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Modification of the existing maximum residue levels for benzovindiflupyr in leeks and spring onions/green onions/Welsh onions

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta Crop Protection AG submitted a request to the competent national authority in France to modify the existing maximum residue levels (MRLs) for the active substance benzovindiflupyr in leeks and spring onions, green onions and Welsh onions. The data submitted in support of the request were found to be sufficient to derive MRL proposals for the crops under assessment. Adequate analytical methods for enforcement are available to control the residues of benzovindiflupyr on the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of benzovindiflupyr according to the reported agricultural practices is unlikely to present a risk to consumer health.

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Keywords: benzovindiflupyr, leeks, spring/green/Welsh onions, fungicide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in France (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance benzovindiflupyr in leeks and spring onions, green onions and Welsh onions. 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 13 April 2021. To accommodate for the intended uses of benzovindiflupyr, the EMS proposed to raise the existing MRLs for leeks and spring onions, green onions and Welsh onions from the limit of quantification (LOQ) of 0.01 to 0.09 mg/kg.

Based on the conclusions derived by EFSA in the framework of (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 benzovindiflupyr following foliar application was investigated in crops belonging to the groups of fruit crops, cereals and pulses/oilseeds. The metabolic pathways in these three crop groups were similar, with parent compound as the major component of residues, except in soya beans. In rotational crops, the major residues identified were the parent compound and certain pyrazole structured metabolites. Studies investigating the effect of processing on the nature of benzovindiflupyr (hydrolysis studies) were assessed and the EU pesticides peer review concluded that benzovindiflupyr is stable under standard processing conditions.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites, the residue definitions for plant products were proposed as 'benzovindiflupyr' for enforcement and risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products. EFSA concluded that for the crops assessed in this application, the metabolism of benzovindiflupyr in primary and in rotational crops, and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical single residue and multiresidue methods based on high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ).

The available residue trials are sufficient to derive MRL proposals of 0.09 mg/kg for leeks and, by extrapolation, for spring onions, green onions and Welsh onions.

The occurrence of benzovindiflupyr residues in rotational crops was investigated in the framework of the EU pesticides peer review and further examined during the present application. Based on the available information, residues of benzovindiflupyr are not expected to occur in rotated crops even following multiannual applications, provided that the active substance is applied to the crops under assessment according to the intended good agricultural practices (GAPs). However, since the potential generation of pyrazole structured metabolites above the LOQ cannot be excluded, in particular in oilseeds and pulses, Member States are recommended to consider the need to implement appropriate mitigation measures in order to avoid the presence of benzovindiflupyr pyrazole structured metabolites in succeeding crops belonging to this group.

Specific studies investigating the magnitude of benzovindiflupyr residues in processed commodities are not required, as significant residues are not expected in raw agricultural commodities (RAC).

Residues of benzovindiflupyr in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.

The toxicological profile of benzovindiflupyr was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acute reference dose (ARfD) of 0.1 mg/kg body weight (bw) and an acceptable daily intake (ADI) of 0.05 mg/kg bw per day.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). Benzovindiflupyr is a racemic mixture of two enantiomers. Since the information on the possible preferential degradation of each isomer in treated food and feed and its single toxicity is not available, the consumer risk assessment was performed by applying a factor of 2, assuming a worst-case scenario where the toxicity is attributed to a single enantiomer and a complete switch of the composition of residues into this enantiomer occurs.

The short-term exposure assessment was performed for the commodities assessed in this application. The calculations were based on the highest residues (HR) derived from supervised field trials and the short-term exposure did not exceed the ARfD for any of the crops assessed.

The long-term exposure assessment was performed taking into account the median residue values (STMR) for the commodities assessed in this application derived from supervised field trials. For the remaining commodities covered by the MRL regulation, the existing EU MRLs and STMR values derived in the EU pesticides peer review, in a previous import tolerance application and by the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) for the Codex MRLs adopted in the MRL regulation were selected as input values. After applying the factor of 2, the estimated long-term dietary intake accounted for 10% of the ADI (NL toddler diet). The contributions of residues expected in the commodities assessed in the present MRL application to the overall long-term exposure were ≤ 0.04% of the ADI (after application of the factor of 2).

EFSA concluded that the proposed use of benzovindiflupyr on leeks and spring onions, green onions and Welsh onions will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

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 to D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Benzovindiflupyr				
0270060	Leeks	0.01*	0.09	The submitted data are sufficient to derive an MRL proposal for the NEU and SEU uses. Risk for consumers unlikely.
0220040	Spring onions/green onions and Welsh onions	0.01*	0.09	The submitted data are sufficient to derive an MRL proposal, by extrapolation, for the NEU and SEU uses. Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.
*: 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.

Table of contents

Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for benzovindiflupyr in leeks and spring onions, green onions and Welsh onions. The detailed description of the intended uses of benzovindiflupyr in leeks and spring onions/ green onions and Welsh onions, which are the basis for the current MRL application, is reported in Appendix A.

Benzovindiflupyr is the ISO common name for *N*-[(1*RS*,4*SR*)-9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Benzovindiflupyr was evaluated in the framework of Regulation (EC) No 1107/2009[1] with France designated as rapporteur Member State (RMS) for the representative uses as foliar spray applications on wheat, rye, barley and oats. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2015). Benzovindiflupyr was approved[2] for the use as a fungicide on 2 March 2016.

The EU MRLs for benzovindiflupyr are established in Annex II of Regulation (EC) No 396/2005[3]. Proposals for setting MRLs covering the representative uses according to good agricultural practices (GAPs) in the EU were assessed during the approval of benzovindiflupyr under Regulation (EC) No 1107/2009 and implemented in Regulation in accordance with Article 11(2) of the Regulation (EC) 1107/2009. EFSA has also issued one reasoned opinion on the modification of MRLs for benzovindiflupyr. The proposals from this reasoned opinion have been considered in recent MRL regulation. In addition, certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation.[4]

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in France (evaluating Member State, EMS) to set MRLs for the active substance benzovindiflupyr in leeks and spring onions/green onions and Welsh onions. 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 13 April 2021. To accommodate for the intended uses of benzovindiflupyr, the EMS proposed to raise the existing MRLs for leeks and spring onions/green onions and Welsh onions from the limit of quantification (LOQ) of 0.01 to 0.09 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (France, 2021), the draft assessment report (DAR) and its addendum (France, 2014, 2015) prepared under Regulation (EC) 1107/2009, the Commission review report on benzovindiflupyr (European Commission, 2020), the conclusion on the peer review of the pesticide risk assessment of the active substance benzovindiflupyr (EFSA, 2015), as well as the conclusions from a previous EFSA opinion on benzovindiflupyr (EFSA, 2016) and from the assessment of the Codex MRLs (EFSA, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011[5] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011). 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[6].

[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) 2016/177 of 10 February 2016 approving the active substance benzovindiflupyr, as a candidate for substitution, 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 Implementing Regulation (EU) No 540/2011 (Text with EEA relevance) OJ L 35, 11.2.2016, p. 1–5.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[4] Commission Regulation (EU) 2018/687 of 4 May 2018 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 acibenzolar-S-methyl, benzovindiflupyr, bifenthrin, bixafen, chlorantraniliprole, deltamethrin, flonicamid, fluazifop-P, isofetamid, metrafenone, pendimethalin and teflubenzuron in or on certain products. OJ L 121, 16.5.2018, p. 63–104.

[5] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

[6] 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.

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 (France, 2021) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of benzovindiflupyr in primary crops belonging to the group of fruit crops (tomato), cereals (wheat), and pulses/oilseeds (soya bean) has been investigated in the framework of the EU pesticides peer review (EFSA, 2015). In the crops tested, benzovindiflupyr was the main residue in tomato fruits (≥ 91% of the total radioactive residue, TRR), in wheat commodities (≥ 81% of the TRR), and soya foliage (67–85% of the TRR). In soya beans benzovindiflupyr represented up to 31% of the TRR, but the major residue was the desmethyl pyrazole carboxylic acid metabolite SYN545720 (47% TRR), present in both free and conjugated forms (conjugation with aspartic acid and sugar). This metabolite SYN545720 was found only at low proportions and levels in wheat and tomatoes (< 1% TRR, up to 0.04 mg eq./kg in wheat straw).

In the framework of the peer review, it was highlighted that the above studies did not investigate the possible impact of plant metabolism on the isomer ratio of benzovindiflupyr (EFSA, 2015). Further investigation on this matter would in principle be required. It is noted that the EFSA guidance on the risk assessment of compounds that may have stereoisomers has been finalised (EFSA, 2019b). EFSA would therefore recommend to reconsider this point in the framework of the peer review for the renewal of approval of the active substance.

For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed and the residue definition for enforcement and risk assessment agreed during the peer review is applicable.

1.1.2. Nature of residues in rotational crops

A rotational crop metabolism study was assessed in the framework of EU pesticides peer review (EFSA, 2015). The fate of benzovindiflupyr was examined in crops belonging to the groups of leafy crops (lettuce), root and tuber crops (turnip), and cereals (wheat) after soil treatment with phenyl-^{14}C and pyrazole-^{14}C-labelled-benzovindiflupyr at ca. 530 g/ha. Crops were sown in the treated soil after periods of 30, 90 and 360 days. The pattern of metabolites found in the samples from the pyrazole-^{14}C experiment was different to that found in the samples from the phenyl-^{14}C treatment because of the presence of metabolites originating from a cleaved parent molecule, retaining only the pyrazole ring. Pyrazole acid (NOA449410) was the major metabolite found in leafy, root/tuber crops and in cereal forage and hay and was mostly present in the conjugated form. Metabolite SYN545720 was also a significant metabolite found in leafy, root/tuber crops and in cereal (forage and hay), in both free and conjugated forms. However, the residue levels of the individual metabolites were mostly below the limit of quantification of 0.01 mg/kg for all plant back intervals.

For the proposed use assessed in this application, no further information is required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of benzovindiflupyr was investigated in the framework of the EU pesticides peer review (EFSA, 2015), which concluded that benzovindiflupyr was hydrolytically stable under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of benzovindiflupyr residues were assessed during the EU pesticides peer review (EFSA, 2015). A single residue method based on high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS), confirmed by a multiresidue method including the Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method, were sufficiently

validated at or above the LOQ of 0.01 mg/kg for matrices with high water content, high oil content, high acid content, dry matrices, and coffee beans.

In the framework of the current application the HPLC method previously validated in the framework of the EU pesticides peer review was additionally validated for leek (France, 2021).

1.1.5. Storage stability of residues in plants

The storage stability of benzovindiflupyr in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2015). The storage stability of benzovindiflupyr was demonstrated for a period of 24 months at −18°C in plant commodities, including the group to which the crops assessed in the framework of this application belong (high water content).

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, a general residue definition for monitoring and for risk assessment were proposed by the EU pesticides peer review (EFSA, 2015):

- Residue definition for risk assessment: benzovindiflupyr
- residue definition for enforcement: benzovindiflupyr

The same residue definitions are applicable to rotational crops and processed products.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.

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

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Leeks, Spring onions GAP (NEU, SEU): 1 × 50 g a.s./ha; BBCH: 41–48; PHI: 21 days

In support of the MRL application, the applicant submitted a total of 12 GAP-compliant independent residue trials performed on leeks: eight trials were conducted in NEU and four in SEU. All trials were conducted during a single growing season of 2017 instead of two as required by Regulation (EU) No 544/2011. This deviation was considered acceptable, as all trials were conducted in different geographic locations widespread in both European residue zones. All trials used an adjuvant, a non-ionic surfactant, mixed in the formulation, as proposed in the intended GAP. Residue decline data from six trials indicate a rapid dissipation of benzovindiflupyr in leeks for the duration of 21 days after the treatment.

The samples were analysed for benzovindiflupyr. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (France, 2021). The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

The applicant proposed to derive an MRL for leeks from the merged NEU and SEU residue data sets and to extrapolate the results from the residue trials on leeks to spring onions/green onions and Welsh onions. EFSA agreed with both proposals. According to the EU guidance document (European Commission, 2017), residue data from leeks can be extrapolated to spring onions/green onions and Welsh onions. Moreover, since the GAPs are identical and residue data from NEU and SEU were found to statistically belong to similar populations (U-test, 5%), the residues data sets from both zones were merged to derive a more robust MRL proposal.

1.2.2. Magnitude of residues in rotational crops

Leeks and spring onions, green onions and Welsh onions can be grown in a crop rotation. The possible transfer of benzovindiflupyr residues to crops that are grown in crop rotation has been previously assessed in the framework of the EU pesticides peer review (EFSA, 2015). The available field studies demonstrated that no significant residues of parent are expected (residues below 0.01 mg/kg, with the exception of one trial on wheat straw 30 days after soil treatment) in succeeding crops belonging to the groups of leafy vegetables, root and tuber crops and cereals planted in soil previously treated at 200 g a.s./ha. Corresponding soil concentrations of the parent and pyrazole structured metabolites were not measured.

Benzovindiflupyr exhibits very high persistence in soil (DT_{50} = 1,216 days) and the concept of the maximum plateau concentration of benzovindiflupyr should be considered. The portion of the total application rate reaching the soil (effective application rate, A_{eff}) deriving from the uses of the present application amounts to 30 g a.s./ha,[7] which matches the maximum A_{eff} from the use on cereals[8] examined during the peer review (EFSA, 2015), corresponding to PEC_{soil} of 0.01 mg/kg soil, 20 cm soil of a density of 1.5 g/cm^3. The total soil concentration of benzovindiflupyr (PEC_{accu}) is calculated at 0.046[9] mg/kg soil after 19 years of consecutive uses. Four rotational crop field trials were considered in the framework of the peer review (EFSA, 2015). In all trials, benzovindiflupyr was applied on bare soil at a dose rate of 200 g a.s./ha (equivalent to a PEC_{soil} of 0.067 g a.s./kg soil; 20 cm soil of a density of 1.5 g/cm^3; no crop-soil interception). Therefore, the dose rate of the rotational field studies represents a 1.5N[10] dose of the uses under assessment. It can, thus, be concluded that no significant benzovindiflupyr residues are anticipated in succeeding crops following multiannual applications, provided that the active substance is applied to the crops under assessment according to the intended GAPs.

During the EU pesticides peer review of the active substance benzovindiflupyr (EFSA, 2015), EFSA noted that the potential presence of pyrazole structured metabolites above the LOQ levels in some particular rotated crops could not be excluded. Since no confined rotational crop metabolism data were available on the pulses and oilseeds, but this crop group seems more critical in view of the amounts of pyrazole structured metabolites generated, rotational crop field trials to determine the magnitude of these metabolites in pulses and in oilseeds were requested (data gap). It was additionally noticed that the exposure to pyrazole ring structured metabolites will have to be looked cumulatively taking into account the multiple sources (i.e. other fungicides belonging to the pyrazole carboxamide group, such as bixafen, fluxapyroxad, isopyrazam, sedaxane) from which these compounds may originate, including their presence as groundwater metabolites.

Pending the submission of these studies, Member States are recommended to consider the need to implement appropriate mitigation measures in order to avoid the presence of benzovindiflupyr pyrazole structured metabolites in succeeding crops belonging to that crop group of pulses and oilseeds.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the crops under assessment were not submitted and are not required, as significant residues (> 0.1 mg/kg) are not expected in raw agricultural commodities (European Commission, 1997d).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for leeks and spring onions/green onions and Welsh onions. In Section 3 EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as leeks and spring onions, green onions and Welsh onions are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019a). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016a).

[7] The amount of benzovindiflupyr reaching the soil (effective soil application (A_{eff})) when the compound is applied on leeks and spring onions, green onions or Welsh onions according to the intended GAPs is calculated at 30 g/ha, assuming 40% crop interception when applied at the BBCH growth stage of 41–48. Information on the crop interception considered was taken from the EFSA guidance document to obtain DegT50 values (EFSA, 2014).

[8] Foliar treatment, 2 × 75 g a.s./ha, 14 days interval, 1st application at 30–32, 2nd at 57–59 or 67–69; A_{eff} = 30 g a.s./ha.

[9] $PEC_{accu} = PEC_{soil\ initial\ (20\ cm)} + PEC_{plateau\ (20\ cm)}$ = 0.01 + 0.0355 = 0.046 mg/kg; 20 cm soil of a density of 1.5 g/cm^3.

[10] 1.5N = 0.067 g a.s./kg soil/0.046 g a.s./kg soil.

The toxicological reference values for benzovindiflupyr used in the risk assessment (i.e. acceptable daily intake (ADI) and acute reference dose (ARfD) values) were derived in the framework of the EU pesticides peer review (European Commission, 2020).

In the framework of the peer review it was highlighted that metabolism studies did not investigate the possible impact of plant and animal metabolism on the isomer ratio of benzovindiflupyr (EFSA, 2015). Further investigation on this matter would in principle be required. It is noted that the EFSA guidance on the risk assessment of compounds that may have stereoisomers has been finalised (EFSA, 2019b). EFSA would therefore recommend to reconsider this point in the framework of the peer review for the renewal of approval of the active substance.

Meanwhile, in the absence of information of the possible preferential degradation of each enantiomer of the racemate mixture in plant and animal commodities, EFSA used in the risk assessment a factor of 2 assuming a complete switch in residue composition of the racemic mixture in the commodities and that all the toxic activities are due to one single isomer. The approach is in line with previous EFSA risk assessments on benzovindiflupyr (EFSA, 2015, 2016).

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodities assessed in this application. The calculations were based on the highest residue (HR) values derived from supervised field trials and the complete list of input values can be found in Appendix D.1.

The short-term exposure did not exceed the ARfD for any of the crops assessed in this application, even after applying the factor of 2 (worst-case assumption), the exposure accounted for 6% of ARfD for leeks and for 1.6% of ARfD for spring onions/green onions and Welsh onions (see Appendix B.3).

For commodities not included in the present MRL application, an indicative short-term exposure assessment was performed with PRIMo 3.1 using the risk assessment values (HR) derived in previous EFSA outputs (EFSA, 2015, 2016) and in the evaluation by the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) (FAO, 2016b) for CXLs adopted in the MRL regulation. It is noted that when using the factor of 2 (worst-case assumption) to take into account possible preferential isomerisation, for table grapes, an exceedance of the ARfD is observed ($59 \times 2 = 118\%$ of the ARfD for the FI child diet). Further refinement of the exposure estimates for this commodity may be possible, such as investigating the impact of the possible preferential isomerisation in plants and animals or establishing an alternative variability factor.

Long-term (chronic) dietary risk assessment

The long-term exposure assessment was performed, taking into account the median residue values (STMR) for the commodities assessed in this application derived from supervised field trials on leeks. For the remaining commodities covered by the MRL regulation, the existing EU MRLs (LOQs) and the STMR values derived in the EU pesticides peer review (EFSA, 2015) and in a previous import tolerance application (EFSA, 2016) were selected as input values. Moreover, STMR values derived by the Joint FAO/WHO Meetings on Pesticide Residues (FAO, 2016b) were selected as input values for CXLs which were implemented by Regulation (EU) 2018/687. It is noted that EU MRLs on animal commodities are set on the basis of CXLs for a residue definition as parent compound only. Conversion factors for risk assessment previously calculated (EFSA, 2016) were used to estimate the contribution of the metabolite monohydroxylated benzovindiflupyr (SYN546039) included in the EU residue definition for risk assessment for animal commodities. The complete list of input values is presented in Appendix D.1.

After applying a factor of 2, the estimated long-term dietary intake amounted to 10% of the ADI (NL toddler diet). The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is minimal ($\leq 0.04\%$ of the ADI). EFSA concluded that the long-term intake of residues of benzovindiflupyr 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.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for leeks and for spring onions/green onions and Welsh onions.

EFSA concluded that the proposed use of benzovindiflupyr on leeks and spring onions/green onions and Welsh onions will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

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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
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EC	emulsifiable concentrate
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
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
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern Europe
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
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organization

Appendix A – Summary of intended GAP 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/L)	Method kind	Range of growth stages and season[c]	Number max	Interval between application (days)	g a.s./ hL	Water (L/ha) min–max	Rate max	Unit		
Leeks	NEU	F	*Puccinia* sp. (PUCCSP)	EC	100	Foliar spray	41–48	1	–	–	300–600	50	g a.s./ha	21	Use of adjuvant is optional dependent on local conditions.
	SEU														
Spring onions/ green onions and Welsh onions	NEU	F	*Puccinia* sp. (PUCCSP)	EC	100	Foliar spray	41–48	1	–	–	300–600	50	g a.s./ha	21	
	SEU														

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.

(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 methods of analysis in plants

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Tomato	4 × ca 132 g/ha foliar spray, 7 days interval	1, 14 DALA	Radiolabelled active substance: [phenyl-^{14}C]-benzovindiflupyr and [pyrazole-^{14}C]-benzovindiflupyr (EFSA, 2015)
	Cereals/grass	Wheat	2 × ca 135 g/ha foliar spray, 35 days interval, BBCH 31 and 69	Forage: 9 DAT1 (BBCH 39); Hay: 10 DALA (BBCH 77); Straw, grain: 40–41 DALA	Radiolabelled active substance: [phenyl-^{14}C]-benzovindiflupyr and [pyrazole-^{14}C]-benzovindiflupyr (EFSA, 2015)
	Pulses/ oilseeds	Soyabean	2 × ca 120 g/ha foliar spray, 21 days interval, BBCH 55-60 and 75	Forage: 11 DAT1 (BBCH 70); Hay: 13 DALA (BBCH 85); Seed: 30 DALA (BBCH 89)	Radiolabelled active substance: [phenyl-^{14}C]-benzovindiflupyr and [pyrazole-^{14}C]-benzovindiflupyr (EFSA, 2015)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Turnip	1 × ca 530 g/ha, soil treatment	30, 90, and 300	Radiolabelled active substance: [phenyl-^{14}C]-benzovindiflupyr and [pyrazole-^{14}C]-benzovindiflupyr (EFSA, 2015)
	Leafy crops	Lettuce			
	Cereal (small grain)	Wheat			
Processed commodities (hydrolysis study)	**Conditions**			**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)			Yes	Radiolabelled active substance: [pyrazole-^{14}C]-benzovindiflupyr (EFSA, 2015)
	Baking, brewing and boiling (60 min, 100°C, pH 5)			Yes	
	Sterilisation (20 min, 120°C, pH 6)			Yes	

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2015)
Rotational crop and primary crop metabolism similar?	Yes	Metabolism more extensive in rotational crops than in primary crops (EFSA, 2015).
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2015)
Plant residue definition for monitoring (RD-Mo)	Benzovindiflupyr	
Plant residue definition for risk assessment (RD-RA)	Benzovindiflupyr	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high oil content, high acid content, dry matrices, and coffee beans: Single residue method (confirmed by multi residue method - QuEChERS). HPLC–MS/MS, LOQ 0.01 mg/kg. ILV available (EFSA, 2015).	

DAT: days after treatment; PBI: plant-back interval; DALA: days after last application; BBCH: growth stages of mono- and dicotyledonous plants; 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. 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	–18	Month	24	Benzovindiflupyr	EFSA (2015)
		Potato	–18	Month	24	Benzovindiflupyr	EFSA (2015)
		Sugar cane	–18	Month	4	Benzovindiflupyr	Investigated up to 4 months EFSA (2015)
	High oil content	Soya bean	–18	Month	24	Benzovindiflupyr	EFSA (2015)
		Coffee bean	–18	Month	4	Benzovindiflupyr	Investigated up to 4 months EFSA (2015)
	High protein content	Broad bean	–18	Month	24	Benzovindiflupyr	EFSA (2015)
	Dry/High starch	Wheat (grain)	–18	Month	24	Benzovindiflupyr	EFSA (2015)
	High acid content	Orange	–18	Month	24	Benzovindiflupyr	EFSA (2015)
	Others	Wheat (straw)	–18	Month	24	Benzovindiflupyr	EFSA (2015)

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]
Leeks, spring onions/green onions and Welsh onions	NEU	0.01; 0.02; 4 × 0.03; 2 × 0.04	Residue trials on leeks conducted with an adjuvant compliant with GAP. NEU and SEU data merged (U-test, 5%). Extrapolation to spring onions/green onions and Welsh onions possible.	0.09	0.05	0.03	–
	SEU	0.01; 2 × 0.03; 0.05					

MRL: maximum residue level; GAP: Good Agricultural Practice.
(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.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No	In a confined rotational crop study lettuce, turnip and wheat were sown in soil treated with benzovindiflupyr at 530 g/ha, residue levels of parent and individual metabolites were mostly below the limit of quantification of 0.01 mg/kg for all plant back intervals (EFSA, 2015).
Residues in rotational and succeeding crops expected based on field rotational crop study?	Inconclusive (pyrazole structured metabolites)	Four rotational crop field trials with leafy, root and tuber vegetables and cereals planted 30, 60 or 360 days after treatment at the dose of 200 g a.s./ha, benzovindiflupyr residue < LOQ of 0.01 mg/kg was found in spinach, carrot (top and root), wheat (grain, forage and straw), except for one trial on wheat straw sowed 30 days after treatment (benzovindiflupyr 0.02 mg/kg). EFSA requested additional crop field trials to determine the magnitude of the parent and its pyrazole structured metabolites in oilseeds and in pulses (data gap) (EFSA, 2015).

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application and are not required.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

ARfD	0.1 mg/kg bw (European Commission, 2020)
Highest IESTI, according to EFSA PRIMo	Leeks: 3% of ARfD Spring onions/green onions, Welsh onions: 0.8% of ARfD
Assumptions made for the calculations	The short-term exposure assessment was calculated for leeks and spring onions/green onions and Welsh onions using the highest residue (HR) levels derived from the residue trials for the commodities under assessment. Even when applying a factor of 2 in the dietary risk assessment assuming a complete switch in residue composition and that the toxicity is attributed to this enantiomer, a risk for consumer is not identified. An exceedance of the ARfD was observed for table grapes after applying the factor of 2 (59 x 2 = 118%). Further refinement of the exposure estimates for this commodity may be possible, such as investigating the impact of the possible preferential isomerisation of the racemic mixture in plants and animals or establishing an alternative variability factor. Calculations performed with PRIMo revision 3.1.

ADI	0.05 mg/kg bw per day (European Commission, 2020)
Highest IEDI, according to EFSA PRIMo	5% ADI (NL toddler diet) Contribution of crops assessed: Leeks: 0.02% of ADI (GEMS/Food G11 diet) Spring onions/green onions, Welsh onions: 0.003% of ADI (IE adult diet)
Assumptions made for the calculations	The long-term exposure assessment was based on the median residue levels derived for raw agricultural commodities (STMR) assessed in the present application. For the remaining commodities covered by the MRL regulation, the STMR values derived in the EU pesticides peer review, in a previous MRL application and by the JMPR were selected as input values (EFSA, 2015, 2016; FAO, 2016b) plus the existing MRLs set at the LOQ were used. For animal commodities conversion factors were applied to estimate risk assessment (EFSA, 2016). Even when applying a factor of 2 in the dietary risk assessment assuming a complete switch in residue composition and that the toxicity is attributed to this enantiomer, a risk for consumer is not identified (max 10% of ADI). Calculations performed with PRIMo revision 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.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: benzovindiflupyr				
0270060	Leeks	0.01*	0.09	The submitted data are sufficient to derive an MRL proposal for the NEU and SEU uses. Risk for consumers unlikely.
0220040	Spring onions/green onions and Welsh onions	0.01*	0.09	The submitted data are sufficient to derive an MRL proposal, by extrapolation, for the NEU and SEU uses. Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.
*: 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

Benzovindiflupyr

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.05	ARfD (mg/kg bw):	0.1
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2020	Year of evaluation:	2020

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	5%	NL toddler	2.70	1%	Apples	1%	Milk: Cattle	0.9%	Table grapes	2%	0.0%
	4%	DE child	1.86	1%	Apples	0.8%	Table grapes	0.4%	Milk: Cattle	0.8%	0.0%
	3%	NL child	1.45	0.7%	Apples	0.6%	Table grapes	0.5%	Milk: Cattle	1.0%	0.0%
	3%	GEMS/Food G07	1.31	0.9%	Wine grapes	0.2%	Barley	0.2%	Table grapes	0.4%	0.0%
	2%	RO general	1.23	1.0%	Wine grapes	0.3%	Tomatoes	0.2%	Milk: Cattle	0.4%	
	2%	GEMS/Food G15	1.23	0.6%	Wine grapes	0.3%	Barley	0.2%	Tomatoes	0.4%	0.0%
	2%	GEMS/Food G06	1.22	0.6%	Tomatoes	0.6%	Table grapes	0.3%	Wheat	0.3%	0.0%
	2%	GEMS/Food G08	1.22	0.6%	Wine grapes	0.3%	Barley	0.2%	Tomatoes	0.4%	0.0%
	2%	GEMS/Food G11	1.21	0.6%	Wine grapes	0.3%	Barley	0.2%	Table grapes	0.4%	0.0%
	2%	PT general	1.19	1%	Wine grapes	0.2%	Table grapes	0.2%	Tomatoes	0.1%	
	2%	IE adult	1.02	0.7%	Wine grapes	0.2%	Table grapes	0.1%	Sheep: Liver	0.4%	0.0%
	2%	FR adult	1.02	1%	Wine grapes	0.1%	Milk: Cattle	0.1%	Wheat	0.2%	0.0%
	2%	FR child 3 15 yr	1.01	0.5%	Milk: Cattle	0.2%	Wine grapes	0.2%	Table grapes	0.9%	0.0%
	2%	DE general	0.99	0.5%	Wine grapes	0.3%	Apples	0.2%	Milk: Cattle	0.5%	0.0%
	2%	DE women 14-50 yr	0.97	0.5%	Wine grapes	0.3%	Apples	0.2%	Milk: Cattle	0.5%	0.0%
	2%	GEMS/Food G10	0.95	0.2%	Tomatoes	0.2%	Wine grapes	0.2%	Barley	0.4%	0.0%
	2%	FR toddler 2 3 yr	0.90	0.6%	Milk: Cattle	0.4%	Apples	0.1%	Wine grapes	0.9%	0.0%
	2%	DK child	0.89	0.3%	Apples	0.3%	Milk: Cattle	0.2%	Rye	0.4%	0.0%
	2%	UK infant	0.87	0.8%	Milk: Cattle	0.2%	Apples	0.1%	Wheat	1%	
	1%	NL general	0.74	0.3%	Wine grapes	0.2%	Milk: Cattle	0.2%	Apples	0.4%	0.0%
	1%	UK toddler	0.74	0.4%	Milk: Cattle	0.2%	Apples	0.2%	Wheat	0.7%	0.0%
	1%	DK adult	0.64	0.6%	Wine grapes	0.1%	Apples	0.1%	Milk: Cattle	0.2%	0.0%
	1%	ES child	0.63	0.2%	Milk: Cattle	0.2%	Wheat	0.2%	Tomatoes	0.5%	0.0%
	1%	ES adult	0.59	0.2%	Wine grapes	0.2%	Barley	0.1%	Tomatoes	0.3%	0.0%
	1%	SE general	0.57	0.2%	Milk: Cattle	0.1%	Tomatoes	0.1%	Wheat	0.5%	0.0%
	1%	UK adult	0.55	0.6%	Wine grapes	0.1%	Tomatoes	0.1%	Wheat	0.2%	0.0%
	1%	UK vegetarian	0.52	0.5%	Wine grapes	0.1%	Tomatoes	0.1%	Wheat	0.2%	0.0%
	1.0%	FI 3 yr	0.49	0.2%	Oat	0.1%	Table grapes	0.1%	Apples	0.1%	0.0%
	0.9%	IT toddler	0.45	0.3%	Wheat	0.3%	Tomatoes	0.1%	Apples	0.1%	0.0%
	0.9%	FR infant	0.43	0.3%	Milk: Cattle	0.2%	Apples	0.0%	Potatoes	0.5%	0.0%
	0.8%	LT adult	0.39	0.2%	Apples	0.1%	Tomatoes	0.1%	Milk: Cattle	0.1%	
	0.8%	FI adult	0.38	0.2%	Wine grapes	0.2%	Coffee beans	0.1%	Tomatoes	0.1%	0.0%
	0.8%	PL general	0.38	0.2%	Apples	0.2%	Table grapes	0.2%	Tomatoes	0.0%	0.0%
	0.7%	FI 6 yr	0.36	0.1%	Oat	0.1%	Table grapes	0.1%	Potatoes	0.1%	0.0%
	0.7%	IT adult	0.36	0.2%	Tomatoes	0.2%	Wheat	0.1%	Apples	0.1%	0.0%
	0.3%	IE child	0.14	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Apples	0.1%	0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Benzovindiflupyr 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 Union.

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

Show results of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
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)
3%	Leeks	0.09/0.05	2.9
0.8%	Spring onions/green onions and Welsh	0.09/0.05	0.78

Expand/collapse list

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

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)
0.7%	Leeks	0.09/0.05	0.66
0.2%	Spring onions/green onions and Welsh	0.09/0.05	0.22

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Leeks/boiled	0.09/0.05	2.9

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
0.9%	Leeks/boiled	0.09/0.05	0.87

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Benzovindiflupyr 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

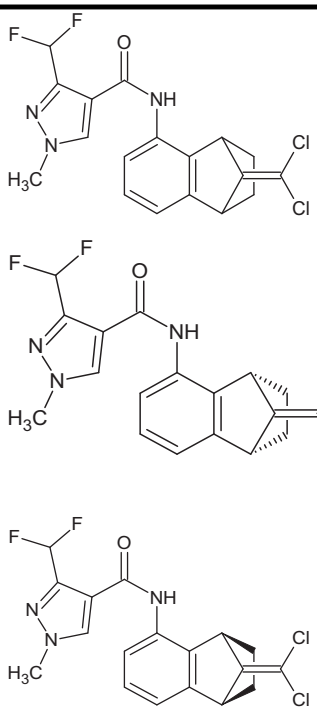
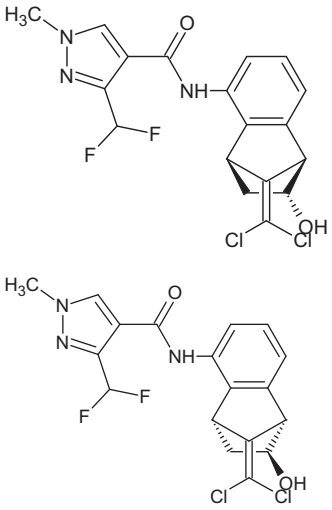
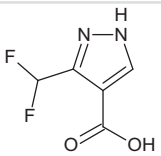
D.1. Consumer risk assessment

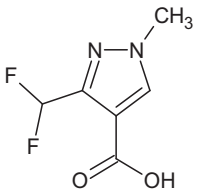
Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[(a)]
Risk assessment residue definition: Benzovindiflupyr						
Apples	0.2	CXL (FAO, 2016b)	0.058	STMR-RAC	0.17	HR-RAC
Pears	0.2	CXL (FAO, 2016b)	0.058	STMR-RAC	0.17	HR-RAC
Quinces	0.2	CXL (FAO, 2016b)	0.058	STMR-RAC	0.17	HR-RAC
Medlar	0.2	CXL (FAO, 2016b)	0.058	STMR-RAC	0.17	HR-RAC
Loquats/Japanese medlars	0.2	CXL (FAO, 2016b)	0.058	STMR-RAC	0.17	HR-RAC
Other pome fruits	0.2	CXL (FAO, 2016b)	0.058	STMR-RAC	0.17	HR-RAC
Table grapes	1	CXL (FAO, 2016b)	0.29	STMR-RAC	0.81	HR-RAC
Wine grapes	1	CXL (FAO, 2016b)	0.29	STMR-RAC	0.81	HR-RAC
Azaroles/Medi. medlars	0.2	CXL (FAO, 2016b)	0.058	STMR-RAC	0.17	HR-RAC
Kaki/Japanese persimmons	0.2	EFSA (2017)	0.058	STMR-RAC	0.17	HR-RAC
Potatoes	0.02	EFSA (2016)	0.01	STMR-RAC	0.02	HR-RAC
Cassava roots/ manioc	0.02	EFSA (2016)	0.01	STMR-RAC	0.02	HR-RAC
Sweet potatoes	0.02	EFSA (2016)	0.01	STMR-RAC	0.02	HR-RAC
Yams	0.02	EFSA (2016)	0.01	STMR-RAC	0.02	HR-RAC
Arrowroots	0.02	EFSA (2016)	0.01	STMR-RAC	0.02	HR-RAC
Other tropical root and tuber vegetables	0.02	EFSA (2016)	0.01	STMR-RAC	0.02	HR-RAC
Jerusalem artichokes	0.02	EFSA (2016)	0.01	STMR-RAC	0.02	HR-RAC
Spring onions/green onions and Welsh onions	**0.09**	**MRL proposal**	**0.03**	**STMR-RAC**	**0.05**	**HR-RAC**
Tomatoes	0.9	CXL (FAO, 2016b)	0.089	STMR-RAC	0.62	HR-RAC
Sweet peppers/bell peppers	1	EFSA (2016)	0.09	STMR-RAC	0.62	HR-RAC
Aubergines/egg plants	0.9	CXL (FAO, 2016b)	0.089	STMR-RAC	0.62	HR-RAC
Okra/lady's fingers	1	EFSA (2016)	0.09	STMR-RAC	0.62	HR-RAC
Other solanacea	1	EFSA (2016)	0.09	STMR-RAC	0.62	HR-RAC
Cucumbers	0.08	EFSA (2016)	0.02	STMR-RAC	0.05	HR-RAC
Gherkins	0.08	EFSA (2016)	0.02	STMR-RAC	0.05	HR-RAC
Courgettes	0.08	EFSA (2016)	0.02	STMR-RAC	0.05	HR-RAC
Other cucurbits - edible peel	0.08	EFSA (2016)	0.02	STMR-RAC	0.05	HR-RAC
Sweet corn	0.01	EFSA (2016)	0.01	STMR-RAC	0.01	HR-RAC
Other fruiting vegetables	0.9	CXL (FAO, 2016b)	0.089	STMR-RAC	0.62	HR-RAC
Leeks	**0.09**	**MRL proposal**	**0.03**	**STMR-RAC**	**0.05**	**HR-RAC**

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[(a)]
Beans	0.2	EFSA (2016)	0.01	STMR-RAC	0.01	STMR-RAC
Lentils	0.2	EFSA (2016)	0.01	STMR-RAC	0.01	STMR-RAC
Peas	0.2	CXL (FAO, 2016b)	0.011	STMR-RAC	0.011	STMR-RAC
Lupins/lupini beans	0.2	EFSA (2016)	0.01	STMR-RAC	0.01	STMR-RAC
Other pulses	0.2	EFSA (2016)	0.01	STMR-RAC	0.01	STMR-RAC
Linseeds	0.15	EFSA (2016)	0.02	STMR-RAC	0.02	STMR-RAC
Peanuts/groundnuts	0.04	CXL (FAO, 2016b)	0.01	STMR-RAC	0.01	STMR-RAC
Poppy seeds	0.15	EFSA (2016)	0.02	STMR-RAC	0.02	STMR-RAC
Rapeseeds/canola seeds	0.2	CXL (FAO, 2016b)	0.023	STMR-RAC	0.023	STMR-RAC
Soyabeans	0.08	CXL (FAO, 2016b)	0.01	STMR-RAC	0.01	STMR-RAC
Mustard seeds	0.15	EFSA (2016)	0.02	STMR-RAC	0.02	STMR-RAC
Cotton seeds	0.15	EFSA (2016)	0.01	STMR-RAC	0.01	STMR-RAC
Gold of pleasure seeds	0.15	EFSA (2016)	0.02	STMR-RAC	0.02	STMR-RAC
Barley	1.5	EFSA (2016)	0.19	STMR-RAC	0.19	STMR-RAC
Maize/corn	0.02	EFSA (2016)	0.01	STMR-RAC	0.01	STMR-RAC
Oat	1.5	EFSA (2016)	0.19	STMR-RAC	0.19	STMR-RAC
Rye	0.1	EFSA (2016)	0.02	STMR-RAC	0.02	STMR-RAC
Wheat	0.1	EFSA (2016)	0.02	STMR-RAC	0.02	STMR-RAC
Coffee beans	0.15	CXL (FAO, 2016b)	0.015	STMR-RAC	0.015	STMR-RAC
Ginger	0.15	EFSA (2016)	0.08	STMR-RAC	0.08	STMR-RAC
Turmeric/curcuma	0.15	EFSA (2016)	0.08	STMR-RAC	0.15	HR-RAC
Sugar canes	0.04	EFSA (2015)	0.015	STMR-RAC	0.02	HR-RAC
Other commodities of plant origin	LOQs as in Regulation (EU) 2018/687					
Risk assessment residue definition: Benzovindiflupyr and mono-hydroxylated benzovindiflupyr, free and conjugated (SYN546039), expressed as benzovindiflupyr						
Swine, bovine, sheep, goat, equine, other farmed animals: Fat tissue	0.03	CXL (FAO, 2016b)	0.06	MRL*CF (2) (EFSA, 2016)	0.06	MRL*CF (2) (EFSA, 2016)
Swine, bovine, sheep, goat, equine, other farmed animals: Liver	0.1	CXL (FAO, 2016b)	0.3	MRL*CF (3) (EFSA, 2016)	0.3	MRL*CF (3) (EFSA, 2016)
Swine, bovine, sheep, goat, equine, other farmed animals: Kidney	0.1	CXL (FAO, 2016b)	0.25	MRL*CF (2.5) (EFSA, 2016)	0.25	MRL*CF (2.5) (EFSA, 2016)
Swine, bovine, sheep, goat, equine, other farmed animals: Edible offal (other than liver and kidney)	0.1	CXL (FAO, 2016b)	0.2	MRL*CF (2) (EFSA, 2016)	0.2	MRL*CF (2) (EFSA, 2016)
Other commodities of animal origin	LOQs as in Regulation (EU) 2018/687					

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; CF: conversion factor; MRL: maximum residue level; CXL: codex maximum residue limit.
(a): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Benzovindiflupyr (SYN545192)	*N*-[(1*RS*,4*SR*)-9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide FC(F)c4nn(C)cc4C(=O)Nc3cccc2C/1CCC(C\1=C(/Cl)Cl)c23 CCCGEKHKTPTUHJ-UHFFFAOYSA-N *N*-[(1*R*,4*S*)-9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide FC(F)c4nn(C)cc4C(=O)Nc3cccc2[C@H]/1CC[C@H](C\1=C(/Cl)Cl)c23 CCCGEKHKTPTUHJ-UHFFFAOYSA-N and *N*-[(1*S*,4*R*)-9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide FC(F)c4nn(C)cc4C(=O)Nc3cccc2[C@@H]/1CC[C@@H](C\1=C(/Cl)Cl)c23 CCCGEKHKTPTUHJ-VHSXEESVSA-N	
SYN546039 (CSCD695908)	*N*-[(1*R*,2*R*,4*S*)-9-(dichloromethylene)-2-hydroxy-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide FC(F)c4nn(C)cc4C(=O)Nc3cccc2[C@@H]1\C(=C(/Cl)Cl)[C@@H](C[C@H]1O)c23 WIDWZCHWWJYFJE-KDDOJWQBSA-N and *N*-[(1*S*,2*S*,4*R*)-9-(dichloromethylene)-2-hydroxy-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide FC(F)c4nn(C)cc4C(=O)Nc3cccc2[C@H]1\C(=C(/Cl)Cl)[C@H](C[C@@H]1O)c23 WIDWZCHWWJYFJE-YDEJPDAXSA-N	
SYN545720 (desmethyl pyrazole acid, CSCD465008)	3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid FC(F)c1nncc1C(O)=O IGQNDARULCASRN-UHFFFAOYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
NOA449410 (pyrazole acid, CSAA798670)	3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxylic acid FC(F)c1nn(C)cc1C(=O)O RLOHOBNEYHBZID-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).
(c): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).