurone and DFA, expressed as flupyradifurone (EFSA, 2015a)
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Honey HPLC–MS/MS method 01596. LOQ 0.01 mg/kg (flupyradifurone), LOQ 0.007 mg/kg (DFA, expressed as DFA). Confirmatory method and ILV available (Netherlands, 2022).

HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.3.1.2. Storage stability of residues in honey

Products of animal origin (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/Source
				Value	Unit		
	–	Honey	1–10	20	Days	Flupyradifurone, DFA	Storage stability under dark conditions (Netherlands, 2022)
			–18	171	Days	Flupyradifurone	Netherlands (2022)
			–18	162	Days	DFA	Netherlands (2022)

B.3.2. Magnitude of residues in honey

B.3.2.1. Summary of residues data from the supervised residue trials

Commodity	Region[(a)]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[(b)] (mg/kg)	STMR[(c)] (mg/kg)	CF[(d)]
Honey	n.r.	**Mo (FPF):** 0.064[(e)]; 0.23[(e)]; 0.44; 0.89 **Mo (DFA):** 2 × < 0.0067[(e)]; 0.0086; 0.0094 **RA:** 0.084[(e)]; 0.25[(e)]; 0.47; 0.92	Semi-field (tunnel) trials on *Phacelia tanacetifolia* treated with 2 × 180 g flupyradifurone/ha at BBCH 62–65 via spray application. The number of trials is sufficient to derive an MRL in honey in support of the critical EU GAP for honey, as selected by the Applicant: Pome fruits, NEU (field), 2 × 180 g a.s./ha, BBCH 60–79.	**Mo (FPF): 2** **Mo (DFA):** 0.02	**Mo (FPF):** 0.89 **Mo (DFA):** 0.01 **RA:** 0.92	**Mo (FPF):** 0.34 **Mo (DFA):** 0.01 **RA:** 0.36	n.r.
	n.r.	**Mo (FPF):** 3 × < 0.01[(f)]; 0.0201[(e),(g)] **Mo (DFA):** < 0.0067[(f)]; 0.0071[(h)]; 0.0084[(e),(i)]; 0.0118[(g)] **RA:** < 0.03[(f)]; 0.0314[(h)]; 0.0401[(e),(g)]; 0.0455[(g)]	Semi-field (tunnel) trials on *Phacelia tanacetifolia* sown at different plant back intervals (PBIs: 22–25, 136–196, 297–358 days) following bare soil treatment at 1 × 300 g flupyradifurone/ha. These trials are considered underdosed as regards to the rotational crop uptake of DFA following the critical EU use of flupyradifurone on primary crops (see Section 1.2.2)	**Mo (FPF):** 0.04 **Mo (DFA):** 0.03	**Mo (FPF):** 0.02 **Mo (DFA):** 0.01 **RA:** 0.05	**Mo (FPF):** 0.01 **Mo (DFA):** 0.01 **RA:** 0.04	n.r.

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment; n.r.: not relevant.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): Residue level measured in dried honey.
(f): Residue level measured in honey sample collected from trials performed with *Phacelia* sown at all PBIs (22, 136–196, 297–358 days).
(g): Residue level measured in honey sample collected from a trial where *Phacelia* was sown at a PBI of 22 days.
(h): Residue level measured in honey sample collected from a trial where *Phacelia* was sown at a PBI of 149 days.
(i): Residue level measured in honey sample collected from a trial where *Phacelia* was sown at a PBI of 136 days.

B.4. Consumer risk assessment

ARfD	0.15 mg/kg bw (European Commission, 2015)
Highest IESTI, according to EFSA PRIMo	**Intake 1** Exposure from residues in animal commodities and treated primary plant commodities: Oranges: 78% of ARfD Peaches: 70% of ARfD Kales: 65% of ARfD Chinese cabbage/pe-tsai: 47% of ARfD Grapefruits: 46% of ARfD Blackberries: 31% of ARfD Milk (cattle): 28% of ARfD Raspberries: 26% of ARfD Apricots: 26% of ARfD Plums: 17% of ARfD Mandarins: 16% of ARfD Chervil: 16% of ARfD Parsley 13% of ARfD Blueberries: 10% of ARfD Other commodities under consideration individually less than 10% ARfD **Intake 2** Exposure from residues in rotational crops (residues taken up via soil, without primary crop treatment): Kales: 12% of ARfD Chinese cabbage/pe-tsai: 9% of ARfD Other commodities under consideration individually less than 10% ARfD **Combined intake** (intake 1 + intake 2) (for annual crops under consideration, taking into account the primary crop treatment and residues taken up via soil) Kales: 77% of ARfD Chinese cabbage: 56% of ARfD Chervil: 16% of ARfD Chives: 10% of ARfD Wheat: 10% of ARfD For other annual crops under consideration, the combined exposure accounts individually for less than 10% of ARfD.
Assumptions made for the calculations	Intake 1) The calculation is based on the highest residue levels calculated in crops from primary treatment only. The peeling factor was applied to the input value of citrus fruits. For sheep, goat fat, swine muscle, swine fat, swine kidney, swine liver, poultry muscle and poultry fat, the HR values as derived under the present assessment for EU livestock dietary burden (Appendix B.2.2.1.4) were higher than derived in the previous EFSA assessment (EFSA, 2020a) and were therefore used as input values. For remaining animal commodities, the risk assessment values were as derived in the framework of the previous EFSA assessment (EFSA, 2020a). For honey, the HR value as derived from the submitted residue trials was used as input value (Appendix B.2.2.1).

	Intake 2) The calculation is based on DFA and flupyradifurone residues (HR) taken up via roots by annual crops grown in soil containing residues at the soil plateau concentrations. The **combined intake** represents the sum of exposure from the intake of annual crop treated as primary crop (intake 1) and the exposure to residues in the respective crop if grown as rotational crop (intake 2). All calculations were performed with PRIMo rev. 3.1

ADI	0.064 mg/kg bw per day (European Commission, 2015)
Highest IEDI, according to EFSA PRIMo	**Intake 1)** Exposure from residues in animal commodities and treated primary plant commodities (expressed as % of ADI): 54% ADI (NL toddler diet) Contribution of commodities assessed: Milk: 31.73% of ADI (NL toddler diet) Wheat: 7.35% of ADI ((GEMS/Food G06) Rye: 5.59% of ADI (DK child) Barley: 1.13% of ADI (GEMS/Food G08) Parsley: 1.05% of ADI (GEMS/food G10) Remaining commodities under consideration individually < 1% of the ADI **Intake 2)** Exposure from residues in rotational crops (no treatment) (EFSA, 2021): 17% ADI (GEMS/Food G06) 15% ADI (NL toddler diet) **Combined** chronic exposure (intake 1 + intake 2): **69% ADI** (NL toddler diet)
Assumptions made for the calculations	Intake 1) The calculation is based on the median residue levels expected in a crop from primary treatment only. A peeling factor was applied to the input value of citrus fruits. For swine fat, kidney and liver, the STMR values as derived under the present assessment for EU livestock dietary burden (Appendix B.2.2.1.4) were higher than derived in the previous EFSA assessment (EFSA, 2020a) and were therefore used as input values. For honey, the STMR value as derived from the submitted residue trials was used as input value (Appendix B.2.2.1). Intake 2) The calculation is based on DFA and flupyradifurone residues (STMR) taken up via roots by annual crops grown in soil containing residues at the soil plateau concentrations. The perennial crops and animal commodities were excluded from the exposure calculation (EFSA, 2021). **Combined long-term intake** was determined for the diet for which the highest total exposure was estimated (i.e, NL toddler diet in this case) from residue intake from primary crops, animal commodities (intake 1) and from residues in rotational crop (intake 2).

All calculations were performed with PRIMo rev. 3.1

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue; CXL: codex maximum residue limit.

B.5. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Flupyradifurone				
0110010	Grapefruits	3	No new proposal	The intended SEU use not sufficiently supported by data. The lowering of the existing EU MRL is not proposed. The existing EU MRL is based on previously assessed import tolerance for which no consumer intake concerns were identified.
0110020	Oranges	3	No new proposal	
0110030	Lemons	1.5	No new proposal	The submitted data are sufficient to derive an MRL proposal of 0.2 mg/kg in support of the intended SEU use. The lowering of the existing EU MRL is not proposed. The existing EU MRL is based on previously assessed import tolerance for which no consumer intake concerns were identified.
0110040	Limes	1.5	No new proposal	
0110050	Mandarins	1.5	No new proposal	
0110990	Other citrus fruits	0.01*	3	The applicant proposes to increase the existing EU MRL based on a previously assessed import tolerance data set in oranges and grapefruits. Risk for consumers unlikely.
0120070	Macadamias	0.02	No new proposal	The submitted data are sufficient to derive an MRL proposal of 0.01* mg/kg in support of the authorised use in Australia. The lowering of the existing EU MRL is not proposed. Risk for consumer unlikely.
0140010	Apricots	0.01*	1	The submitted data are sufficient to support the import tolerance request from the authorised US GAP. Risk for consumers unlikely.
0140020	Cherries (sweet)	0.01*	2	The submitted data are sufficient to support the intended NEU and SEU uses. The MRL proposal is based on the critical use (SEU). The data submitted in support of the import tolerance from the USA are insufficient to derive an MRL proposal. Risk for consumers unlikely.
0140030	Peaches	0.01*	1.5	The submitted data are sufficient to support the import tolerance request from the USA. Risk for consumers unlikely.
0140040	Plums	0.01*	0.4	The submitted data are sufficient to support the intended NEU, SEU uses and import tolerance request. The MRL proposal is based on the critical use (USA). Risk for consumers unlikely.
0140990	Other stone fruits	0.01*	1.5	The applicant proposes to extrapolate MRL proposal as derived for peaches to the group of 'other stone fruit'. Risk for consumers unlikely.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0153000	Cane fruits	6	No new proposal	The submitted residue data are sufficient to support the intended EU indoor use and to derive an MRL proposal of 1.5 mg/kg. The lowering of the existing EU MRL is not proposed. Risk for consumers unlikely.
0154010	Blueberries	4	No new proposal	The residue data submitted in support of the intended EU indoor use result in a lower MRL proposal of 0.7 mg/kg. The lowering of the existing EU MRL is not proposed. Risk for consumers unlikely.
0154020	Cranberries	0.01*	0.7	The submitted residue data are sufficient to support the intended EU indoor use. Risk for consumers unlikely.
0154030	Currants	0.01*	0.7	
0154040	Gooseberries	0.01*	0.7	
0154050	Rose hips	0.01*	0.7	
0154060	Mulberries	0.01*	0.7	
0154070	Azaroles	0.01*	0.7	
0154080	Elderberries	0.01*	0.7	
0154990	Other small fruits and berries	0.01*	0.7	
0243010	Chinese cabbages/ pe-tsai	0.01*	4	The submitted residue data are sufficient to support the intended NEU and SEU uses. Risk for consumers unlikely.
0243020	Kales	5	5 or 4 Further risk management consideration required	The submitted residue data are sufficient to support the intended NEU and SEU uses. The lowering of the existing EU MRL in kales is proposed by the applicant and is supported by data. Risk for consumers unlikely.
0243990	Others (leafy brassica)	0.01*	4	The submitted residue data are sufficient to support the intended NEU and SEU uses. Risk for consumers unlikely.
0256000	Herbs and edible flowers	6	40	The submitted residue data are sufficient to support the intended EU indoor use. Risk for consumers unlikely.
0401050	Sunflower seeds	0.01*	0.07	The submitted residue data are sufficient to support the intended SEU use. The intended NEU use is not sufficiently supported by data. Risk for consumers unlikely.
0500010	Barley	3	No new proposal	The submitted residue data are sufficient to support the intended NEU use and import tolerance from the USA. The intended SEU use not sufficiently supported by data. The existing EU MRL is confirmed for the critical authorised use (USA). Risk for consumers unlikely.
0500030	Maize/corn	0.02	No new proposal	The submitted residue data are sufficient to support the intended NEU use and import tolerance from the USA. The intended SEU use not sufficiently supported by data. The existing EU MRL is confirmed for the critical authorised use (USA). Risk for consumers unlikely.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0500040	Common millet/ proso millet	0.01*	0.02	The submitted residue data are sufficient to support the intended NEU use and import tolerance from the USA. The intended SEU use is not sufficiently supported by data. The MRL proposal is based on the critical authorised use (USA). Risk for consumers unlikely.
0500050	Oat	0.01*	3	The submitted residue data are sufficient to support the intended NEU use and import tolerance from the USA. The intended SEU use not sufficiently supported by data. The MRL proposal is based on the critical authorised use (USA). Risk for consumers unlikely.
0500070	Rye	0.01*	1	The submitted residue data are sufficient to support the intended NEU and SEU uses and import tolerance from the USA. The MRL proposal is based on the critical authorised use (USA). Risk for consumers unlikely.
050090	Wheat	1	No new proposal	The submitted residue data are sufficient to support the intended NEU and SEU uses and import tolerance from the USA. The existing EU MRL is confirmed for the critical authorised use (USA). Risk for consumers unlikely.
1011020	Swine, fat	0.015	0.02	The MRL proposal is based on an updated calculation considering the EU livestock exposure. Risk for consumers unlikely.
1011030	Swine, liver	0.08	0.10	The MRL proposal is based on an updated calculation considering the EU livestock exposure. Risk for consumers unlikely.
1011040	Swine, kidney	0.09	0.15	The MRL proposal is based on an updated calculation considering the EU livestock exposure. Risk for consumers unlikely.
1011050	Swine, edible offal	0.09	0.15	
1040000	Honey and other apiculture products	0.05*	2	The submitted residue data are sufficient to derive an MRL in honey. Risk for consumers unlikely.
Enforcement residue definition: difluoroacetic acid (DFA), expressed as DFA				
0110010	Grapefruit	0.05	No new proposal	The submitted residue data are not sufficient to derive a new MRL proposal.
0110020	Oranges	0.05	No new proposal	
0110030	Lemons	0.05	0.09	The submitted residue data are sufficient to support the intended SEU use of flupyradifurone. Risk for consumers unlikely.
0110040	Limes	0.05	0.09	
0110050	Mandarins	0.05	0.09	
0110990	Other citrus fruits	0.02*	0.09	The applicant proposes to extrapolate the MRL proposal from small citrus fruits to 'other citrus fruits'. Risk for consumers unlikely.
0120070	Macadamias	0.04	0.3	The submitted residue data are sufficient to support the authorised use of flupyradifurone in Australia. Risk for consumers unlikely.
0140010	Apricots	0.02*	0.3	The submitted data are sufficient to support the use of flupyradifurone in the USA. Risk for consumers unlikely.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0140020	Cherries (sweet)	0.02*	0.15	The submitted data are sufficient to support the intended NEU and SEU uses of flupyradifurone. The MRL proposal is based on the critical use (SEU). The data submitted in support of the import tolerance from the USA are not sufficient to derive an MRL proposal. Risk for consumers unlikely.
0140030	Peaches	0.02*	0.3	The submitted data are sufficient to support the use of flupyradifurone in the USA. Risk for consumers unlikely.
0140040	Plums	0.02*	0.3	The submitted data are sufficient to support the intended NEU, SEU uses and the use of flupyradifurone in the USA. The MRL proposal based on the critical use (USA). Risk for consumers unlikely.
0140990	Other stone fruits	0.02*	0.3	Proposal to extrapolate the highest MRL proposal in stone fruits to 'other stone fruits'.
0153010	Blackberries	0.07	No new proposal	The data submitted in support of the intended EU indoor use of flupyradifurone confirm the existing EU MRL.
0153020	Dewberries	0.02*	0.07	The submitted residue data are sufficient to support the intended EU indoor use of flupyradifurone. Risk for consumers unlikely.
0153030	Raspberries	0.07	No new proposal	The data submitted in support of the intended EU indoor use of flupyradifurone confirm the existing EU MRL.
0153990	Other cane fruits	0.02*	0.07	The applicant proposes to extrapolate MRL proposal to 'other cane fruits'.
0154010	Blueberries	0.05	No new proposal	The submitted residue data are sufficient to support the intended EU indoor use of flupyradifurone and to derive an MRL proposal of 0.01* mg/kg. The lowering of existing EU MRLs is not proposed.
0154020	Cranberries	0.02*	No new proposal	
0154030	Currants	0.02*	No new proposal	
0154040	Gooseberries	0.02*	No new proposal	
0154050	Rose hips	0.02*	No new proposal	
0154060	Mulberries	0.02*	No new proposal	
0154070	Azaroles	0.02*	No new proposal	
0154080	Elderberries	0.02*	No new proposal	
0154990	Other small fruits and berries	0.02*	No new proposal	
0243010	Chinese cabbages/pe-tsai	0.02*	0.5 or 0.7 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.5 mg/kg. The MRL proposal for EU uses reflecting direct treatment and residues taken up via roots would require an MRL of 0.7 mg/kg. Risk for consumers unlikely in both scenarios.
0243020	Kales	0.6	0.5 or 0.7 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.5 mg/kg (lower than the existing MRL). The MRL proposal for EU uses reflecting direct treatment and residues taken up via roots would require an MRL of 0.7 mg/kg. Risk for consumers unlikely in both scenarios.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0243990	Others (leafy brassica)	0.02*	0.5 or 0.7 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.5 mg/kg. The MRL proposal for EU uses reflecting direct treatment and residues taken up via roots would require an MRL of 0.7 mg/kg. Risk for consumers unlikely in both scenarios.
0256000	Herbs and edible flowers	0.3	No new proposal	The submitted data considering residues from the primary crop treatment and residues taken up via roots indicate no need to modify the existing EU MRL. Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.03 mg/kg.
0401050	Sunflower seeds	0.05	0.09 or 0.15 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.09 mg/kg. The MRL proposal for EU uses reflecting direct treatment and residues taken up via roots would require an MRL of 0.15 mg/kg. Risk for consumers unlikely in both scenarios.
0500010	Barley	0.8	No new proposal	The submitted data considering residues from the primary crop treatment and residues taken up via roots indicate no need to modify the existing EU MRL. Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.6 mg/kg.
0500030	Maize/corn	0.1	No new proposal or 0.15 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would result in an MRL of 0.05 mg/kg (lower than the existing MRL). The MRL proposal for EU uses reflecting direct treatment and residues taken up via roots would require an MRL of 0.15 mg/kg. Risk for consumers unlikely in both scenarios.
0500040	Common millet/ proso millet	0.3	No new proposal	The submitted data considering residues from the primary crop treatment and residues taken up via roots indicate no need to modify the existing EU MRL. Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 0.05 mg/kg.
0500050	Oat	0.3	0.6 or 0.8 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require a MRL of 0.6 mg/kg. The MRL proposal for US use reflecting direct treatment and residues taken up via roots would require an MRL of 0.8 mg/kg. Risk for consumers unlikely in both scenarios.
0500070	Rye	0.3	1 or 1.5 Further risk management consideration required	Direct treatment of the crop with flupyradifurone (primary crop treatment) would require an MRL of 1 mg/kg. The MRL proposal for US use reflecting direct treatment and residues taken up via roots would require an MRL of 1.5 mg/kg. Risk for consumers unlikely in both scenarios.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0500090	Wheat	1.5	No new proposal	The submitted data considering residues from the primary crop treatment and residues taken up via roots indicate no need to modify the existing EU MRL. Direct treatment of the crop with flupyradifurone (primary crop treatment) would require a MRL of 1 mg/kg.
1011020	Swine, fat	0.1	0.2	MRL proposal based on an updated calculation considering the EU livestock exposure. The MRL proposal considers livestock exposure to residues from the intake of primary and rotational crops. Risk for consumers unlikely.
1013020	Sheep, fat	0.15	0.3	MRL proposal based on an updated calculation considering the EU livestock exposure. The MRL proposal considers livestock exposure to residues from the intake of primary and rotational crops. Risk for consumers unlikely.
1014020	Goat, fat	0.15	0.3	MRL proposal based on an updated calculation considering the EU livestock exposure. The MRL proposal considers livestock exposure to residues from the intake of primary and rotational crops. Risk for consumers unlikely.
1016020	Poultry, fat	0.03	0.04	MRL proposal based on an updated calculation considering the EU livestock exposure. The MRL proposal considers livestock exposure to residues from the intake of primary and rotational crops. Risk for consumers unlikely.
1040000	Honey and other apiculture products	0.05*	No change proposed	The submitted residue data indicate that an MRL of 0.02 m/kg would be sufficient to cover the DFA residues in honey resulting from the use of flupyradifurone on primary crops. Additional (underdosed) trials indicated that the soil uptake of DFA in rotational crops may result in DFA residues at the range of < 0.007–0.012 mg/kg in honey; despite the possible underestimation, these data indicate the existing MRL value does not need to be changed. An analytical enforcement method validated at the LOQ of 0.007 mg/kg is available. The lowering of the current MRL value of 0.05 mg/kg is not proposed, but removal of the asterisk (*) could be considered. Further risk management consideration is required.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Flupyradifurone

LOQs (mg/kg) range from:	0.01	to:	6.0
Toxicological reference values			
ADI (mg/kg bw per day):	0.064	ARfD (mg/kg bw):	0.15
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2015	Year of evaluation:	2015

Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
69%	NL toddler	44.20	14%	Milk: Cattle	10%	Apples	7%	Table grapes	0.0%	69%
60%	DE child	38.48	12%	Apples	8%	Oranges	7%	Wheat	0.1%	60%
46%	GEMS/Food G08	29.57	6%	Wheat	6%	Olives for oil production	5%	Wine grapes	0.0%	46%
44%	GEMS/Food G10	28.14	8%	Soyabeans	6%	Wheat	3%	Lettuces	0.0%	44%
43%	GEMS/Food G07	27.81	7%	Wine grapes	7%	Wheat	4%	Soyabeans	0.0%	43%
43%	GEMS/Food G11	27.66	9%	Soyabeans	6%	Wheat	5%	Wine grapes	0.0%	43%
43%	GEMS/Food G06	27.32	11%	Wheat	5%	Table grapes	4%	Tomatoes	0.0%	43%
40%	GEMS/Food G15	25.40	7%	Wheat	5%	Wine grapes	4%	Soyabeans	0.0%	40%
39%	NL child	25.26	6%	Wheat	6%	Milk: Cattle	5%	Apples	0.0%	39%
37%	FR child 3 15 yr	23.37	7%	Wheat	6%	Oranges	5%	Milk: Cattle	0.1%	37%
35%	IE adult	22.13	6%	Wine grapes	4%	Wheat	2%	Basil and edible flowers	0.0%	35%
34%	ES child	21.49	7%	Wheat	6%	Olives for oil production	4%	Oranges	0.1%	34%
33%	PT general	21.06	12%	Wine grapes	6%	Wheat	2%	Olives for oil production		33%
32%	DK child	20.44	9%	Rye	7%	Wheat	3%	Milk: Cattle	0.0%	32%
30%	FR toddler 2 3 yr	18.97	7%	Milk: Cattle	5%	Wheat	3%	Apples	0.1%	30%
29%	DE women 14-50 yr	18.60	4%	Wine grapes	4%	Oranges	3%	Wheat	0.0%	29%
29%	RO general	18.44	8%	Wheat	8%	Wine grapes	3%	Milk: Cattle	0.0%	29%
29%	DE general	18.32	4%	Wine grapes	3%	Wheat	3%	Oranges	0.0%	29%
27%	UK toddler	17.59	6%	Wheat	5%	Milk: Cattle	4%	Oranges	0.2%	27%
27%	SE general	17.47	5%	Wheat	4%	Lettuces	3%	Milk: Cattle	0.3%	27%
27%	ES adult	17.45	5%	Lettuces	4%	Wheat	3%	Olives for oil production	0.0%	27%
27%	UK infant	17.08	9%	Milk: Cattle	4%	Wheat	2%	Oranges	0.2%	27%
26%	FR adult	16.72	11%	Wine grapes	3%	Wheat	1%	Other lettuce and other salad plants	0.0%	26%
25%	IT toddler	15.89	10%	Wheat	3%	Lettuces	2%	Tomatoes	0.0%	25%
22%	NL general	14.21	3%	Wheat	3%	Wine grapes	2%	Milk: Cattle	0.0%	22%
22%	IT adult	14.14	6%	Wheat	4%	Lettuces	1%	Other lettuce and other salad plants	0.0%	22%
19%	FI adult	12.00	9%	Coffee beans	1%	Wine grapes	1%	Lettuces	0.0%	19%
17%	UK vegetarian	11.04	4%	Wine grapes	3%	Wheat	2%	Beans	0.0%	17%
17%	FI 3 yr	10.78	3%	Oat	2%	Wheat	2%	Raspberries (red and yellow)	0.0%	17%
16%	FR infant	10.07	4%	Milk: Cattle	2%	Spinaches	2%	Carrots	0.0%	16%
15%	UK adult	9.67	5%	Wine grapes	3%	Wheat	1%	Lettuces	0.0%	15%
15%	DK adult	9.35	4%	Wine grapes	2%	Wheat	1%	Milk: Cattle	0.0%	15%
14%	FI 6 yr	8.69	2%	Wheat	1%	Oat	1%	Raspberries (red and yellow)	0.0%	14%
10%	LT adult	6.51	2%	Apples	2%	Rye	2%	Wheat	0.0%	10%
8%	PL general	5.39	2%	Apples	2%	Table grapes	1.0%	Tomatoes		8%
4%	IE child	2.88	2%	Wheat	0.8%	Milk: Cattle	0.3%	Apples	0.0%	4%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Flupyradifurone is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 4

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
152%	Lettuces	6/6	228	76%	Chards/beet leaves	6/6	113
146%	Table grapes	3/3	219	68%	Table grapes	3/3	102
117%	Kales	4/4	176	68%	Chinese cabbages/pe-tsai	4/4	101
106%	Oranges	3/1.2	159	51%	Kales	4/4	77
95%	Peaches	1.5/1.5	143	49%	Lettuces	6/6	73
90%	Spinaches	6/6	136	47%	Wine grapes	3/3	71
86%	Chinese cabbages/pe-tsai	4/4	129	33%	Blackberries	6/6	49
63%	Grapefruits	3/1.2	94	32%	Parsley	40/40	48
62%	Chards/beet leaves	6/6	94	25%	Oranges	3/1.2	37
55%	Pears	0.6/0.6	83	24%	Blueberries	4/4	36
43%	Apples	0.6/0.6	65	22%	Raspberries (red and yellow)	6/6	32
43%	Blackberries	6/6	64	21%	Red mustards	6/6	32
38%	Carrots	0.9/0.9	57	20%	Swedes/rutabagas	0.9/0.9	31
37%	Raspberries (red and	6/6	55	19%	Peaches	1.5/1.5	28
37%	Beans	3/3	55	18%	Aubergines/egg plants	1/1	27
36%	Sweet peppers/bell peppers	0.9/0.9	54	16%	Spinaches	6/6	24
34%	Chervil	40/40	52	14%	Grapefruits	3/1.2	21
34%	Beetroots	0.9/0.9	51	14%	Beetroots	0.9/0.9	21
33%	Celeriacs/turnip rooted	0.9/0.9	50	13%	Cherries (sweet)	2/2	20
31%	Swedes/rutabagas	0.9/0.9	47	13%	Beans	3/3	20
29%	Parsley	40/40	44	12%	Lentils	3/3	18
27%	Tomatoes	0.7/0.7	41	12%	Pears	0.6/0.6	18
26%	Cucumbers	0.6/0.6	39	12%	Carrots	0.9/0.9	18
24%	Mandarins	1.5/0.6	36	11%	Apples	0.6/0.6	17
23%	Apricots	1/1	35	11%	Cucumbers	0.6/0.6	17
23%	Cauliflowers	0.6/0.6	35	10%	Sweet peppers/bell peppers	0.9/0.9	15
22%	Chives	40/40	33	10%	Barley	3/3	15
22%	Parsnips	0.9/0.9	33	10%	Broccoli	0.6/0.6	14
22%	Turnips	0.9/0.9	32	9%	Courgettes	0.6/0.6	14
20%	Sage	40/40	30	9%	Cauliflowers	0.6/0.6	14
20%	Avocados	0.6/0.6	30	9%	Celery leaves	40/40	13
19%	Basil and edible flowers	40/40	29	8%	Parsnips	0.9/0.9	13
19%	Salsifies	0.9/0.9	28	8%	Head cabbages	0.3/0.3	13
19%	Courgettes	0.6/0.6	28	8%	Purslanes	6/6	11
19%	Wine grapes	3/3	28	8%	Lamb's lettuce/corn salads	6/6	11
17%	Aubergines/egg plants	1/1	25	7%	Tomatoes	0.7/0.7	11
17%	Broccoli	0.6/0.6	25	7%	Apricots	1/1	11
16%	Cherries (sweet)	2/2	24	7%	Mandarins	1.5/0.6	11
16%	Blueberries	4/4	24	7%	Celeriacs/turnip rooted	0.9/0.9	11
15%	Radishes	0.9/0.9	22	7%	Turnips	0.9/0.9	10
14%	Lemons	1.5/0.6	21	7%	Peas	3/3	10.0
13%	Lentils	3/3	20	6%	Salsifies	0.9/0.9	9.6
13%	Peas	3/3	20	6%	Radishes	0.9/0.9	9.4
13%	Celery leaves	40/40	19	6%	Parsley roots/Hamburg roots	0.9/0.9	9.2
12%	Milk: Cattle	0.15/0.15	19	6%	Quinces	0.6/0.6	9.1
12%	Watermelons	0.15/0.15	18	6%	Avocados	0.6/0.6	9.0
11%	Table olives	5/5	17	6%	Dewberries	6/6	8.7
11%	Table olives	5/5	17	6%	Jerusalem artichokes	0.9/0.9	8.4
11%	Plums	0.4/0.4	17	6%	Wheat	1/1	8.4
11%	Barley	3/3	17	6%	Soyabeans	1.5/1.5	8.3
11%	Roman rocket/rucola	6/6	16	5%	Sage	40/40	8.0
10%	Quinces	0.6/0.6	15	5%	Plums	0.4/0.4	7.1
10%	Wheat	1/1	14	5%	Roman rocket/rucola	6/6	7.1
9%	Head cabbages	0.3/0.3	13	5%	Chives	40/40	6.8
8%	Limes	1.5/0.6	12	4%	Horseradishes	0.9/0.9	6.6
7%	Dewberries	6/6	11	4%	Watermelons	0.15/0.15	6.1
6%	Sorghum	3/3	9.6	4%	Milk: Cattle	0.15/0.15	5.8
6%	Medlar	0.6/0.6	8.3	4%	Lemons	1.5/0.6	5.4
5%	Bovine: Liver	1/1	8.1	3%	Table olives	5/5	5.0

5%	Potatoes	0.05/0.05	7.7	3%	Basil and edible flowers	40/40	4.9
5%	Bovine: Edible offals (other	1/1	7.3	3%	Rye	1/1	4.9
4%	Strawberries	0.4/0.4	6.5	3%	Currants (red, black and	0.7/0.7	4.6
4%	Olives for oil production	5/5	6.4	3%	Limes	1.5/0.6	4.2
4%	Rye	1/1	6.3	3%	Medlar	0.6/0.6	4.1
4%	Beans (with pods)	0.5/0.5	5.7	3%	Tarragon	40/40	4.0
4%	Currants (red, black and	0.7/0.7	5.5	3%	Rosemary	40/40	4.0
3%	Kohlrabies	0.09/0.09	4.7	3%	Rosemary	40/40	4.0
3%	Gooseberries (green, red	0.7/0.7	4.1	3%	Rosemary	40/40	4.0
3%	Peas (with pods)	0.5/0.5	4.1	3%	Rosemary	40/40	4.0
3%	Parsley roots/Hamburg	0.9/0.9	4.0	3%	Olives for oil production	5/5	3.9
3%	Bovine: Kidney	1/1	3.8	3%	Beans (with pods)	0.5/0.5	3.9
2%	Milk: Goat	0.15/0.15	3.6	2%	Strawberries	0.4/0.4	3.7
2%	Soyabeans	1.5/1.5	3.5	2%	Gherkins	0.6/0.6	3.6
2%	Oat	3/3	3.3	2%	Bovine: Edible offals (other	1/1	3.3
2%	Peas (without pods)	0.4/0.4	3.3	2%	Chervil	40/40	3.2
2%	Beans (without pods)	0.4/0.4	3.2	2%	Gooseberries (green, red	0.7/0.7	3.2
2%	Cranberries	0.7/0.7	3.1	2%	Sheep: Liver	1/1	2.8
2%	Escaroles/broad-leaved	0.07/0.07	2.8	2%	Milk: Goat	0.15/0.15	2.8
2%	Witloofs/Belgian endives	0.07/0.07	2.8	2%	Cress and other sprouts and	6/6	2.3
2%	Thyme	40/40	2.4	2%	Milk: Sheep	0.15/0.15	2.3
2%	Lentils (fresh)	0.4/0.4	2.3	1%	Peas (without pods)	0.4/0.4	2.1
1%	Sweet corn	0.05/0.05	2.2	1%	Bovine: Kidney	1/1	2.1
1%	Bovine: Muscle/meat	0.3/0.3	2.2	1%	Oat	3/3	1.9
1%	Equine: Muscle/meat	0.3/0.3	1.8	1%	HOPS (dried)	10/10	1.8
1%	Cress and other sprouts	6/6	1.8	1%	Bovine: Muscle	0.3/0.3	1.7
1%	Gherkins	0.6/0.6	1.7	1%	Peas (with pods)	0.5/0.5	1.7
1%	Sheep: Muscle/meat	0.3/0.3	1.6	1%	Beans (without pods)	0.4/0.4	1.6
1%	Yams	0.05/0.05	1.6	1%	Rose hips	0.7/0.7	1.5
0.8%	Rosemary	40/40	1.2	1.0%	Potatoes	0.05/0.05	1.5
0.5%	Brussels sprouts	0.09/0.09	0.76	1.0%	Equine: Muscle/meat	0.3/0.3	1.4
0.5%	Coffee beans	1/1	0.70	0.9%	Sheep: Muscle/meat	0.3/0.3	1.4
0.4%	Azarole/Mediteranean	0.7/0.7	0.63	0.9%	Yams	0.05/0.05	1.4
0.4%	Milk: Sheep	0.15/0.15	0.54	0.9%	Escaroles/broad-leaved	0.07/0.07	1.4
0.3%	Swine: Edible offals (other	0.15/0.15	0.45	0.9%	Lentils (fresh)	0.4/0.4	1.3
0.3%	HOPS (dried)	10/10	0.42	0.9%	Witloofs/Belgian endives	0.07/0.07	1.3
0.3%	Bovine: Fat tissue	0.2/0.2	0.42	0.8%	Kohlrabies	0.09/0.09	1.3
0.3%	Rapeseeds/canola seeds	0.3/0.3	0.41	0.7%	Sweet potatoes	0.05/0.05	1.0
0.3%	Laurel/bay leaves	40/40	0.40	0.6%	Sorghum	3/3	0.90
0.3%	Cassava roots/manioc	0.05/0.05	0.40	0.5%	Sweet corn	0.05/0.05	0.80
0.2%	Celeries	0.01/0.01	0.37	0.5%	Cranberries	0.7/0.7	0.80
0.2%	Horseradishes	0.9/0.9	0.37	0.5%	Coffee beans	1/1	0.75
0.2%	Swine: Muscle/meat	0.03/0.03	0.36	0.5%	Sheep: Edible offals (other	1/1	0.68
0.2%	Mustard seeds	0.3/0.3	0.31	0.4%	Brussels sprouts	0.09/0.09	0.54
0.2%	Coconuts	0.02/0.02	0.29	0.3%	Goat: Muscle	0.3/0.3	0.47
0.2%	Sweet potatoes	0.05/0.05	0.26	0.3%	Swine: Edible offals (other	0.15/0.15	0.39
0.1%	Sunflower seeds	0.07/0.07	0.22	0.2%	Swine: Kidney	0.15/0.15	0.33
0.1%	Swine: Kidney	0.15/0.15	0.19	0.1%	Mustard seeds	0.3/0.3	0.21
0.1%	Poultry: Muscle/meat	0.01/0.01	0.17	0.1%	Bovine: Fat tissue	0.2/0.2	0.19
0.1%	Cocoa beans	0.05/0.05	0.16	0.1%	Coconuts	0.02/0.02	0.17
0.09%	Maize/corn	0.02/0.02	0.13	0.1%	Celeries	0.01/0.01	0.16
0.08%	Eggs: Chicken	0.01/0.01	0.12	0.1%	Rapeseeds/canola seeds	0.3/0.3	0.16
0.08%	Swine: Liver	0.1/0.1	0.12	0.1%	Cassava roots/manioc	0.05/0.05	0.15
0.08%	Peanuts/groundnuts	0.04/0.04	0.12	0.10%	Swine: Muscle/meat	0.03/0.03	0.15
0.08%	Pistachios	0.02/0.02	0.12	0.09%	Swine: Liver	0.1/0.1	0.14
0.06%	Chestnuts	0.02/0.02	0.08	0.08%	Poultry: Muscle	0.01/0.01	0.12
0.04%	Walnuts	0.02/0.02	0.07	0.07%	Sheep: Kidney	1/1	0.10
0.04%	Hazelnuts/cobnuts	0.02/0.02	0.07	0.06%	Peanuts/groundnuts	0.04/0.04	0.09
0.04%	Almonds	0.02/0.02	0.06	0.06%	Chestnuts	0.02/0.02	0.09
0.04%	Pecans	0.02/0.02	0.06	0.06%	Cocoa beans	0.05/0.05	0.08
0.03%	Cashew nuts	0.02/0.02	0.05	0.06%	Watercress	0.07/0.07	0.08
0.02%	Swine: Fat tissue	0.02/0.02	0.03	0.05%	Sunflower seeds	0.07/0.07	0.07
0.02%	Watercress	0.07/0.07	0.03	0.04%	Pistachios	0.02/0.02	0.05
0.02%	Common millet/proso millet	0.02/0.02	0.03	0.03%	Poultry: Liver	0.01/0.01	0.05
0.01%	Brazil nuts	0.02/0.02	0.02	0.03%	Pecans	0.02/0.02	0.05
0.01%	Poultry: Liver	0.01/0.01	0.01	0.03%	Walnuts	0.02/0.02	0.04
0.01%	Macadamia	0.02/0.02	0.01	0.03%	Maize/corn	0.02/0.02	0.04
0.01%	Grape leaves and similar	0.03/0.03	0.01	0.03%	Eggs: Chicken	0.01/0.01	0.04
0.00%	Pine nut kernels	0.02/0.02	0.01	0.03%	Macadamia	0.02/0.02	0.04
0.00%	Poultry: Fat tissue	0.01/0.01	0.00	0.03%	Swine: Fat tissue	0.02/0.02	0.04
				0.02%	Cashew nuts	0.02/0.02	0.03
				0.02%	Almonds	0.02/0.02	0.03
				0.02%	Grape leaves and similar	0.03/0.03	0.03
				0.02%	Hazelnuts/cobnuts	0.02/0.02	0.02
				0.01%	Pine nut kernels	0.02/0.02	0.02
				0.01%	Common millet/proso millet	0.02/0.02	0.02
				0.01%	Eggs: Quail	0.01/0.01	0.01
				0.01%	Brazil nuts	0.02/0.02	0.01
				0.01%	Poultry: Kidney	0.01/0.01	0.01
				0.00%	Eggs: Goose	0.01/0.01	0.01
				0.00%	Poultry: Fat tissue	0.01/0.01	0.00

Expand/collapse list	
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 4	

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			1	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
124%	Chards/beet leaves/boiled	6/6	187	50%	Chards/beet leaves/boiled	6/6	75
87%	Wine grapes/juice	3/3	131	42%	Wine grapes/juice	3/3	62
74%	Kales/boiled	4/4	110	33%	Spinaches/frozen; boiled	6/6	50
56%	Spinaches/frozen; boiled	6/6	83	23%	Beetroots/boiled	0.9/0.9	35
47%	Raspberries/juice	6/6	70	22%	Grapefruits/juice	3/3	33
32%	Broccoli/boiled	0.6/0.6	47	19%	Wine grapes/wine	3/3	28
30%	Turnips/boiled	0.9/0.9	46	17%	Cauliflowers/boiled	0.6/0.6	25
30%	Parsnips/boiled	0.9/0.9	46	16%	Purslanes/boiled	6/6	25
28%	Cauliflowers/boiled	0.6/0.6	42	14%	Barley/beer	3/0.6	22
27%	Beetroots/boiled	0.9/0.9	40	14%	Beans/canned	3/3	21
26%	Peaches/canned	1.5/1.5	39	13%	Apples/juice	0.6/0.6	20
22%	Apples/juice	0.6/0.6	32	13%	Parsnips/boiled	0.9/0.9	19
22%	Carrots/juice	0.9/0.9	32	12%	Table grapes/raisins	3/14.1	17
18%	Oranges/juice	3/0.51	27	11%	Turnips/boiled	0.9/0.9	17
17%	Peaches/juice	1.5/1.5	25	11%	Celeriacs/boiled	0.9/0.9	16
Expand/collapse list							

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 4 commodities.

For processed commodities, the toxicological reference value was exceeded in one or several cases.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Flupyradifurone

LOQs (mg/kg) range from:	0.01	to:	6.0
Toxicological reference values			
ADI (mg/kg bw per day):	0.064	ARfD (mg/kg bw):	0.15
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2015	Year of evaluation:	2015

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
54%	NL toddler	34.86	32%	Milk: Cattle	5%	Apples	4%	Wheat	0.0%	54%
32%	DE child	20.17	10%	Milk: Cattle	5%	Apples	4%	Wheat	0.0%	32%
31%	UK infant	19.56	21%	Milk: Cattle	3%	Wheat	2%	Bovine: Muscle/meat	0.0%	31%
28%	NL child	17.97	13%	Milk: Cattle	4%	Wheat	3%	Apples	0.0%	28%
27%	FR toddler 2 3 yr	17.25	16%	Milk: Cattle	3%	Wheat	2%	Bovine: Muscle/meat	0.0%	27%
26%	FR child 3 15 yr	16.89	12%	Milk: Cattle	5%	Wheat	3%	Bovine: Muscle/meat	0.0%	26%
24%	DK child	15.37	7%	Milk: Cattle	6%	Rye	4%	Wheat	0.0%	24%
23%	SE general	14.49	8%	Bovine: Muscle/meat	7%	Milk: Cattle	3%	Wheat	0.0%	23%
22%	UK toddler	14.23	11%	Milk: Cattle	4%	Wheat	2%	Bovine: Muscle/meat	0.0%	22%
20%	ES child	12.59	7%	Milk: Cattle	5%	Wheat	2%	Bovine: Muscle/meat	0.0%	20%
19%	GEMS/Food G07	12.04	4%	Wheat	3%	Milk: Cattle	2%	Bovine: Muscle/meat	0.0%	19%
18%	GEMS/Food G15	11.65	5%	Wheat	4%	Milk: Cattle	1.0%	Barley	0.0%	18%
18%	GEMS/Food G08	11.52	4%	Wheat	3%	Milk: Cattle	1%	Barley	0.0%	18%
18%	RO general	11.39	6%	Milk: Cattle	5%	Wheat	2%	Wine grapes		18%
18%	GEMS/Food G10	11.33	4%	Wheat	3%	Milk: Cattle	2%	Bovine: Muscle/meat	0.0%	18%
18%	GEMS/Food G11	11.24	4%	Milk: Cattle	4%	Wheat	1%	Bovine: Muscle/meat	0.0%	18%
17%	GEMS/Food G06	10.72	7%	Wheat	1%	Milk: Cattle	1%	Table grapes	0.0%	17%
16%	DE general	10.16	7%	Milk: Cattle	2%	Wheat	1%	Apples	0.0%	16%
16%	DE women 14-50 yr	10.14	7%	Milk: Cattle	2%	Wheat	1%	Apples	0.0%	16%
15%	IE adult	9.36	2%	Wheat	2%	Milk: Cattle	1%	Wine grapes	0.0%	15%
14%	FR infant	8.79	9%	Milk: Cattle	0.8%	Wheat	0.7%	Apples	0.0%	14%
13%	NL general	8.28	5%	Milk: Cattle	2%	Wheat	1%	Bovine: Muscle/meat	0.0%	13%
12%	ES adult	7.55	3%	Milk: Cattle	2%	Wheat	1%	Bovine: Muscle/meat	0.0%	12%
11%	FR adult	7.27	2%	Milk: Cattle	2%	Wheat	2%	Wine grapes	0.0%	11%
10%	IT toddler	6.68	7%	Wheat	0.5%	Lettuces	0.4%	Apples	0.0%	10%
10%	PT general	6.61	4%	Wheat	2%	Wine grapes	0.5%	Potatoes		10%
9%	DK adult	5.61	3%	Milk: Cattle	1%	Wheat	0.9%	Bovine: Muscle/meat	0.0%	9%
8%	IT adult	5.20	4%	Wheat	0.7%	Lettuces	0.4%	Other herbs	0.0%	8%
8%	UK adult	4.82	2%	Wheat	2%	Milk: Cattle	1%	Bovine: Muscle/meat	0.0%	8%
7%	LT adult	4.71	2%	Milk: Cattle	1%	Rye	1%	Wheat		7%
7%	UK vegetarian	4.57	2%	Wheat	2%	Milk: Cattle	0.8%	Wine grapes	0.0%	7%
6%	FI 3 yr	3.73	1%	Wheat	0.7%	Oat	0.7%	Rye	0.0%	6%
5%	FI adult	3.29	2%	Coffee beans	0.7%	Rye	0.3%	Wheat	0.0%	5%
5%	FI 6 yr	3.01	1.0%	Wheat	0.6%	Rye	0.4%	Oat	0.0%	5%
4%	IE child	2.54	2%	Milk: Cattle	1%	Wheat	0.1%	Apples	0.0%	4%
3%	PL general	1.83	0.9%	Apples	0.3%	Potatoes	0.3%	Table grapes		3%

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Flupyradifurone is unlikely to present a public health concern.

DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
95%	Table grapes	3/1.95	142	44%	Table grapes	3/1.95	66
81%	Lettuces	6/3.2	122	40%	Chards/beet leaves	6/3.2	60
78%	Oranges	3/0.88	117	37%	Chinese cabbages/pe-tsai	4/2.2	56
70%	Peaches	1.5/1.1	105	32%	Aubergines/egg plants	1/1.8	49
65%	Sweet peppers/bell peppers	0.9/1.65	98	31%	Wine grapes	3/1.95	46
65%	Kales	4/2.2	97	28%	Kales	4/2.2	42
64%	Pears	0.6/0.69	96	26%	Lettuces	6/3.2	39
50%	Apples	0.6/0.69	74	24%	Blackberries	6/4.3	35
48%	Spinaches	6/3.2	72	18%	Oranges	3/0.88	27
47%	Chinese cabbages/pe-tsai	4/2.2	71	18%	Sweet peppers/bell peppers	0.9/1.65	27
46%	Grapefruits	3/0.88	69	16%	Blueberries	4/2.59	24
33%	Chards/beet leaves	6/3.2	50	15%	Swedes/rutabagas	0.9/0.68	23
32%	Cauliflowers	0.6/0.82	48	15%	Raspberries (red and yellow)	6/4.3	23
31%	Blackberries	6/4.3	46	15%	Parsley	40/18.2	22
30%	Aubergines/egg plants	1/1.8	45	14%	Pears	0.6/0.69	21
29%	Cucumbers	0.6/0.66	43	14%	Peaches	1.5/1.1	21
29%	Carrots	0.9/0.68	43	13%	Broccoli	0.6/0.82	20
28%	Milk: Cattle	0.15/0.34	42	13%	Apples	0.6/0.69	19
26%	Raspberries (red and	6/4.3	40	13%	Cauliflowers	0.6/0.82	19
26%	Beetroots	0.9/0.68	39	12%	Cucumbers	0.6/0.66	18
26%	Apricots	1/1.1	38	11%	Red mustards	6/3.2	17
25%	Celeriacs/turnip rooted	0.9/0.68	38	10%	Grapefruits	3/0.88	16
23%	Swedes/rutabagas	0.9/0.68	35	10%	Beetroots	0.9/0.68	16
23%	Broccoli	0.6/0.82	34	10%	Courgettes	0.6/0.66	15
20%	Courgettes	0.6/0.66	31	9%	Carrots	0.9/0.68	13
18%	Tomatoes	0.7/0.47	27	9%	Milk: Cattle	0.15/0.34	13
17%	Plums	0.4/0.59	25	9%	Spinaches	6/3.2	13
16%	Parsnips	0.9/0.68	25	8%	Head cabbages	0.3/0.29	12
16%	Turnips	0.9/0.68	24	8%	Apricots	1/1.1	12
16%	Chervil	40/18.2	24	7%	Plums	0.4/0.59	11
16%	Mandarins	1.5/0.4	23	7%	Quinces	0.6/0.69	10
15%	Watermelons	0.15/0.19	23	6%	Cherries (sweet)	2/0.96	9.6
14%	Salsifies	0.9/0.68	21	6%	Parsnips	0.9/0.68	9.6
13%	Parsley	40/18.2	20	5%	Celeriacs/turnip rooted	0.9/0.68	8.1
12%	Avocados	0.6/0.36	18	5%	Bovine: Edible offals (other	1/2.39	7.9
12%	Wine grapes	3/1.95	18	5%	Watermelons	0.15/0.19	7.7
12%	Bovine: Edible offals (other	1/2.39	17	5%	Bovine: Liver	1/1.91	7.6
11%	Quinces	0.6/0.69	17	5%	Turnips	0.9/0.68	7.6
11%	Radishes	0.9/0.68	17	5%	Tomatoes	0.7/0.47	7.5
10%	Blueberries	4/2.59	15	5%	Salsifies	0.9/0.68	7.3
10%	Bovine: Liver	1/1.91	15	5%	Mandarins	1.5/0.4	7.1
10%	Potatoes	0.05/0.1	15	5%	Radishes	0.9/0.68	7.1
10%	Chives	40/18.2	15	5%	Parsley roots/Hamburg roots	0.9/0.68	7.0
10%	Beans	3/0.79	14	5%	Bovine: Muscle	0.3/1.22	7.0
9%	Sage	40/18.2	14	4%	Jerusalem artichokes	0.9/0.68	6.4
9%	Basil and edible flowers	40/18.2	13	4%	Dewberries	6/4.3	6.2
9%	Kohlrabies	0.09/0.25	13	4%	Purslanes	6/3.2	6.1
9%	Head cabbages	0.3/0.29	13	4%	Lamb's lettuce/corn salads	6/3.2	6.0
8%	Cherries (sweet)	2/0.96	12	4%	Celery leaves	40/18.2	5.9
7%	Table olives	5/3.3	11	4%	Equine: Muscle/meat	0.3/1.22	5.9
7%	Sweet corn	0.05/0.25	11	4%	Wheat	1/0.65	5.5
7%	Lemons	1.5/0.29	10	4%	Avocados	0.6/0.36	5.4
6%	Medlar	0.6/0.69	9.5	3%	Beans	3/0.79	5.2
6%	Wheat	1/0.65	9.4	3%	Bovine: Kidney	1/2.39	5.0
6%	Bovine: Kidney	1/2.39	9.0	3%	Horseradishes	0.9/0.68	5.0
6%	Lamb's lettuce/corn salads	6/3.2	9.0	3%	Lentils	3/0.79	4.9
6%	Bovine: Muscle/meat	0.3/1.22	8.8	3%	Medlar	0.6/0.69	4.7
6%	Celery leaves	40/18.2	8.7	3%	Poultry: Muscle	0.01/0.39	4.6
6%	Roman rocket/rucola	6/3.2	8.6	3%	Gherkins	0.6/0.66	4.0

5%	Dewberries	6/4.3	7.6	3%	Sweet corn	0.05/0.25	4.0
5%	Equine: Muscle/meat	0.3/1.22	7.3	3%	Sheep: Muscle/meat	0.3/0.84	4.0
4%	Poultry: Muscle/meat	0.01/0.39	6.6	3%	Barley	3/0.81	3.9
4%	Limes	1.5/0.29	5.9	3%	Sheep: Liver	1/1.39	3.9
4%	Lentils	3/0.79	5.3	3%	Roman rocket/rucola	6/3.2	3.8
3%	Peas	3/0.79	5.2	2%	Sage	40/18.2	3.6
3%	Swine: Muscle/meat	0.03/0.41	5.0	2%	Kohlrabies	0.09/0.25	3.5
3%	Sheep: Muscle/meat	0.3/0.84	4.6	2%	Milk: Goat	0.15/0.18	3.3
3%	Barley	3/0.81	4.5	2%	Table olives	5/3.3	3.3
3%	Milk: Goat	0.15/0.18	4.4	2%	Poultry: Liver	0.01/0.69	3.3
3%	Beans (with pods)	0.5/0.37	4.2	2%	Rye	1/0.65	3.2
3%	Rye	1/0.65	4.1	2%	Chives	40/18.2	3.1
3%	Eggs: Chicken	0.01/0.31	3.8	2%	Potatoes	0.05/0.1	3.0
2%	Strawberries	0.4/0.22	3.6	2%	Beans (with pods)	0.5/0.37	2.9
2%	Honey and other apiculture	2/0.92	3.3	2%	Yams	0.05/0.1	2.8
2%	Yams	0.05/0.1	3.1	2%	Milk: Sheep	0.15/0.18	2.7
2%	Bovine: Fat tissue	0.2/1.48	3.1	2%	Peas	3/0.79	2.6
2%	Currants (red, black and	0.7/0.39	3.1	2%	Lemons	1.5/0.29	2.6
2%	Parsley roots/Hamburg	0.9/0.68	3.0	2%	Currants (red, black and	0.7/0.39	2.6
2%	Peas (with pods)	0.5/0.37	3.0	1%	Basil and edible flowers	40/18.2	2.2
2%	Peas (without pods)	0.4/0.36	3.0	1%	Sweet potatoes	0.05/0.1	2.1
2%	Beans (without pods)	0.4/0.36	2.8	1%	Limes	1.5/0.29	2.1
2%	Escaroles/broad-leaved	0.07/0.07	2.8	1%	Strawberries	0.4/0.22	2.1
2%	Brussels sprouts	0.09/0.31	2.6	1%	Swine: Muscle/meat	0.03/0.41	2.0
2%	Witloofs/Belgian endives	0.07/0.06	2.4	1%	Peas (without pods)	0.4/0.36	1.9
2%	Gooseberries (green, red	0.7/0.39	2.3	1%	Brussels sprouts	0.09/0.31	1.9
1%	Lentils (fresh)	0.4/0.36	2.1	1%	Rosemary	40/18.2	1.8
1%	Sorghum	3/0.64	2.1	1%	Rosemary	40/18.2	1.8
1%	Swine: Edible offals (other	0.15/0.63	1.9	1%	Rosemary	40/18.2	1.8
1%	Gherkins	0.6/0.66	1.9	1%	Rosemary	40/18.2	1.8
1%	Cranberries	0.7/0.39	1.7	1%	Gooseberries (green, red	0.7/0.39	1.8
1%	Coconuts	0.02/0.11	1.6	1%	Swine: Edible offals (other	0.15/0.63	1.6
0.7%	Thyme	40/18.2	1.1	1.0%	Chervil	40/18.2	1.5
0.6%	Swine: Fat tissue	0.02/0.57	0.97	1.0%	Bovine: Fat tissue	0.2/1.48	1.4
0.6%	Cress and other sprouts	6/3.2	0.94	0.9%	Beans (without pods)	0.4/0.36	1.4
0.6%	Oat	3/0.81	0.90	0.9%	Escaroles/broad-leaved	0.07/0.07	1.4
0.5%	Swine: Kidney	0.15/0.63	0.80	0.9%	Swine: Kidney	0.15/0.63	1.4
0.5%	Cassava roots/manioc	0.05/0.1	0.80	0.9%	Eggs: Chicken	0.01/0.31	1.3
0.5%	Poultry: Liver	0.01/0.69	0.76	0.9%	Goat: Muscle	0.3/0.84	1.3
0.4%	Milk: Sheep	0.15/0.18	0.64	0.8%	Honey and other apiculture	2/0.92	1.3
0.4%	Olives for oil production	5/0.5	0.64	0.8%	Peas (with pods)	0.5/0.37	1.3
0.4%	Pistachios	0.02/0.11	0.64	0.8%	Cress and other sprouts and	6/3.2	1.2
0.4%	Rosemary	40/18.2	0.55	0.8%	Lentils (fresh)	0.4/0.36	1.2
0.4%	Sweet potatoes	0.05/0.1	0.53	0.8%	Sheep: Edible offals (other	1/1.72	1.2
0.3%	Swine: Liver	0.1/0.38	0.46	0.8%	Swine: Fat tissue	0.02/0.57	1.2
0.3%	Chestnuts	0.02/0.11	0.46	0.7%	Witloofs/Belgian endives	0.07/0.06	1.1
0.3%	Maize/corn	0.02/0.06	0.40	0.6%	Coconuts	0.02/0.11	0.95
0.2%	Celeries	0.01/0.01	0.37	0.6%	Poultry: Kidney	0.01/0.69	0.89
0.2%	Walnuts	0.02/0.11	0.37	0.6%	Rose hips	0.7/0.39	0.86
0.2%	Hazelnuts/cobnuts	0.02/0.11	0.36	0.6%	Soyabeans	1.5/0.15	0.83
0.2%	Cocoa beans	0.05/0.11	0.35	0.5%	Macadamia	0.02/0.37	0.78
0.2%	Azarole/Mediteranean	0.7/0.39	0.35	0.4%	HOPS (dried)	10/3.55	0.65
0.2%	Sunflower seeds	0.07/0.11	0.35	0.4%	Swine: Liver	0.1/0.38	0.53
0.2%	Soyabeans	1.5/0.15	0.35	0.3%	Oat	3/0.81	0.52
0.2%	Almonds	0.02/0.11	0.32	0.3%	Chestnuts	0.02/0.11	0.50
0.2%	Rapeseeds/canola seeds	0.3/0.23	0.32	0.3%	Cranberries	0.7/0.39	0.44
0.2%	Pecans	0.02/0.11	0.30	0.3%	Eggs: Quail	0.01/0.31	0.43
0.2%	Cashew nuts	0.02/0.11	0.28	0.3%	Olives for oil production	5/0.5	0.39
0.2%	Horseradishes	0.9/0.68	0.28	0.2%	Cassava roots/manioc	0.05/0.1	0.30
0.2%	Mustard seeds	0.3/0.23	0.23	0.2%	Pistachios	0.02/0.11	0.29
0.1%	Macadamia	0.02/0.37	0.20	0.2%	Pecans	0.02/0.11	0.25
0.1%	Laurel/bay leaves	40/18.2	0.18	0.2%	Walnuts	0.02/0.11	0.24
0.1%	Peanuts/groundnuts	0.04/0.06	0.17	0.1%	Sorghum	3/0.64	0.19
0.1%	Coffee beans	1/0.24	0.17	0.1%	Cashew nuts	0.02/0.11	0.19
0.10%	HOPS (dried)	10/3.55	0.15	0.1%	Cocoa beans	0.05/0.11	0.19
0.06%	Brazil nuts	0.02/0.11	0.10	0.1%	Coffee beans	1/0.24	0.18
0.06%	Common millet/proso millet	0.02/0.06	0.08	0.1%	Sheep: Kidney	1/1.72	0.17
0.02%	Pine nut kernels	0.02/0.11	0.04	0.1%	Mustard seeds	0.3/0.23	0.16
0.02%	Watercress	0.07/0.06	0.03	0.1%	Celeries	0.01/0.01	0.16
0.01%	Poultry: Fat tissue	0.01/0.1	0.01	0.1%	Almonds	0.02/0.11	0.16
0.01%	Grape leaves and similar	0.03/0.03	0.01	0.1%	Eggs: Goose	0.01/0.31	0.16
				0.09%	Peanuts/groundnuts	0.04/0.06	0.14
				0.09%	Hazelnuts/cobnuts	0.02/0.11	0.13
				0.09%	Maize/corn	0.02/0.06	0.13
				0.08%	Rapeseeds/canola seeds	0.3/0.23	0.12
				0.07%	Pine nut kernels	0.02/0.11	0.11
				0.07%	Pine nut kernels	0.02/0.11	0.11
				0.05%	Brazil nuts	0.02/0.11	0.08
				0.05%	Watercress	0.07/0.06	0.07
				0.04%	Common millet/proso millet	0.02/0.06	0.05
				0.02%	Poultry: Fat tissue	0.01/0.1	0.03
				0.02%	Grape leaves and similar	0.03/0.03	0.03

Expand/collapse list	
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)	

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
66%	Chards/beet leaves/boiled	6/3.2	100	27%	Chards/beet leaves/boiled	6/3.2	40
43%	Broccoli/boiled	0.6/0.82	65	23%	Cauliflowers/boiled	0.6/0.82	34
40%	Kales/boiled	4/2.2	61	18%	Spinaches/frozen; boiled	6/3.2	26
38%	Cauliflowers/boiled	0.6/0.82	57	18%	Beetroots/boiled	0.9/0.68	26
30%	Spinaches/frozen; boiled	6/3.2	45	13%	Broccoli/boiled	0.6/0.82	20
23%	Turnips/boiled	0.9/0.68	34	12%	Wine grapes/wine	3/1.95	18
23%	Parsnips/boiled	0.9/0.68	34	10%	Courgettes/boiled	0.6/0.66	15
20%	Beetroots/boiled	0.9/0.68	30	10%	Parsnips/boiled	0.9/0.68	14
19%	Peaches/canned	1.5/1.1	29	9%	Purslanes/boiled	6/3.2	13
18%	Wine grapes/juice	3/0.62	27	9%	Turnips/boiled	0.9/0.68	13
16%	Courgettes/boiled	0.6/0.66	23	9%	Wine grapes/juice	3/0.62	13
12%	Oranges/juice	3/0.34	18	8%	Celeriacs/boiled	0.9/0.68	12
12%	Salsifies/boiled	0.9/0.68	18	7%	Table grapes/raisins	3/9.17	11
12%	Jerusalem artichokes/boiled	0.9/0.68	17	6%	Apples/juice	0.6/0.28	9.3
11%	Raspberries/juice	6/1.4	16	6%	Peaches/canned	1.5/1.1	9.0
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Flupyradifurone is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Flupyradifurone			
LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.064	ARfD (mg/kg bw):	0.15
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2015	Year of evaluation:	2015

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
17%	GEMS/Food G06	10.89	5%	Wheat	3%	Tomatoes	1%	Watermelons		17%
15%	NL toddler	9.76	5%	Maize/corn	3%	Wheat	2%	Potatoes		15%
11%	DK child	7.14	4%	Rye	3%	Wheat	2%	Cucumbers		11%
11%	IE adult	7.06	2%	Wheat	1%	Peas	1%	Sweet potatoes		11%
11%	RO general	6.83	3%	Wheat	2%	Tomatoes	1%	Potatoes		11%
10%	GEMS/Food G15	6.69	3%	Wheat	1%	Potatoes	1%	Tomatoes		10%
10%	GEMS/Food G10	6.57	3%	Wheat	1%	Tomatoes	1%	Potatoes		10%
10%	UK toddler	6.46	4%	Beans	3%	Wheat	1%	Potatoes		10%
10%	GEMS/Food G08	6.16	3%	Wheat	1%	Potatoes	1%	Tomatoes		10%
10%	FR child 3 15 yr	6.09	3%	Wheat	0.9%	Lentils	0.9%	Beans		10%
9%	IT toddler	5.89	4%	Wheat	1%	Tomatoes	1%	Other cereals		9%
9%	PT general	5.72	3%	Wheat	2%	Potatoes	0.9%	Tomatoes		9%
9%	GEMS/Food G07	5.65	3%	Wheat	1%	Potatoes	1%	Tomatoes		9%
9%	ES child	5.61	3%	Wheat	1%	Lentils	1.0%	Tomatoes		9%
9%	UK infant	5.57	2%	Beans	2%	Wheat	1%	Potatoes		9%
8%	GEMS/Food G11	5.28	2%	Wheat	1%	Potatoes	0.9%	Tomatoes		8%
8%	DE child	5.26	3%	Wheat	1.0%	Tomatoes	0.9%	Potatoes		8%
7%	SE general	4.78	2%	Wheat	1%	Potatoes	0.7%	Tomatoes		7%
7%	NL child	4.60	3%	Wheat	1%	Potatoes	0.5%	Tomatoes		7%
7%	FR toddler 2 3 yr	4.53	2%	Wheat	1%	Beans (with pods)	0.7%	Potatoes		7%
7%	FI 3 yr	4.39	2%	Potatoes	1.0%	Cucumbers	0.8%	Wheat		7%
7%	IT adult	4.17	3%	Wheat	1%	Tomatoes	0.5%	Other cereals		7%
6%	FI 6 yr	3.77	1%	Potatoes	0.7%	Cucumbers	0.7%	Wheat		6%
6%	UK vegetarian	3.76	2%	Beans	1%	Wheat	0.6%	Tomatoes		6%
6%	ES adult	3.59	2%	Wheat	0.8%	Tomatoes	0.5%	Lentils		6%
5%	NL general	3.07	1%	Wheat	0.9%	Potatoes	0.4%	Tomatoes		5%
5%	FR adult	3.00	1%	Wheat	0.6%	Beans	0.4%	Tomatoes		5%
4%	LT adult	2.81	1%	Potatoes	0.7%	Rye	0.7%	Wheat		4%
4%	DE general	2.78	1%	Wheat	0.6%	Tomatoes	0.4%	Potatoes		4%
4%	DE women 14-50 yr	2.77	1%	Wheat	0.7%	Tomatoes	0.4%	Potatoes		4%
4%	UK adult	2.68	1%	Wheat	1%	Beans	0.5%	Potatoes		4%
4%	FR infant	2.42	0.7%	Beans (with pods)	0.7%	Potatoes	0.5%	Wheat		4%
3%	DK adult	2.01	0.8%	Wheat	0.5%	Tomatoes	0.5%	Potatoes		3%
3%	PL general	1.98	1%	Potatoes	0.9%	Tomatoes	0.2%	Head cabbages		3%
3%	FI adult	1.83	0.5%	Tomatoes	0.5%	Rye	0.4%	Potatoes		3%
2%	IE child	1.03	0.8%	Wheat	0.2%	Potatoes	0.2%	Rice		2%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Flupyradifurone is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
86%	Melons	0/0.85	129	23%	Watermelons	0/0.85	35
69%	Watermelons	0/0.85	104	22%	Melons	0/0.85	33
55%	Potatoes	0/0.54	83	16%	Cucumbers	0/0.85	24
39%	Beans	0/3.19	58	15%	Aubergines/egg plants	0/0.85	23
37%	Cucumbers	0/0.85	56	14%	Beans	0/3.19	21
34%	Sweet peppers/bell peppers	0/0.85	51	13%	Courgettes	0/0.85	20
33%	Tomatoes	0/0.85	49	13%	Lentils	0/3.19	20
26%	Courgettes	0/0.85	40	12%	Beans (with pods)	0/2.27	18
18%	Leeks	0/0.47	28	11%	Head cabbages	0/0.4	17
17%	Beans (with pods)	0/2.27	26	11%	Potatoes	0/0.54	16
15%	Cauliflowers	0/0.4	23	10%	Yams	0/0.54	15
15%	Pumpkins	0/0.85	23	9%	Sweet peppers/bell peppers	0/0.85	14
14%	Lentils	0/3.19	21	9%	Tomatoes	0/0.85	13
14%	Aubergines/egg plants	0/0.85	21	8%	Pumpkins	0/0.85	12
14%	Peas	0/3.19	21	8%	Peas (without pods)	0/2.27	12
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
50%	Pumpkins/boiled	0/0.85	75	31%	Pumpkins/boiled	0/0.85	47
34%	Potatoes/fried	0/0.54	50	15%	Beans/canned	0/3.19	23
21%	Broccoli/boiled	0/0.4	32	13%	Courgettes/boiled	0/0.85	19
20%	Courgettes/boiled	0/0.85	30	11%	Cauliflowers/boiled	0/0.4	17
19%	Beans (with pods)/boiled	0/2.27	28	11%	Celeries/boiled	0/0.47	16
19%	Cauliflowers/boiled	0/0.4	28	8%	Beans (without pods)/	0/2.27	12
18%	Sweet potatoes/boiled	0/0.54	27	7%	Cassava roots/boiled	0/0.54	10
18%	Leeks/boiled	0/0.47	27	6%	Broccoli/boiled	0/0.4	9.6
17%	Lentils/boiled	0/3.19	26	6%	Florence fennels/boiled	0/0.47	9.1
17%	Witloofs/boiled	0/0.29	26	6%	Kohlrabies/boiled	0/0.4	8.5
15%	Peas/canned	0/1.28	23	6%	Peas/canned	0/1.28	8.5
14%	Florence fennels/boiled	0/0.47	21	6%	Sweet potatoes/boiled	0/0.54	8.3
13%	Gherkins/pickled	0/0.85	20	5%	Leeks/boiled	0/0.47	8.2
13%	Escaroles/broad-leaved endi	0/0.29	19	5%	Beetroots/boiled	0/0.21	8.2
12%	Rhubarbs/sauce/puree	0/0.47	18	5%	Peas (with pods)/boiled	0/2.27	7.8
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Flupyradifurone is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feeding of animals in EU considering primary and rotational crops grown in the EU as well as imported feed items from the USA and their by-products

Flupyradifurone

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment
Kale leaves	0.85	STMR	2.10	HR
Sunflower meal	0.05	STMR × PF (2)[(b)]	0.05	STMR × PF (2)[(b)]
Maize, stover	0.16	STMR (NEU)	0.45	HR (NEU)
Barley straw	0.5	STMR (SEU)	4.8	HR (SEU)
Millet grain	0.01	STMR (USA)	0.01	STMR (USA)
Millet straw/stover	0.18	STMR (SEU)	0.46	HR (SEU)
Wheat straw	0.43	STMR (SEU)	2.6	HR (SEU)
Rye grain	0.15	STMR (USA)	0.15	STMR (USA)
Rye straw	0.43	STMR (SEU)	2.6	HR (SEU)
Oat grain	0.45	STMR (US)	0.45	STMR (US)
Oat straw	0.11	STMR (NEU)	0.69	HR (NEU)
Rape seed meal	0.18	STMR × PF (2)[(b)] (EFSA, 2020b)	0.18	STMR × PF (2)[(b)] (EFSA, 2020b)
Apple, wet pomace	0.18	STMR × PF (1.6) (EFSA, 2015a)	0.18	STMR × PF (1.6) (EFSA, 2015a)
Citrus, dried pulp	2.07	STMR (mandarins) × PF (4.6) (EFSA, 2020a)	2.07	STMR (mandarins) × PF (4.6) (EFSA, 2020a)
Head cabbage	0.05	STMR (SEU) (EFSA, 2020a)	0.13	HR (SEU) (EFSA, 2020a)
Potato culls, cassava/tapioca roots	0.01	STMR (EFSA, 2020a)	0.04	HR (EFSA, 2020a)
Potato process waste	0.2	STMR × PF (20) (EFSA, 2020a)	0.2	STMR × PF (20) (EFSA, 2020a)
Potato dried pulp	0.38	STMR × PF (38) (EFSA, 2020a)	0.38	STMR × PF (38) (EFSA, 2020a)
Carrot culls, swede, roots, turnip roots	0.02	STMR (EFSA, 2020a)	0.6	HR (EFSA, 2020a)
Dry beans, lupins, cowpeas, peas	0.57	STMR (US) (EFSA, 2020a)	0.57	STMR (US) (EFSA, 2020a)
Lupin seed meal	0.63	STMR × PF (1.1) (EFSA, 2020a)	0.63	STMR × PF (1.1) (EFSA, 2020a)
Peanut meal	0.02	STMR × PF (2) (EFSA, 2020a)	0.02	STMR × PF (2) (EFSA, 2020a)
Soybean seed	0.06	STMR (EFSA, 2020a)	0.06	STMR (EFSA, 2020a)
Soybean meal	0.07	STMR × PF (1.1) (EFSA, 2020a)	0.07	STMR × PF (1.1) (EFSA, 2020a)
Soybean hulls	0.04	STMR × PF (0.6) (EFSA, 2020a)	0.04	STMR × PF (0.6) (EFSA, 2020a)
Cotton seed	0.02	STMR (US) (EFSA, 2020a)	0.02	STMR (US) (EFSA, 2020a)
Cotton seed meal	0.02	STMR × PF (1) (EFSA, 2020a)	0.02	STMR × PF (1) (EFSA, 2020a)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value[(a)] (mg/kg)	**Comment**	**Input value[(a)] (mg/kg)**	**Comment**
Barley grain	0.45	STMR (EFSA, 2020a)	0.45	STMR (EFSA, 2020a)
Barley, brewer's grain	0.45	STMR × PF (1) (EFSA, 2020a)	0.45	STMR × PF (1) (EFSA, 2020a)
Maize grain	0.01	STMR (EFSA, 2020a)	0.01	STMR (EFSA, 2020a)
Maize, milled by-products, hominy meal, gluten feed, gluten meal	0.01	STMR × PF (1) (EFSA, 2020a)	0.01	STMR × PF (1) (EFSA, 2020a)
Sorghum grain	0.51	STMR (EFSA, 2020a)	0.51	STMR (EFSA, 2020a)
Wheat grain	0.15	STMR (EFSA, 2020a)	0.15	STMR (EFSA, 2020a)
Distiller's grain dried (from wheat)	0.50	STMR × PF (3.3) (EFSA, 2020a)	0.50	STMR × PF (3.3) (EFSA, 2020a)
Wheat gluten meal	0.15	STMR × PF (1) (EFSA, 2020a)	0.15	STMR × PF (1) (EFSA, 2020a)
Wheat, milled by-products	0.36	STMR × PF (bran, 2.4) (EFSA, 2020a)	0.36	STMR × PF (bran, 2.4) (EFSA, 2020a)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.
(b): For sunflower and rapeseed meal the default processing factor of 2 was included in the calculation to consider the potential concentration of residues in these commodities.

Difluoroacetic acid (DFA)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value[(a)] (mg/kg)	**Comment**	**Input value[(a)] (mg/kg)**	**Comment**
Kale leaves	0.25	STMR (0.15) + STMR (0.10; brassica RC at EU plateau)	0.43	HR (0.3) + HR (0.13, brassica RC at EU plateau)
Sunflower meal	0.11	STMR (0.024) + STMR (0.03 rape seed RC at EU plateau) × PF (2)[(b)]	0.11	STMR (0.024) + STMR (0.03 rape seed RC at EU plateau) × PF (2)[(b)]
Maize grain	0.07	STMR (0.01) + STMR (0.06, maize grain RC at EU plateau)	0.07	STMR (0.01) + STMR (0.06, maize grain RC at EU plateau)
Maize, milled by-products, hominy meal, gluten feed, gluten meal	0.07	STMR (0.01) + STMR (0.06, maize grain RC at EU plateau) × PF (1)[(c)]	0.07	STMR (0.01) + STMR (0.06, maize grain RC at EU plateau) × PF (1)[(c)]
Barley grain	0.19	STMR (0.05) + STMR (0.14, barley grain RC at EU plateau)	0.19	STMR (0.05) + STMR (0.14, barley grain RC at EU plateau)
Barley straw	0.08	STMR (0.02) + STMR (0.06, barley straw RC at EU plateau)	0.65	HR (0.58) + HR (0.07, barley straw RC at EU plateau)
Barley, brewer's grain	0.19	STMR (0.05) barley grain + STMR (0.14, barley grain RC at EU plateau) × PF (1)[(c)]	0.19	STMR (0.05) barley grain + STMR (0.14, barley grain RC at EU plateau) × PF (1)[(c)]
Millet grain	0.07	STMR (0.01) + STMR ((0.06, maize grain RC at EU plateau)	0.07	STMR (0.01) + STMR ((0.06, maize grain RC at EU plateau)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value[(a)] (mg/kg)	**Comment**	**Input value[(a)] (mg/kg)**	**Comment**
Millet straw, maize stover	0.031	STMR (0.011) + STMR (0.02, maize stover RC at EU plateau)	0.072	HR (0.022) + HR (0.05, maize stover RC at EU plateau)
Wheat grain	0.26	STMR (0.12; NEU) + STMR (0.14, barley grain RC at EU plateau)	0.26	STMR (0.12; NEU) + STMR (0.14, barley grain RC at EU plateau)
Wheat straw	0.10	STMR (0.04) + STMR (0.06, barley straw RC at EU plateau)	0.24	HR (0.17) + HR (0.07, barley straw RC at EU plateau)
Distiller's grain dried (from wheat)	0.86	STMR (wheat grain, see above) × PF (3.3)[(b)] (EFSA, 2020a)	0.86	STMR (wheat grain, see above) × PF (3.3)[(b)] (EFSA, 2020a)
Wheat gluten meal	0.10	STMR (wheat grain, see above) × PF (0.4) (EFSA, 2020a)	0.10	STMR (wheat grain, see above) × PF (0.4) (EFSA, 2020a)
Wheat, milled by-products	0.28	STMR × PF (bran, 1.07) (EFSA, 2020a)	0.28	STMR × PF (bran, 1.07) (EFSA, 2020a)
Rye grain	0.26	STMR (0.12; NEU) + STMR (0.14, barley grain RC at EU plateau)	0.26	STMR (0.12; NEU) + STMR (0.14, barley grain RC at EU plateau)
Rye straw	0.10	STMR (0.04) + STMR (0.06, barley straw RC at EU plateau)	0.24	HR (0.17) + HR (0.07, barley straw RC at EU plateau)
Oat grain	0.19	STMR (0.05) + STMR (0.14, barley grain RC at EU plateau) or (STMR 0.1; USA) + STMR (0.09, barley grain RC at USA plateau)	0.19	STMR (0.05) + STMR (0.14, barley grain RC at EU plateau) or (STMR 0.1; USA) + STMR (0.09, barley grain RC at USA plateau)
Oat straw	0.08	STMR (0.02) + STMR (0.06, barley straw RC at EU plateau)	0.11	HR (0.04) + HR (0.07, barley straw RC at EU plateau)
Rape seed meal	0.12	STMR × PF (2) (EFSA, 2020b)	0.12	STMR × PF (2) (EFSA, 2020b)
Apple, wet pomace	0.08	STMR × PF[(c)] (EFSA, 2015a)	0.08	STMR × PF[(c)] (EFSA, 2015a)
Citrus, dried pulp	0.03	STMR (mandarins) × PF (1.5) (EFSA, 2020a)	0.03	STMR (mandarins) × PF (1.5) (EFSA, 2020a)
Head cabbage	0.15	STMR + STMR (brassica rotational crop (RC) at EU plateau) (EFSA, 2020a)	0.22	HR + HR (brassica rotational crop (RC) at EU plateau) (EFSA, 2020a)
Potato culls, cassava/tapioca roots	0.08	STMR (potato RC at EU plateau) (EFSA, 2020a)	0.18	HR (potato RC at EU plateau) (EFSA, 2020a)
Potato process waste, dried pulp	0.08	STMR (potato RC at EU plateau) × PF (1) (EFSA, 2020a)	0.18	HR (potato RC at EU plateau) × PF (1) (EFSA, 2020a)
Carrot culls, swede, roots, turnip roots	0.07	STMR + STMR (carrot/turnip RC at US plateau (EFSA, 2020a)	0.25	HR + HR (carrot/turnip RC at US plateau (EFSA, 2020a)
Dry lupins, cowpeas, peas, beans	1.14	STMR + STMR (pea RC at EU plateau) (EFSA, 2020a)	1.14	STMR + STMR (pea RC at EU plateau) (EFSA, 2020a)
Lupin seed meal	1.25	STMR pea + STMR (pea RC at EU plateau) × PF (1.1) (EFSA, 2020a)	1.25	STMR pea + STMR (pea RC at EU plateau) × PF (1.1) (EFSA, 2020a)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment
Peanut meal	0.08	STMR (peanut) + STMR (rape seed RC at US plateau × PF (2) (EFSA, 2020a)	0.08	STMR (peanut) + STMR (rape seed RC at US plateau × PF (2) (EFSA, 2020a)
Linseed, safflower meal	0.06	STMR (rape seed RC at EU plateau) × PF (2) (EFSA, 2020a)	0.06	STMR (rape seed RC at EU plateau) × PF (2) (EFSA, 2020a)
Soybean seed	0.05	STMR + STMR (RC rape seed at NA plateau) (EFSA, 2020a)	0.05	STMR + STMR (RC rape seed at NA plateau) (EFSA, 2020a)
Soybean meal	0.07	STMR (soybean seed) + STMR (rape seed RC at NA plateau) × PF (1.3) (EFSA, 2020a)	0.07	STMR (soybean seed) + STMR (rape seed RC at NA plateau) × PF (1.3) (EFSA, 2020a)
Soybean hulls	0.05	STMR (soybean seed) + STMR (rape seed RC at NA plateau) × PF (0.9) (EFSA, 2020a)	0.05	STMR (soybean seed) + STMR (rape seed RC at NA plateau) × PF (0.9) (EFSA, 2020a)
Cotton seed	0.05	STMR+ STMR (rape seed RC at EU plateau) (EFSA, 2020a)	0.05	STMR+ STMR (rape seed RC at EU plateau) (EFSA, 2020a)
Cotton seed meal	0.07	STMR (rape seed RC at EU plateau) × PF (1.3) (EFSA, 2020a)	0.07	STMR (rape seed RC at EU plateau) × PF (1.3) (EFSA, 2020a)
Sorghum grain	0.11	STMR + STMR (barley grain RC at NA plateau) (EFSA, 2020a)	0.11	STMR + STMR (barley grain RC at NA plateau) (EFSA, 2020a)
Triticale	0.09	STMR (barley grain RC at NA plateau) (EFSA, 2020a)	0.09	STMR (barley grain RC at NA plateau) (EFSA, 2020a)
Forages of alfalfa, clover, trefoil, grass, cereals (except maize), oilseeds (except rape) and legumes, clover silage	0.04	STMR (barley forage RC at EU plateau) (EFSA, 2020a)	0.09	HR (barley forage RC at EU plateau) (EFSA, 2020a)
Alfalfa hay, meal	0.10	STMR (barley forage RC at EU plateau) × PF (2.5) (EFSA, 2020a)	0.23	HR (barley forage RC at EU plateau) × PF (2.5) (EFSA, 2020a)
Alfalfa silage	0.04	STMR (barley forage RC at EU plateau) × PF (1.1) (EFSA, 2020a)	0.1	HR (barley forage RC at EU plateau) × PF (1.1) (EFSA, 2020a)
Rape forage	0.07	STMR (rape forage RC at EU plateau) (EFSA, 2020a)	0.18	HR (rape forage RC at EU plateau) (EFSA, 2020a)
Maize forage	0.03	STMR (maize forage RC at EU plateau) (EFSA, 2020a)	0.04	HR (maize forage RC at EU plateau) (EFSA, 2020a)
Straw of cereals (other than mentioned above)	0.06	STMR (barley straw RC at EU plateau) (EFSA, 2020a)	0.07	HR (barley straw RC at EU plateau) (EFSA, 2020a)
Silage of cereals	0.05	STMR (barley forage RC at EU plateau) × PF (1.3) (EFSA, 2020a)	0.12	HR (barley forage RC at EU plateau) × PF (1.3) (EFSA, 2020a)
Grass, pea silage	0.06	STMR (barley forage RC at EU plateau) × PF (1.6) (EFSA, 2020a)	0.14	HR (barley forage RC at EU plateau) × PF (1.6) (EFSA, 2020a)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment
Soybean, sorghum silage	0.02	STMR (barley forage RC at EU plateau) × PF (0.5) (EFSA, 2020a)	0.05	HR (barley forage RC at EU plateau) × PF (0.5) (EFSA, 2020a)
Clover, oat hay	0.12	STMR (barley forage RC at EU plateau) × PF (3) (EFSA, 2020a)	0.27	HR (barley forage RC at EU plateau) × PF (3) (EFSA, 2020a)
Cowpea, triticale hay	0.12	STMR (barley forage RC at EU plateau) × PF (2.9) (EFSA, 2020a)	0.26	HR (barley forage RC at EU plateau) × PF (2.9) (EFSA, 2020a)
Grass, pea, wheat hay	0.14	STMR (barley forage RC at EU plateau) × PF (3.5) (EFSA, 2020a)	0.32	HR (barley forage RC at EU plateau) × PF (3.5) (EFSA, 2020a)
Soybean hay	0.06	STMR (barley forage RC at EU plateau) × PF (1.5) (EFSA, 2020a)	0.14	HR (barley forage RC at EU plateau) × PF (1.5) (EFSA, 2020a)
Trefoil hay	0.11	STMR (barley forage RC at EU plateau) × PF (2.8) (EFSA, 2020a)	0.25	HR (barley forage RC at EU plateau) × PF (2.8) (EFSA, 2020a)
Tops of beets and turnips	0.02	STMR (lettuce RC at EU plateau) (EFSA, 2020a)	0.08	HR (lettuce RC at EU plateau) (EFSA, 2020a)

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; RC: rotational crop; NA: North America; EU: European Union.

(a): Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

(b): For sunflower meal and distiller's grain, in the absence of processing factors supported by data, default processing factors of 2 and 3.3, respectively, were included in the calculation to consider the potential concentration of residues in these commodities.

(c): No accumulation of residues expected according to processing studies (EFSA, 2015a, 2020a)

D.2. Consumer risk assessment

Scenario 1: Exposure to residues from the intake of primary crops and commodities of animal origin.

Commodity	Existing/ proposed MRL for flupyradifurone	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment
Risk assessment residue definition: flupyradifurone and the DFA, expressed as flupyradifurone						
Grapefruits	3	Existing MRL (EFSA, 2020a)	0.136	STMR-RAC × PeF	0.88	HR-RAC × PeF
Oranges	3	Existing MRL (EFSA, 2020a)	0.136	STMR-RAC × PeF	0.88	HR-RAC × PeF
Lemons	1.5	Existing MRL (EFSA, 2020a)	0.14	STMR-RAC × PeF	0.292	HR-RAC × PeF
Limes	1.5	Existing MRL (EFSA, 2020a)	0.14	STMR-RAC × PeF	0.292	HR-RAC × PeF
Mandarins	1.5	Existing MRL (EFSA, 2020a)	0.2	STMR-RAC × PeF	0.396	HR-RAC × PeF
Other citrus fruits	**3**	New MRL proposal	0.136	STMR-RAC × PeF	0.88	HR-RAC × PeF
Almonds	0.02	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.11	HR-RAC

Commodity	Existing/ proposed MRL for flupyradifurone	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment
Brazil nuts	0.02	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.11	HR-RAC
Cashew nuts	0.02	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.11	HR-RAC
Chestnuts	0.02	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.11	HR-RAC
Coconuts	0.02	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.11	HR-RAC
Hazelnuts/ cobnuts	0.02	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.11	HR-RAC
Macadamia	0.02	Existing MRL (EFSA, 2020a)	0.19	STMR-RAC	0.37	HR-RAC
Pecans	0.02	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.11	HR-RAC
Pine nut kernels	0.02	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.11	HR-RAC
Pistachios	0.02	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.11	HR-RAC
Walnuts	0.02	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.11	HR-RAC
Other tree nuts	0.02	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	–	–
Apples	0.6	Existing MRL (EFSA, 2020a)	0.28	STMR-RAC	0.69	HR-RAC
Pears	0.6	Existing MRL (EFSA, 2020a)	0.28	STMR-RAC	0.69	HR-RAC
Quinces	0.6	Existing MRL (EFSA, 2020a)	0.28	STMR-RAC	0.69	HR-RAC
Medlar	0.6	Existing MRL (EFSA, 2020a)	0.28	STMR-RAC	0.69	HR-RAC
Loquats/Japanese medlars	0.6	Existing MRL (EFSA, 2020a)	0.28	STMR-RAC	0.69	HR-RAC
Other pome fruit	0.6	Existing MRL (EFSA, 2020a)	0.28	STMR-RAC	–	–
Apricots	**1.0**	New MRL proposal	0.37	STMR-RAC	1.1	HR-RAC
Cherries (sweet)	**2**	New MRL proposal	0.65	STMR-RAC	0.96	HR-RAC
Peaches	**1.5**	New MRL proposal	0.35	STMR-RAC	1.1	HR-RAC
Plums	**0.4**	New MRL proposal	0.22	STMR-RAC	0.59	HR-RAC
Other stone fruit	**1.5**	New MRL proposal	0.37	STMR-RAC	1.1	HR-RAC
Table grapes	3	Existing MRL (EFSA, 2020a)	0.62	STMR-RAC	1.95	HR-RAC
Wine grapes	3	Existing MRL (EFSA, 2020a)	0.62	STMR-RAC	1.95	HR-RAC
Strawberries	0.4	Existing MRL (EFSA, 2016)	0.15	STMR-RAC	0.22	HR-RAC

Commodity	Existing/ proposed MRL for flupyradifurone	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment
Blackberries	6	Existing MRL (JMPR, 2019)	1.4	STMR-RAC	4.3	HR-RAC
Dewberries	6	Existing MRL (JMPR, 2019)	1.4	STMR-RAC	4.3	HR-RAC
Raspberries (red and yellow)	6	Existing MRL (JMPR, 2019)	1.4	STMR-RAC	4.3	HR-RAC
Other cane fruit	6	Existing MRL (JMPR, 2019)	1.4	STMR-RAC	–	–
Blueberries	4	Existing MRL (EFSA, 2020a)	0.86	STMR-RAC	2.59	HR-RAC
Cranberries	**0.7**	New MRL proposal	0.16	STMR-RAC	0.39	HR-RAC
Currants (red, black and white)	**0.7**	New MRL proposal	0.16	STMR-RAC	0.39	HR-RAC
Gooseberries (green, red and yellow)	**0.7**	New MRL proposal	0.16	STMR-RAC	0.39	HR-RAC
Rose hips	**0.7**	New MRL proposal	0.16	STMR-RAC	0.39	HR-RAC
Mulberries (black and white)	**0.7**	New MRL proposal	0.16	STMR-RAC	0.39	HR-RAC
Azarole/ Mediterranean medlar	**0.7**	New MRL proposal	0.16	STMR-RAC	0.39	HR-RAC
Elderberries	**0.7**	New MRL proposal	0.16	STMR-RAC	0.39	HR-RAC
Other small fruit & berries	**0.7**	New MRL proposal	0.16	STMR-RAC	–	–
Table olives	5	Existing MRL (EFSA, 2020a)	0.5	STMR-RAC	3.3	HR-RAC
Avocados	0.6	Existing MRL (JMPR, 2019)	0.28	STMR-RAC	0.36	HR-RAC
Potatoes	0.05	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.1	HR-RAC
Cassava roots/ manioc	0.05	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.1	HR-RAC
Sweet potatoes	0.05	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.1	HR-RAC
Yams	0.05	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.1	HR-RAC
Arrowroots	0.05	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.1	HR-RAC
Other tropical root and tuber vegetables	0.05	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	–	–
Beetroots	0.9	Existing MRL (EFSA, 2020a)	0.15	STMR-RAC	0.68	HR-RAC
Carrots	0.9	Existing MRL (EFSA, 2020a)	0.15	STMR-RAC	0.68	HR-RAC
Celeriacs/turnip rooted celeries	0.9	Existing MRL (EFSA, 2020a)	0.15	STMR-RAC	0.68	HR-RAC

Commodity	Existing/ proposed MRL for flupyradifurone	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment
Horseradishes	0.9	Existing MRL (EFSA, 2020a)	0.15	STMR-RAC	0.68	HR-RAC
Jerusalem artichokes	0.9	Existing MRL (EFSA, 2020a)	0.15	STMR-RAC	0.68	HR-RAC
Parsnips	0.9	Existing MRL (EFSA, 2020a)	0.15	STMR-RAC	0.68	HR-RAC
Parsley roots/ Hamburg roots parsley	0.9	Existing MRL (EFSA, 2020a)	0.15	STMR-RAC	0.68	HR-RAC
Radishes	0.9	Existing MRL (EFSA, 2020a)	0.15	STMR-RAC	0.68	HR-RAC
Salsifies	0.9	Existing MRL (EFSA, 2020a)	0.15	STMR-RAC	0.68	HR-RAC
Swedes/ rutabagas	0.9	Existing MRL (EFSA, 2020a)	0.15	STMR-RAC	0.68	HR-RAC
Turnips	0.9	Existing MRL (EFSA, 2020a)	0.15	STMR-RAC	0.68	HR-RAC
Other root and tuber vegetables	0.9	Existing MRL (EFSA, 2020a)	0.15	STMR-RAC	–	–
Tomatoes	0.7	Existing MRL (EFSA, 2015a)	0.47	STMR-RAC	0.12	HR-RAC
Sweet peppers/ bell peppers	0.9	Existing MRL (EFSA, 2020a)	0.24	STMR-RAC	1.65	HR-RAC
Aubergines/egg plants	1	Existing MRL (EFSA, 2020a)	0.2	STMR-RAC	1.8	HR-RAC
Okra/lady's fingers	0.9	Existing MRL (EFSA, 2021)	0.26	STMR-RAC	0.6	HR-RAC
Cucumbers	0.6	Existing MRL (EFSA, 2015a)	0.13	STMR-RAC	0.66	HR-RAC
Gherkins	0.6	Existing MRL (EFSA, 2015a)	0.13	STMR-RAC	0.66	HR-RAC
Courgettes	0.6	Existing MRL (EFSA, 2015a)	0.13	STMR-RAC	0.66	HR-RAC
Watermelons	0.15	Existing MRL (EFSA, 2015a)	0.065	STMR-RAC (pulp)	0.19	HR-RAC (pulp)
Sweet corn	0.05	Existing MRL (EFSA, 2020a)	0.13	STMR-RAC	0.25	HR-RAC
Broccoli	0.6	Existing MRL (EFSA, 2020a)	0.27	STMR-RAC	0.82	HR-RAC
Cauliflowers	0.6	Existing MRL (EFSA, 2020a)	0.27	STMR-RAC	0.82	HR-RAC
Other flowering brassica	0.6	Existing MRL (EFSA, 2020a)	0.27	STMR-RAC	–	–
Brussels sprouts	0.09	Existing MRL (EFSA, 2020a)	0.16	STMR-RAC	0.31	HR-RAC
Head cabbages	0.3	Existing MRL (EFSA, 2020a)	0.21	STMR-RAC	0.29	HR-RAC
Chinese cabbages/pe-tsai	**4**	New MRL proposal	1.3	STMR-RAC	2.2	HR-RAC
Kales	**4**	New MRL proposal	1.3	STMR-RAC	2.2	HR-RAC

Commodity	Existing/ proposed MRL for flupyradifurone	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment
Other leafy brassica	**4**	New MRL proposal	1.3	STMR-RAC	–	–
Kohlrabies	0.09	Existing MRL (EFSA, 2020a)	0.19	STMR-RAC	0.25	HR-RAC
Lamb's lettuce/ corn salads	6	Existing MRL (EFSA, 2020a)	1.36	STMR-RAC	3.2	HR-RAC
Lettuces	6	Existing MRL (EFSA, 2020a)	1.12	STMR-RAC	3.2	HR-RAC
Escaroles/broad-leaved endives	0.07	Existing MRL (EFSA, 2020a)	0.07	MRL	0.07	MRL
Cress and other sprouts and shoots	6	Existing MRL (EFSA, 2020a)	1.36	STMR-RAC	3.2	HR-RAC
Land cress	6	Existing MRL (EFSA, 2020a)	1.36	STMR-RAC	3.2	HR-RAC
Roman rocket/ rucola	6	Existing MRL (EFSA, 2020a)	1.36	STMR-RAC	3.2	HR-RAC
Red mustards	6	Existing MRL (EFSA, 2020a)	1.36	STMR-RAC	3.2	HR-RAC
Baby leaf crops (including brassica species)	6	Existing MRL (EFSA, 2020a)	1.36	STMR-RAC	3.2	HR-RAC
Other lettuce and other salad plants	6	Existing MRL (EFSA, 2020a)	1.36	STMR-RAC	–	–
Spinaches	6	Existing MRL (EFSA, 2020a)	1.36	STMR-RAC	3.2	HR-RAC
Purslanes	6	Existing MRL (EFSA, 2020a)	1.36	STMR-RAC	3.2	HR-RAC
Chards/beet leaves	6	Existing MRL (EFSA, 2020a)	1.36	STMR-RAC	3.2	HR-RAC
Other spinach and similar	6	Existing MRL (EFSA, 2020a)	1.36	STMR-RAC	–	–
Grape leaves and similar species	0.03	Existing MRL	0.03	MRL	0.03	MRL
Watercress	0.07	Existing MRL (EFSA, 2020a)	0.01	STMR-RAC	0.06	HR-RAC
Witloofs/Belgian endives	0.07	Existing MRL (EFSA, 2020a)	0.01	STMR-RAC	0.06	HR-RAC
Chervil	**40**	New MRL proposal	15.9	STMR-RAC	18.2	HR-RAC
Chives	**40**	New MRL proposal	15.9	STMR-RAC	18.2	HR-RAC
Celery leaves	**40**	New MRL proposal	15.9	STMR-RAC	18.2	HR-RAC
Parsley	**40**	New MRL proposal	15.9	STMR-RAC	18.2	HR-RAC
Sage	**40**	New MRL proposal	15.9	STMR-RAC	18.2	HR-RAC
Rosemary	**40**	New MRL proposal	15.9	STMR-RAC	18.2	HR-RAC

Commodity	Existing/ proposed MRL for flupyradifurone	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment
Thyme	**40**	New MRL proposal	15.9	STMR-RAC	18.2	HR-RAC
Basil and edible flowers	**40**	New MRL proposal	15.9	STMR-RAC	18.2	HR-RAC
Laurel/bay leaves	**40**	New MRL proposal	15.9	STMR-RAC	18.2	HR-RAC
Tarragon	**40**	New MRL proposal	15.9	STMR-RAC	18.2	HR-RAC
Other herbs	**40**	New MRL proposal	15.9	STMR-RAC	–	–
Beans (with pods)	0.5	Existing MRL (EFSA, 2020a)	0.19	STMR-RAC	0.37	HR-RAC
Beans (without pods)	0.4	Existing MRL (EFSA, 2020a)	0.16	STMR-RAC	0.36	HR-RAC
Peas (with pods)	0.5	Existing MRL (EFSA, 2020a)	0.19	STMR-RAC	0.37	HR-RAC
Peas (without pods)	0.4	Existing MRL (EFSA, 2020a)	0.16	STMR-RAC	0.36	HR-RAC
Lentils (fresh)	0.4	Existing MRL (EFSA, 2020a)	0.16	STMR-RAC	0.36	HR-RAC
Celeries	0.01	Existing MRL (EFSA, 2020a)	0.01	LOQ	0.01	LOQ
Beans	3	Existing MRL (EFSA, 2020a)	0.79	STMR-RAC	0.79	STMR-RAC
Lentils	3	Existing MRL (EFSA, 2020a)	0.79	STMR-RAC	0.79	STMR-RAC
Peas	3	Existing MRL (EFSA, 2020a)	0.79	STMR-RAC	0.79	STMR-RAC
Lupins/lupini beans	3	Existing MRL (EFSA, 2020a)	0.79	STMR-RAC	0.79	STMR-RAC
Other pulses	3	Existing MRL (EFSA, 2020a)	0.79	STMR-RAC	–	–
Peanuts/ groundnuts	0.04	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.06	STMR-RAC
Sunflower seeds	**0.07**	New MRL proposal	0.11	STMR-RAC	0.11	STMR-RAC
Rapeseeds/canola seeds	0.3	Existing MRL (EFSA, 2020b)	0.23	STMR-RAC	0.23	STMR-RAC
Soya beans	1.5	Existing MRL (EFSA, 2020a)	0.15	STMR-RAC	0.15	STMR-RAC
Mustard seeds	0.3	Existing MRL (EFSA, 2020a)	0.23	STMR-RAC	0.23	STMR-RAC
Cotton seeds	0.8	Existing MRL (EFSA, 2020a)	0.17	STMR-RAC	0.17	STMR-RAC
Olives for oil production	5	Existing MRL (EFSA, 2020a)	0.5	STMR-RAC	0.5	STMR-RAC
Barley	3	Existing MRL (EFSA, 2020a)	0.81	STMR-RAC	0.81	STMR-RAC
Maize/corn	0.02	Existing MRL (EFSA, 2020a)	0.06	STMR-RAC	0.06	STMR-RAC

Commodity	Existing/ proposed MRL for flupyradifurone	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment
Common millet/ proso millet	**0.02**	New MRL proposal	0.06	STMR-RAC	0.06	STMR-RAC
Oat	**3**	New MRL proposal	0.81	STMR-RAC	0.81	STMR-RAC
Rye	**1**	New MRL proposal	0.65	STMR-RAC	0.65	STMR-RAC
Sorghum	3	Existing MRL (EFSA, 2020a)	0.64	STMR-RAC	0.64	STMR-RAC
Wheat	1	Existing MRL (EFSA, 2020a)	0.65	STMR-RAC	0.65	STMR-RAC
Coffee beans	1	Existing MRL (EFSA, 2020a)	0.24	STMR-RAC	0.24	STMR-RAC
Cocoa beans	0.05	Existing MRL (EFSA, 2020a)	0.07	STMR-RAC	0.11	HR-RAC
HOPS (dried)	10	Existing MRL (JMPR, 2019)	3.55	STMR-RAC	3.55	HR-RAC
Swine: Muscle/ meat	0.03	Existing MRL (EFSA, 2020a)	0.16	STMR-RAC	0.41	HR-RAC
Swine: Fat tissue	**0.02**	New MRL proposal	0.169	STMR-RAC	0.57	HR-RAC
Swine: Liver	**0.1**	New MRL proposal	0.15	STMR-RAC	0.378	HR-RAC
Swine: Kidney	**0.15**	New MRL proposal	0.251	STMR-RAC	0.628	HR-RAC
Swine: Edible offals (other than liver and kidney)	**0.15**	New MRL proposal	0.251	STMR-RAC	0.628	HR-RAC
Bovine: Muscle/ meat	0.3	Existing MRL (EFSA, 2020a)	1.1	STMR-RAC	1.22	HR-RAC
Bovine: Fat tissue	0.2	Existing MRL (EFSA, 2020a)	1.03	STMR-RAC	1.48	HR-RAC
Bovine: Liver	1	Existing MRL (EFSA, 2020a)	1.74	STMR-RAC	1.91	HR-RAC
Bovine: Kidney	1	Existing MRL (EFSA, 2020a)	2.24	STMR-RAC	2.39	HR-RAC
Bovine: Edible offals (other than liver and kidney)	1	Existing MRL (EFSA, 2020a)	2.24	STMR-RAC	2.39	HR-RAC
Sheep: Muscle/ meat	0.3	Existing MRL (EFSA, 2020a)	0.54	STMR-RAC	0.84	HR-RAC
Sheep: Fat tissue	0.2	Existing MRL (EFSA, 2020a)	0.38	STMR-RAC	0.881	HR-RAC
Sheep: Liver	1	Existing MRL (EFSA, 2020a)	1.21	STMR-RAC	1.39	HR-RAC
Sheep: Kidney	1	Existing MRL (EFSA, 2020a)	1.39	STMR-RAC	1.72	HR-RAC
Sheep: Edible offals (other than liver and kidney)	1	Existing MRL (EFSA, 2020a)	1.39	STMR-RAC	1.72	HR-RAC
Goat: Muscle/ meat	0.3	Existing MRL (EFSA, 2020a)	0.54	STMR-RAC	0.84	HR-RAC

Commodity	Existing/ proposed MRL for flupyradifurone	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment
Goat: Fat tissue	0.2	Existing MRL (EFSA, 2020a)	0.38	STMR-RAC	0.881	HR-RAC
Goat: Liver	1	Existing MRL (EFSA, 2020a)	1.21	STMR-RAC	1.39	HR-RAC
Goat: Kidney	1	Existing MRL (EFSA, 2020a)	1.39	STMR-RAC	1.72	HR-RAC
Goat: Edible offals (other than liver and kidney)	1	Existing MRL (EFSA, 2020a)	1.39	STMR-RAC	1.72	HR-RAC
Equine: Muscle/ meat	0.3	Existing MRL (EFSA, 2020a)	1.1	STMR-RAC	1.22	HR-RAC
Equine: Fat tissue	0.2	Existing MRL (EFSA, 2020a)	1.03	STMR-RAC	1.48	HR-RAC
Equine: Liver	1	Existing MRL (EFSA, 2020a)	1.74	STMR-RAC	1.91	HR-RAC
Equine: Kidney	1	Existing MRL (EFSA, 2020a)	2.24	STMR-RAC	2.39	HR-RAC
Equine: Edible offals (other than liver and kidney)	1	Existing MRL (EFSA, 2020a)	2.24	STMR-RAC	2.39	HR-RAC
Poultry: Muscle/ meat	0.01*	Existing MRL (EFSA, 2020a)	0.32	STMR-RAC	0.39	HR-RAC
Poultry: Fat tissue	0.01*	Existing MRL (EFSA, 2020a)	0.09	STMR-RAC	0.102	HR-RAC
Poultry: Liver	0.01*	Existing MRL (EFSA, 2020a)	0.68	STMR-RAC	0.69	HR-RAC
Poultry: Kidney	0.01*	Existing MRL (EFSA, 2020a)	0.68	STMR-RAC	0.69	HR-RAC
Poultry: Edible offals (other than liver and kkidney)	0.01	Existing MRL (EFSA, 2020a)	0.68	STMR-RAC	0.69	HR-RAC
Milk: Cattle	0.15	Existing MRL (EFSA, 2020a)	0.34	STMR-RAC	0.34	STMR-RAC
Milk: Sheep	0.15	Existing MRL (EFSA, 2020a)	0.18	STMR-RAC	0.18	STMR-RAC
Milk: Goat	0.15	Existing MRL (EFSA, 2020a)	0.18	STMR-RAC	0.18	STMR-RAC
Eggs: Chicken	0.01*	Existing MRL (EFSA, 2020a)	0.25	STMR-RAC	0.31	HR-RAC
Eggs: Duck	0.01*	Existing MRL (EFSA, 2020a)	0.25	STMR-RAC	0.31	HR-RAC
Eggs: Goose	0.01*	Existing MRL (EFSA, 2020a)	0.25	STMR-RAC	0.31	HR-RAC
Eggs: Quail	0.01*	Existing MRL (EFSA, 2020a)	0.25	STMR-RAC	0.31	HR-RAC
Eggs: Others	0.01*	Existing MRL (EFSA, 2020a)	0.25	STMR-RAC	–	–
Honey	2	New MRL proposal	0.36	STMR-RAC	0.92	HR-RAC

(a): Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

Scenario 2: Exposure to flupyradifurone and DFA residues (expressed as flupyradifurone) from rotational crops.

–	Chronic risk assessment		Acute risk assessment	
	Input value[(a)] (mg/kg)	**Comment**	**Input value[(a)] (mg/kg)**	**Comment**
Strawberries	0.33	STMR DFA RC strawberry at EU plateau (EFSA, 2020a)	0.74	HR DFA RC strawberry at EU plateau (EFSA, 2020a)
Potatoes, tropical root and tuber vegetables	0.23	STMR DFA in RC potatoes at EU plateau (EFSA, 2020a)	0.54	HR DFA in RC potatoes at EU plateau (EFSA, 2020a)
Root and tuber vegetables (except sugar beets)	0.11	STMR DFA in RC carrot/turnip at EU plateau (EFSA, 2020a)	0.21	HR DFA in RC carrot/turnip at EU plateau (EFSA, 2020a)
Bulb vegetables	0.13	STMR DFA in RC onions at EU plateau (EFSA, 2020a)	0.33	HR DFA in RC onions at EU plateau (EFSA, 2020a)
Tomatoes, aubergines, peppers	0.62	STMR DFA in RC cucumber at EU plateau (EFSA, 2020a)	0.85	HR DFA in RC cucumber at EU plateau (EFSA, 2020a)
Cucurbits (edible peel)	0.62	STMR DFA in RC cucumber at EU plateau (EFSA, 2020a)	0.85	HR DFA in RC cucumber at EU plateau (EFSA, 2020a)
Cucurbits (inedible peel)	0.62	STMR DFA in RC cucumbers at EU plateau (EFSA, 2020a)	0.85	HR DFA[(b)] in RC cucumbers at EU plateau (EFSA, 2020a)
Sweet corn	0.17	STMR DFA in RC maize grain at EU plateau (EFSA, 2020a)	0.23	HR DFA in RC maize grain at EU plateau (EFSA, 2020a)
Brassica vegetables	0.3	STMR DFA in RC cauliflower/ broccoli at EU plateau (EFSA, 2020a)	0.4	HR DFA in RC cauliflower/broccoli at EU plateau (EFSA, 2020a)
Lettuce and other salad plants Herbs and edible flowers Spinach and similar	0.08	STMR flupyradifurone (0.01 mg/kg) at EU plateau + STMR DFA in RC lettuce at EU plateau (EFSA, 2020a)	0.29	HR flupyradifurone (0.06 mg/kg) lettuce at EU plateau + HR DFA in RC lettuce at EU plateau (EFSA, 2020a)
Grape leaves, watercress, witloofs/Belgian endives	0.08	STMR flupyradifurone (0.01 mg/kg) at EU plateau + STMR DFA in RC lettuce at EU plateau (EFSA, 2020a)	0.29	HR flupyradifurone (0.06 mg/kg) lettuce at EU plateau + HR DFA in RC lettuce at EU plateau (EFSA, 2020a)
Legume vegetables	0.98	STMR DFA in RC beans with pods at EU plateau (EFSA, 2020a)	2.27	HR DFA in RC beans with pods at EU plateau (EFSA, 2020a)
Stem vegetables	0.14	STMR DFA in RC leek at EU plateau (EFSA, 2020a)	0.47	HR DFA in RC leek at EU plateau (EFSA, 2020a)
Pulses	3.19	STMR DFA in RC peas (dry) at EU plateau (EFSA, 2020a)	3.19	STMR DFA in RC peas (dry) at EU plateau (EFSA, 2020a)
Oilseeds	0.09	STMR DFA in RC rapeseed at EU plateau (EFSA, 2020a)	0.09	STMR DFA in RC rapeseed at EU plateau (EFSA, 2020a)
Cereals	0.43	STMR flupyradifurone (0.01 mg/kg) barley grain at EU plateau +STMR DFA (0.42 mg/kg) in RC barley grain at EU plateau (EFSA, 2020a)	0.43	STMR flupyradifurone (0.01 mg/kg) barley grain at EU plateau +STMR DFA (0.42 mg/kg) in RC barley grain at EU plateau (EFSA, 2020a)
Okra/lady's fingers	0.62	STMR (EFSA, 2021)	0.85	HR (EFSA, 2021)

STMR: supervised trials median residue; HR: highest residue; RC: rotational crop; EU: European Union.
(a): Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.
(b): Average processing factor from two studies.

Appendix E – Residues of DFA in rotational crops

Table E.1: Residues of DFA, expressed as DFA, (scaled) in rotational crops (mg/kg)

Crop	Residue trials submitted under previous assessment (EFSA, 2020a)			
	Scaled to C_{min}[(a)] (0.062 mg/kg) from critical intended EU uses (2.06 x)		Scaled to C_{min}[(a)] (0.042 mg/kg) from US authorised uses (1.4 x)	
	STMR	**HR**	**STMR**	**HR**
Potato tuber	0.05	0.18	0.04	0.12
Carrot/turnip	–	–	–	–
Leek	–	–	–	–
Onion	–	–	–	–
Barley grain	0.14	0.25	0.09	0.17
Maize seed	0.06	0.08	0.04	0.05
Lettuce head	–	–	–	–
Cauliflower/broccoli	0.10	0.13	0.07	0.09
Rape seed	0.03	0.05	0.02	0.03
Dry peas	–	–	–	–
Bean with pods	–	–	–	–
Cucumber	–	–	–	–
Strawberry	0.11	0.25	0.10	0.17
Barley straw	0.06	0.07	0.04	0.05
Barley forage	0.04	0.09	0.03	0.06
Rape forage	0.07	0.18	0.05	0.12
Maize stover	0.02	0.05	0.01	0.03
Maize forage	0.03	0.04	0.02	0.03

STMR: supervised trials median residue; HR: highest residue; PBI: Plant-back interval; C_{min}: soil plateau concentration.
(a): Worst case background/plateau soil residue concentrations estimated from the critical seasonal application rate.

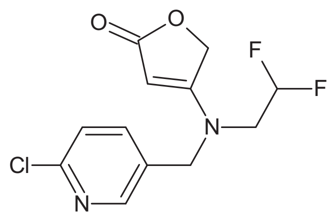
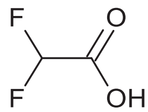
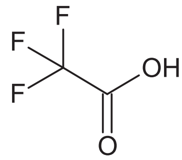
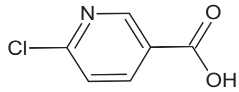
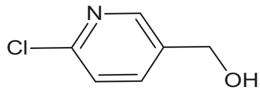
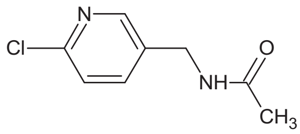
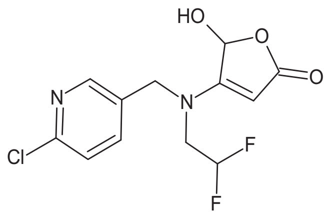
Table E.2: MRL proposals for DFA for plant products (in mg/kg)

Crop under assessment	Origin of the GAP	MRL proposal (primary crop treatment)	HR (representative rotational crop at EU plateau soil concentration for flupyradifurone)	HR in rotational crops (at US/CA plateau soil concentration flupyradifurone	MRL primary crop + HR for RC	MRL proposal[(a)]
Leafy brassica	EU	0.5	0.13 (broccoli, cauliflower)	–	0.63	**0.7**
Herbs and edible flowers	EU	0.03	0.08 (lettuce)	–	0.11	**0.1**
Sunflower seeds	EU	0.09	0.05 (rape seed)	–	0.14	**0.15**
Barley grain	EU	0.15	0.25 (barley grain)	–	0.40	0.4
Barley grain	USA	0.6	–	0.17 (barley grain)	0.77	**0.8**
Maize grain	EU	0.03	0.08 (maize grain)	–	0.11	**0.15**
Maize grain	USA	0.05	–	0.05 (maize grain)	0.10	0.1
Millet grain	EU	0.03	0.08 (maize grain)	–	0.13	**0.15**
Millet grain	USA	0.05	–	0.05 (maize grain)	0.10	0.10
Oat grain	EU	0.15	0.25 (barley)	–	0.40	0.4
Oat grain	USA	0.6	–	0.17(barley grain)	0.77	**0.8**
Rye grain	EU	0.6	0.25 (barley)	–	0.85	0.9
Rye grain	USA	1	–	0.17 (barley grain)	1.17	**1.5**

Crop under assessment	Origin of the GAP	MRL proposal (primary crop treatment)	HR (representative rotational crop at EU plateau soil concentration for flupyradifurone)	HR in rotational crops (at US/CA plateau soil concentration flupyradifurone	MRL primary crop + HR for RC	MRL proposal[(a)]
Wheat grain	EU	0.6	0.25 (barley)	–	0.85	0.9
Wheat grain	USA	1	–	0.17 (barley grain)	1.17	**1.5**

HR: highest residue; MRL: maximum residue level.
(a): The MRL proposals representing the critical GAP for the commodity under assessment is highlighted in bold.

Appendix F – Used compound codes

Code/trivial name[(a)]	IUPAC name/SMILES notation/InChiKey[(b)]	Structural formula[(c)]
flupyradifurone	4-{[(6-chloro-3-pyridyl)methyl](2,2-difluoroethyl) amino}furan-2(5*H*)-one FC(F)CN(Cc1ccc(Cl)nc1)C1=CC(=O)OC1 QOIYTRGFOFZNKF-UHFFFAOYSA-N	
DFA	difluoroacetic acid FC(F)C(=O)O PBWZKZYHONABLN-UHFFFAOYSA-N	
TFA	Trifluoroacetic acid FC(F)(F)C(=O)O DTQVDTLACAAQTR-UHFFFAOYSA-N	
6-CNA	6-chloropyridine-3-carboxylic acid OC(=O)c1cnc(Cl)cc1 UAWMVMPAYRWUFX-UHFFFAOYSA-N	
CHMP 6-CPA (6-chloro-picolylalcohol)	(6-chloropyridin-3-yl)methanol OCc1cnc(Cl)cc1 GOXYBEXWMJZLJB-UHFFFAOYSA-N	
acetyl-AMCP	*N*-[(6-chloropyridin-3-yl)methyl]acetamide Clc1ccc(CNC(C)=O)cn1 PKLYKZAYVXYVQX-UHFFFAOYSA-N	
flupyradifurone-hydroxy M8 metabolite	4-{[(6-chloropyridin-3-yl)methyl](2,2-difluoroethyl) amino}-5-hydroxyfuran-2(5*H*)-one VCISBQOTABLQEA-UHFFFAOYSA-N OC1OC(=O)C=C1N(CC(F)F)Cc1ccc(Cl)nc1	

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).
(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).