Review of the existing maximum residue levels for isopyrazam according to Article 12 of Regulation (EC) No 396/2005

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance isopyrazam. To assess the occurrence of isopyrazam residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011, the MRLs established by the Codex Alimentarius Commission as well as the import tolerances and European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and one MRL proposal derived by EFSA still requires further consideration by risk managers.

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Keywords: isopyrazam, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, fungicide

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Summary

Isopyrazam was approved on 1 April 2013 by means of Commission Implementing Regulation (EU) No 1037/2012 in the framework of Regulation (EC) No 1107/2009 as implemented by Commission Implementing Regulations (EU) No 540/2011 and 541/2011.

As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation.

As the basis for the MRL review, on 18 February 2020 EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK were invited to submit by 17 March 2020 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State Norway to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States and the UK were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 9 June 2020. On the basis of all the data submitted by Member States, the UK and by the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file were provided by the RMS to EFSA on 25 September 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States, the UK and the EURLs, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011, EFSA prepared in March 2021 a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure. Comments received by 29 April 2021 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of isopyrazam in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement can be proposed as isopyrazam (sum of isomers) and for risk assessment as sum of isopyrazam (sum of isomers) and its metabolite CSCD459488 (free and conjugated), expressed as isopyrazam. These residue definitions are also applicable to processed commodities.

Fully validated analytical methods are available for the enforcement of the proposed residue definition at the limit of quantification (LOQ) of 0.01 mg/kg in high water content, high oil content and dry matrices. According to the EURLs, isopyrazam can be monitored in high water content, high acid content, dry and high fat content commodities with an LOQ of 0.01 mg/kg.

Available residue trials data were considered sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation. Specific MRLs for rotational crops are not needed, provided that Member States will take adequate risk mitigation measures (e.g. define plant back-interval for root crops) in order to avoid significant residues to occur in rotational crops.

Isopyrazam is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance document on residues in livestock (OECD, 2013). The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in all commodities of animal origin.

The metabolism of isopyrazam residues in livestock was investigated in lactating goats and laying hens at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement was proposed as isopyrazam (sum of isomers) and for risk assessment as isopyrazam (sum of isomers) and all its metabolites containing the CSAA798670 moiety, expressed as isopyrazam.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.005 mg/kg (0.0025 mg/kg anti- and syn-isomers) in all matrices is available. According to the EURLs, the LOQ of 0.01 mg/kg may be achievable based on screening data and the general analytical behaviour of isopyrazam in routine analyses.

Livestock feeding study on lactating cows was used to derive MRL and risk assessment values in milk and tissues of ruminants at the LOQ. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs.
For poultry, the metabolism study was sufficient to conclude that residue levels would remain below the enforcement LOQ of 0.01 mg/kg in muscle, fat, liver and eggs.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMO. The highest chronic exposure was calculated for the Dutch toddler, representing 14% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for peach, representing 19% of the acute reference dose (ARfD). Including the existing CXLs in the calculations had no impact on the consumer exposure.

These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Therefore, these uses are unlikely to pose a risk to consumer’s health.

In addition, EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the enantiomer ratio of isopyrazam and further investigation on this matter would in principle be required. EFSA notes that in view of the large margin of safety in the exposure calculations, the potential change of isomer ratios in the final residues is not expected to be of concern for the authorised uses reported in the framework of this review. In case future uses of isopyrazam would lead to a higher consumer exposure, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required.
Background

Regulation (EC) No 396/2005\(^1\) (hereinafter referred to as ‘the Regulation’) establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC\(^2\) a reasoned opinion on the review of the existing MRLs for that active substance.

As isopyrazam was approved on 1 April 2013 by means of Commission Implementing Regulation (EU) No 1037/2012\(^3\) in the framework of Regulation (EC) No 1107/2009\(^4\) as implemented by Commission Implementing Regulations (EU) No 540/2011\(^5\) and 541/2011\(^6\), EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EU) No 188/2011\(^7\) isopyrazam was evaluated by the United Kingdom, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2012b). Furthermore, according to the provisions of the approval regulation, confirmatory information was requested, among others, as regards the relevance of the metabolites CSCD459488 and CSCD459489 for groundwater, to be submitted by 31 March 2015. The Commission Implementing Regulation (EU) No 2015/1106 had extended the deadline for the submission of the confirmatory data to 31 July 2017. In 2020 EFSA finalised a Technical Report on the outcome of the assessment of confirmatory data concerning the risk assessment of isopyrazam (EFSA, 2020). EFSA considered the confirmatory data not addressed, since the non-relevance of metabolite CSCD459488 for groundwater cannot be established.

Furthermore, on 10 December 2020, the Committee for Risk Assessment (RAC) of the European Chemicals Agency adopted an opinion\(^8\) in which it concluded that isopyrazam meets the criteria to be classified as toxic for reproduction category 1B and as carcinogenic category 2.

Accordingly, the confirmatory data were not addressed, since the non-relevance of metabolite CSCD459488 for groundwater cannot be established.

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Furthermore, on 10 December 2020, the Committee for Risk Assessment (RAC) of the European Chemicals Agency adopted an opinion\(^9\) in which it concluded that isopyrazam meets the criteria to be classified as toxic for reproduction category 1B and as carcinogenic category 2.

Given that metabolite CSCD459488 exceeds the limit of 0.1 \(\mu\)g/L in all scenarios for all representative uses and the opinion of RAC that isopyrazam should be classified as R1B, it appears that isopyrazam might no longer satisfy the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It

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1 Regulation (EC) No 396/2005 of the European 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.
2 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32. Repealed by Regulation (EC) No 1107/2009.
3 Commission Implementing Regulation (EU) No 1037/2012 of 7 November 2012 approving the active substance isopyrazam, 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 308, 8.11.2012, p. 15-18.
4 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.
5 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1-186.
6 Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187-188.
7 Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years before the date of notification of that Directive. OJ L 53, 26.2.2011, p. 51-55.
8 Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of Reaction mass of 3-(difluoromethyl)-1-methyl-N-[(1R5,4SR,9SR)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide and 3-(difluoromethyl)-1-methyl-N-[(1R5,4SR,9SR)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide [78% syn-isomers < 15% anti-isomers relative content]; isopyrazam. EC Number: - CAS Number: 881685-58-1 CLH-0-0000006915-65-01/F Adopted 10 December 2020.
should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

As the basis for the MRL review, on 18 February 2020 EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK\(^9\) were invited to submit by 17 March 2020 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation 18 Member States and the UK provided feedback on their national authorisations of isopyrazam. Based on the GAP data submitted, the designated RMS Norway was asked to identify the critical GAPs to be further considered in the assessment, in the format of specific GAP overview file. Subsequently, in a second step, Member States and the UK were requested to provide residue data supporting the critical GAPs by 9 June 2020.

On the basis of all the data submitted by Member States, the UK and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked Norway to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were submitted to EFSA on 25 September 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, and taking into account the MRLs established by the Codex Alimentarius Commission (CAC) (i.e. codex maximum residue limit; CXLs), EFSA prepared in March 2021 a draft reasoned opinion, which was circulated to Member States and EURLs for commenting via a written procedure. All comments received by 29 April 2021 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Norway, 2020), taking into account also the information provided by Member States during the collection of data, and the EURLs report on analytical methods (EURLs, 2020) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2021a) and the Member States consultation report (EFSA, 2021b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROFile as well as the GAP overview file listing all authorised uses and import tolerances are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

**Terms of Reference**

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;

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\(^9\) The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the United Kingdom from the EU, and with the established transition period, the EU requirements on data reporting also apply to the United Kingdom data collected until 31 December 2020.
• the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
• the inclusion of the recommended MRLs in Annex II or III to the Regulation;
• the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

The active substance and its use pattern

Isopyrazam is the ISO common name for a mixture of 3-(difluoromethyl)-1-methyl-N-[(1R,4S,9R)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide [2 syn-isomers] and 3-(difluoromethyl)-1-methyl-N-[(1R,4S,9S)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide [2 anti-isomers] (IUPAC).

The chemical structure of the active substance and its main metabolites are reported in Appendix F.

The EU MRLs for isopyrazam are established in Annexes IIIA of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for isopyrazam were also established by the CAC. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

| Procedure                     | Legal implementation | Remarks                                                                 |
|-------------------------------|----------------------|------------------------------------------------------------------------|
| Implementation of CAC 2018    | Commission Regulation (EU) No 552/2019¹ | Azaroles/Mediterranean medlars, Kaki/Japanese persimmons (EFSA, 2018a) |
| MRL application               | Commission Regulation (EU) No 1101/2015² | Various crops: tomatoes, aubergines, cucurbits-edible peel and cucurbits-inedible peel (EFSA, 2015) |
| MRL application               | Commission Regulation (EU) No 834/2013³ | Pome fruits, apricots, peaches, linseed, poppy seed, rape seed and mustard seed (EFSA, 2013b) |
| MRL application               | Commission Regulation (EU) No 364/2014⁴ | Various vegetables: various root and tuber vegetables, peppers and cucurbits (edible and inedible peel) (EFSA, 2013a) |
| MRL application               | Commission Regulation (EU) No 978/2011⁵ | Bananas (EFSA, 2011)                                                   |
| MRL application               | Commission Regulation (EU) No 524/2011⁶ | Several cereals and food commodities of animal origin: wheat, rye, barley, oats, bovine fat, kidney, liver, meat, milk (EFSA, 2010) |

¹: Commission Regulation (EU) 2019/552 of 4 April 2019 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 azoxystrobin, bicyclopyrone, chlorimequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumizopyrim in or on certain products. OJ L 96, 5.4.2019, p. 6-49.
²: Commission Regulation (EU) 2015/1101 of 8 July 2015 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 difenoconazole, fluopicolide, fluopyram, isopyrazam and pendimethalin in or on certain products. OJ L 181, 9.7.2015, p. 27-53.
³: Commission Regulation (EU) No 834/2013 of 30 August 2013 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 acequinocyl, bixaen, diazinon, difenoconazole, etoxazole, fenhexamid, fludioxonil, isopyrazam, lambda-cyhalothrin, profenofos and prothiocynacozole in or on certain products. OJ L 233, 31.8.2013, p. 11-42.
⁴: Commission Regulation (EU) No 364/2014 of 4 April 2014 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 fenpyroximate, flubenimidazole, isopyrazam, kresoxim-methyl, spirotetramat and thiacloprid in or on certain products. OJ L 112, 15.4.2014, p. 1-34.
⁵: Commission Regulation (EU) No 978/2011 of 3 October 2011 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 acetamiprid, biphenvyl, captan, chlorantraniliprole, cyflufenamid, cymoxanil, dichlorprop-P, difenoconazole, dimethomorph, dithiocarbamates, epoxiconazole, ethophon, flutriafol, flupyroxad, isopyrazam, propamocarb, pyraclostrobin, pyrimethanil and spirotetramat in or on certain products. OJ L 258, 4.10.2011, p. 12-69.
⁶: Commission Regulation (EU) No 524/2011 of 26 May 2011 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 biphenvyl, deltamethrin, ethofumesate, isopyrazam, propiconazole, pymetrozine, pyrimethanil and tebuconazole in or on certain products. OJ L 142, 28.5.2011, p. 1-56.

For the purpose of this MRL review, all the uses of isopyrazam currently authorised within the EU and in third countries as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for isopyrazam are given in Appendix A.
Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Norway, 2020);
- the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2010, 2012);
- the conclusion on the peer review of the pesticide risk assessment of the active substance isopyrazam (EFSA, 2012b);
- the review report on isopyrazam (European Commission, 2012);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2017);
- the previous reasoned opinions on isopyrazam (EFSA, 2010, 2011, 2013a,b, 2015).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013; EFSA, 2019b).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

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 isopyrazam was investigated after foliar treatment in fruits (grapes), leafy vegetables (lettuce) and cereals (wheat) (United Kingdom, 2012) and assessed in the framework of the peer-review (EFSA, 2012b). In all studies isopyrazam was radiolabelled in the phenyl ring and the pyrazole ring of the molecule with a ratio of syn- and anti-isomers of 70:30 or 95:5.

Grapes were treated once at a rate of 400 g a.s./ha, while lettuce and wheat were treated with three foliar applications of 125 g a.s./ha. Samples were taken at 21 (grape berries and vine leaves); 3 and 14 (immature and mature lettuce); 13 (forage) and 46–48 (straw, grain) days after last treatment.

In all cases, parent remained by far the major component of the total radioactive residues (TRR) accounting for 35% to 91% TRR in the mature crops. In mature lettuce, also metabolite CSCD459488 (syn-hydroxy isopyrazam) including its conjugates was a major component (up to 16% TRR). CSCD459489 (anti-hydroxy isopyrazam) and all other metabolites (including CSCD465008) were present in much lower proportions and concentrations.

Overall, a similar metabolic pathway was observed in all crops. The metabolism of isopyrazam is limited, only metabolite CSCD459488 in lettuces was detected above 10% TRR.

1.1.2. Nature of residues in rotational crops

Isopyrazam is authorised on crops that may be grown in rotation. The field DT$_{90}$ of isopyrazam and of metabolite CSCD459488, reported in the soil degradation studies evaluated in the framework of the peer review were more than 1 year and the DT$_{90}$ of metabolite CSCD465008 exceeded 100 days (EFSA, 2012b).

The metabolism and distribution of isopyrazam in rotational crops were investigated in wheat, turnips and lettuce in the framework of the peer review (EFSA, 2012b). Isopyrazam radiolabelled on the pyrazole or the phenyl ring was applied to bare soil at a rate of 0.36 kg as/ha. Crops were planted 30, 90 and 300 days after treatment (DAT).

The total radioactive residues in the edible parts of the rotational crops at harvest and at all plant back intervals were low with a maximum level of 0.03 mg/kg in lettuce and 0.02 mg/kg in wheat grain and turnip roots and 0.05 mg/kg in turnip tops. The total residues in wheat straw amounted to up to

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10 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.
0.92 mg/kg at the 30-day plant-back interval (PBI) and slightly decreased to 0.71 mg/kg at the 300-day PBI.

Isopyrazam and its metabolites were below the limit of quantification (LOQ) of 0.01 mg/kg in all edible part of crops, with the exception of CSCD465008 found at 0.01 mg/kg in lettuce (up to 35% TRR). CSCD465008 was also significant in turnip tops (up to 0.02 mg eq/kg; 32% TRR). Residues of CSCD459488 (free and conjugated) were found at significant levels in straw (up to 13% TRR, 0.13 mg eq/kg in straw).

Altogether, the studies indicated that the parent molecule is cleaved and uptake of components containing the pyrazole ring structure (e.g. CSCD465008, CSAA798670), in particular into leafy crop parts, is more pronounced.

The metabolism and distribution of isopyrazam in rotational crops and in primary crops is broadly similar.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were assessed in the framework of the peer review (United Kingdom, 2012; EFSA, 2012b). Studies were conducted with radiolabelled isopyrazam on the pyrazole and phenyl ring simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). It was concluded that isopyrazam is stable to hydrolysis under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation (EFSA, 2012b).

1.1.4. Methods of analysis in plants

During the peer review a multi-residue method S19 based on high performance liquid chromatography (HPLC) coupled to tandem mass spectrometry (MS/MS) detection was validated in high water (apple) content, high oil (rape seed) content and dry (wheat grain) commodities, with an LOQ of 0.01 mg/kg (0.005 mg/kg for the syn- and anti-isomer, each). Validation data were provided for two different mass transitions. This primary method is supported by an independent laboratory validation (ILV) for high oil content and dry matrices (EFSA, 2012b). An ILV was also provided for the determination of isopyrazam residues in high water content commodities in the framework of the current review (Norway, 2020). The method is not enantioselective.

According to the EURLs, isopyrazam can be monitored in high water content, high acid content, dry and high fat content commodities with an LOQ of 0.01 mg/kg. In high water content and high acid content commodities, even lower levels down to 0.002 mg/kg were successfully validated. Dry and high fat content commodities were successfully validated down to 0.005 mg/kg (EURLs, 2020).

1.1.5. Stability of residues in plants

The storage stability of isopyrazam and its metabolites CSCD459488 and CSCD459489 (syn-anti hydroxy-isopyrazam), CSCD465008 and CSAA798670 was investigated in the framework of the peer review (EFSA, 2012b).

In high water content (tomato, apple, lentils, potatoes), high oil content (rapeseed) matrices, and dry/high starch content (cereal grain) commodities, and in straw the storage stability for isopyrazam was demonstrated for at least 24 months when stored at –18°C. The storage stability for metabolite CSCD459488 was demonstrated for at least 28 months in high water content (apple, lentils, carrots, spinach), high acid (orange), high oil content (rapeseed) matrices, and dry/high starch content (cereal grain) commodities, and in straw. Metabolites CSCD465008 and CSAA798670, investigated in rotational field trials, were stable for at least 12 months in wheat grain and straw, barley forage, spinach, carrot tops and roots.

1.1.6. Proposed residue definitions

The metabolism of isopyrazam was similar in all rotational and primary crops assessed. The processing of isopyrazam is not expected to modify the nature of residues.

As isopyrazam was found to be a sufficient marker in all crops investigated, the residue definition for enforcement is proposed as isopyrazam (sum of isomers).

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in high water content, high oil content and dry matrices is available (EFSA, 2012b;
Norway, 2020). According to the EURLs isopyrazam can be monitored in high water content, high acid content, dry and high fat content commodities with an LOQ of 0.01 mg/kg (EURLs, 2020).

For risk assessment, parent and metabolite CSCD459488 (free and conjugated) are toxico logically relevant and thus should be considered in the consumer exposure. The toxicological reference values set for isopyrazam are also applicable to its hydroxy-isopyrazam metabolite CSCD459488 (EFSA, 2012b). In addition, the toxicological reference values set for isopyrazam can be applied in the dietary risk assessment up to a ratio of 50:50 syn-/anti-isomers (EFSA, 2012b).

CSCD465008 (3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid), a soil metabolite, which is taken up at low levels in rotational leafy crops in field trials (see Sections 1.1.2 and 1.2.2), is a common metabolite with bixafen, fluxapyroxad, and sedaxane. During the peer-review on fluxapyroxad, an acceptable daily intake (ADI) of 0.3 mg/kg body weight (bw) per day for CSCD465008 (M700F002) was proposed, whereas no acute reference dose (ARID) was considered necessary (EFSA, 2012a). Overall, considering the results from the rotational crop field trials, it can be concluded that for the authorised uses of isopyrazam, consumers are not expected to be exposed to significant residues of this metabolite and therefore there is no need to include it in the residue definition for risk assessment.

Therefore, the residue for risk assessment set by the peer review as the sum of isopyrazam (sum of isomers) and its metabolite CSCD459488 (free and conjugated), expressed as isopyrazam remains applicable.

Isopyrazam is a mixture of two enantiomeric pairs of syn- and anti-isomers, respectively. The methods of analysis used in the residue studies were able to distinguish syn-isomers from anti-isomers, but the methods were not enantioselective. Thus, no information on the behaviour of the individual enantiomers is available. Therefore, all residues reported as either syn- or anti-isopyrazam or its syn- or anti- metabolites are for the sum of enantiomers, respectively. In addition, EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the enantiomer ratio of isopyrazam and further investigation on this matter would in principle be required. In view of the large margin of safety in the exposure calculation, the potential change in enantiomer ratios in the final residue is not expected to be of concern for the authorised uses in the framework of this review. In case future uses of isopyrazam would lead to a higher consumer exposure, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of isopyrazam residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Norway, 2020) as well as the residue trials evaluated in the framework of the peer review (EFSA, 2012b) or in the framework of a previous MRL application (EFSA, 2010, 2011, 2013a,b, 2015). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected.

Moreover, the change of ratio of syn- and anti-isomers of isopyrazam was not significant in the assessed commodities (EFSA, 2012b, 2015).

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

Available residue trials are sufficient to derive (tentative) MRL and risk assessment values, taking note of the following considerations:

- **Tomato**: MRL and risk assessment values can be derived from the indoor GAP. Although the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop, as the indoor GAP is clearly more critical, further residue trials supporting the southern outdoor GAP are not required.
- **Rapeseeds**: MRL and risk assessment values can be derived from the southern outdoor GAP. Although the northern GAP is supported by overdosed trials, as it is clearly less critical, further residue trials compliant with the northern outdoor GAP are not required.
- **Mustard seeds**: Although tentative MRL and risk assessment values can be derived from the northern overdosed residue trials, four trials compliant with the northern GAP are still required.
1.2.2. Magnitude of residues in rotational crops

According to the confined rotational crop studies, isopyrazam and its metabolites may be taken up in rotational crops. As the DT$_{90}$ value for isopyrazam exceeds 1 year, it is likely to accumulate in soils treated for several consecutive years. Therefore, particular attention has to be paid to the plateau concentration expected in soil after several years of applications.

Considering the degradation rates of isopyrazam, the maximum application rate of 2 × 125 g/ha per year assessed in this review (foliar treatment authorised on root vegetables), a soil bulk density of 1.5 g/cm$^3$, a soil mixing depth of 20 cm and 25% + 60% crop interception for first and second application, respectively, the total soil concentration of isopyrazam in soil (PEC soil total), resulting from the multiannual use of isopyrazam at the critical GAP (PEC plateau background) plus the maximal seasonal application rate (to cover possible crop failure), was calculated as 0.145 mg/kg soil, equivalent to 435 g/ha.

Rotational crop residue trials, conducted at 375 g a.s./ha (~0.9N of the expected plateau concentration of isopyrazam in soil), were assessed during the peer review (EFSA, 2012b). Winter wheat was treated as primary crop (3 × 250 g a.s./ha), destroyed 10–18 days, 40–46 days or 1 year later and ploughed back into the soil. Within roughly 30, 60 or 365 days after the last application (DAT), rotational crops (barley, spinach and carrots) were planted. Samples from rotational crops were taken up to maturity and analysed for isopyrazam [syn- and anti-isomers], CSCD459488, CSCD459489, CSCD465008 and CSAA798670.

With few exceptions, residues in crops for human consumption were below the LOQ of the analytical method for syn- and anti-isopyrazam and the four pertinent metabolites (B.1.2.2). At harvest, isopyrazam (sum of isomers) was always below the LOQ at any PBI in all crop parts, except once in carrot roots it was detected at the LOQ of 0.01 mg/kg (PBI of 30 days).

Residues of CSCD459488 were detected in spinaches up to 0.015 mg/kg at the (PBI 60 days), and in barley grain up to 0.03 mg/kg (PBI 60 days). For the PBI of 365 days, CSCD459488 was only detected in one sample, at low levels in spinaches and grain (0.006 mg/kg and 0.008 mg/kg, respectively). It is underlined that no information is available, whether in the field trials, metabolite CSCD459488 was formed at sufficient levels in soil to cover its accumulation following multiannual use of isopyrazam. Therefore, the level of CSCD459488 in rotational crops may be underestimated.

The common metabolite, CSCD465008 was only identified in spinaches up to 0.06 mg/kg (PBI 60 days) and could still be detected at low levels (up to 0.02 mg/kg) at PBI 365 days and in carrot tops (up to 0.15 mg/kg PBI 60 days).

CSAA798670 was below the LOQ of 0.01 mg/kg in all crops at all PBIs.

Based on the study results, EFSA concludes that, in case of a crop failure, residues of isopyrazam (sum of isomers) at or above 0.01 mg/kg cannot be excluded in rotated root crops. This information should be considered by risk managers for the adoption of possible mitigation measures. Parent isopyrazam is not expected to be present in leafy crops, in the aerial part of root crops or cereals grown in rotation at any of the PBIs. Although metabolite CSCD459488 may occur in succeeding crops (cereals, leafy crops), in view of the large margin of safety for consumers (Appendix B.3.1) it is not considered to be of concern at the levels present.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on apples, bananas, tomatoes, melons, barley, wheat (EFSA, 2011, 2012b, 2013a,b, 2015). An overview of all available processing studies is available in Appendix B.1.2.3. Robust processing factors (fully supported by data) could be derived for processed commodities from apple (juice, dry and wet pomace, sauce); bananas (peeled); tomato (unpeeled and canned, paste, ketchup, juice, dried); melons (peeled); barley (beer, pot/pearl, brewing malt, dry brewer's grain), wheat (whole-meal flour, whole-meal bread, white flour).

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for mustard seeds, where tentative MRLs are
derived. Tentative MRLs were also derived for cereal straw in view of the future need to set MRLs in feed items.

Specific MRLs for rotational crops are not needed, provided that Member States will take adequate risk mitigation measures (e.g. define plant back-interval for root crops) in order to avoid significant residues to occur in rotational crops.

2. Residues in livestock

Isopyrazam is authorised for use on several crops e.g. pome fruits, root vegetables, cereals that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in all commodities of animal origin.

Although for turnip tops, which may also be fed to animals, no residue data were available, this is not expected to have a major impact on the outcome of the dietary burden considering the high contribution of straw.

2.1. Nature of residues and methods of analysis in livestock

The metabolism of isopyrazam residues in livestock was investigated in lactating goats and laying hens at dose rates covering the maximum dietary burdens calculated in this review. These studies were assessed in the framework of the peer-review (EFSA, 2012b). Studies were conducted with isopyrazam radiolabelled in the phenyl ring and the pyrazole ring of the molecule with a ratio of syn- and anti-isomers of 70:30 or 95:5. Additionally, the metabolism of 14C-labelled CSCD459488, the major plant metabolite, was also investigated in goats.

Lactating goats were dosed at a rate of 29–45 mg/kg in feed (0.78–0.93 mg/kg bw per day, 6.5N–7.5N) for 7 days with 14C-labelled isopyrazam. Parent isopyrazam and its metabolite CDCD656800 were the major components identified in milk and other animal commodities. Isopyrazam was the predominant contributor of residues in fat (up to 50% TRR), while CDCD656800 (syn/anti-dihydroxy-isopyrazam) was the predominant residue in all other animal commodities (17–44% TRR). In the study conducted with 14C labelled CSCD459488, metabolite CDCD656800 was the predominant component of the residue in all animal commodities (33–56% TRR), even in fat. The same metabolism pattern was observed in the studies conducted with laying hens fed with 11 mg/kg feed (0.82–0.89 mg/kg bw; 8N). In both goats and poultry, further metabolites were observed in amounts greater than 10% of the TRR, in individual matrices only.

Considering the performance of the analytical methods for enforcement and used in the studies, the peer review established the residue definition for monitoring as isopyrazam (sum of isomers) and for risk assessment as isopyrazam (sum of isomers) and all its metabolites containing the CSAA798670 moiety, expressed as isopyrazam. These residue definitions are considered still applicable.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.005 mg/kg (0.0025 mg/kg anti- and syn-isomers) in all matrices is available (EFSA, 2012b). According to the EURLs, based on screening data, isopyrazam can be monitored in milk, muscle and honey at the default LOQ of 0.01 mg/kg. Based on the experience gained for muscle, honey and milk, and the general analytical behaviour of isopyrazam, the EURLs assumed that the default LOQ of 0.01 mg/kg would also be achievable for other main commodity groups of animal origin (liver, kidney, fat)(EURLs, 2020).

The storage stability of isopyrazam (anti- and syn-isomers) and its metabolites containing the CSAA798670 moiety was demonstrated for a period of 14 months and 12 months, respectively at –18°C in muscle, fat, liver, kidney, milk and eggs (United Kingdom, 2012; EFSA, 2012b).

Given the accumulation of residues in fatty tissues, the residue definition is considered fat soluble (EFSA, 2012b).

2.2. Magnitude of residues in livestock

A livestock feeding study with isopyrazam (syn/anti ratio of 70:30) was carried out on dairy cows (dose levels of 15, 42 and 140 mg/kg feed DM per day, equivalent to 0.37, 1.13 and 3.59 mg/kg bw per day, for 28 consecutive days) and assessed in the DAR (United Kingdom, 2010, 2012) and in the conclusion of the peer review (EFSA, 2012b).
The study performed on dairy cows was used to derive MRL and risk assessment values in milk and tissues of ruminants. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. In this study, samples of tissues and milk were analysed for both isopyrazam, and isopyrazam plus its metabolites containing the CSAA798670 moiety. The storage period of the samples was covered by the conditions for which storage stability was demonstrated thus decline of residues during storage of the trial samples is not expected.

Based on the cow feeding study, significant residues are not expected and MRL and risk assessment values were derived for all ruminant, pig and horse commodities at the LOQ of 0.01 mg/kg, with the exception of sheep fat (Appendix B.2.2).

According to the peer review, there was also indication that the syn/anti ratio of isomers of isopyrazam in animal products had changed from 70:30 to 50:50 possibly due to preferential metabolism or excretion of the syn-isomer by the animals. Considering the very low residues in animal matrices and the applicability of the isopyrazam toxicological reference values to a ratio of 50:50 syn/- anti-isomers, the observed change of the ratio of isomers was considered not to be of concern for the consumer (EFSA, 2012b).

For poultry, the metabolism study (performed at 8N rate compared to the maximum dietary burden) is sufficient to conclude that residues of isopyrazam and its metabolites are expected to remain below the enforcement LOQ of 0.01 mg/kg in muscle, fat, liver and eggs. Hence, no livestock feeding study is needed and MRLs and risk assessment values for the relevant commodities in poultry can be established at the LOQ level.

3. Consumer risk assessment

In the framework of this review, only the uses of isopyrazam reported by the RMS in Appendix A were considered; however, the use of isopyrazam was previously also assessed by the JMPR (FAO, 2011, 2017). The CXLs, resulting from these assessments by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

The residue definition for enforcement in plants and animals established by JMPR is the same as in the current assessment. However, the residue definition for risk assessment in plants does not include the conjugates of CSCD459488, whereas in animal commodities it is limited to parent only. Nonetheless, as the proposed EU MRLs cover the existing Codex MRLs, with the exception of peanuts and some animal commodities (fat, liver and kidney) and by the use of the CF for animal commodities established for the EU MRLs, the uncertainty due to the narrower residue definitions compared to the one proposed by EFSA is of minor relevance.

3.1. Consumer risk assessment without and with consideration of the existing CXLs

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018b, 2019a). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). An overview of the input values used for this exposure calculation is provided in Appendix D.1.

In a second calculation of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix E and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. An overview of the input values used for this exposure calculation is provided in Appendix D.2.

The exposure values calculated were compared with the toxicological reference values for isopyrazam, derived by EFSA (EFSA, 2012b). The highest chronic exposure was calculated for the Dutch toddler, representing 14% of the ADI, and the highest acute exposure was calculated for peach, representing 19% of the ARfD. Including the existing CXLs in the calculations had no impact on the consumer exposure.
These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Therefore, these uses are unlikely to pose a risk to consumer’s health.

In addition, EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the enantiomer ratio of isopyrazam and further investigation on this matter would in principle be required. EFSA notes that in view of the large margin of safety in the exposure calculations, the potential change of enantiomer ratios in the final residues is not expected to be of concern for the authorised uses reported in the framework of this review. In case future uses of isopyrazam would lead to a higher consumer exposure, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required.

Conclusions

The metabolism of isopyrazam in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement can be proposed as isopyrazam (sum of isomers) and for risk assessment as sum of isopyrazam (sum of isomers) and its metabolite CSCD459488 (free and conjugated), expressed as isopyrazam. These residue definitions are also applicable to processed commodities.

Fully validated analytical methods are available for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in high water content, high oil content and dry matrices. According to the EURLs isopyrazam can be monitored in high water content, high acid content, dry and high fat content commodities with an LOQ of 0.01 mg/kg.

Available residue trials data were considered sufficient to derive (tentative) MRL proposals as well as risk assessment values for all commodities under evaluation. Specific MRLs for rotational crops are not needed, provided that Member States will take adequate risk mitigation measures (e.g. define plant back-interval for root crops) in order to avoid significant residues to occur in rotational crops.

Isopyrazam is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance document on residues in livestock (OECD, 2013). The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in all commodities of animal origin.

The metabolism of isopyrazam residues in livestock was investigated in lactating goats and laying hens at dose rate covering the maximum dietary burdens calculated in this review. According to the results of these studies, the residue definition for enforcement was proposed as isopyrazam (sum of isomers) and for risk assessment as isopyrazam (sum of isomers) and all its metabolites containing the CSAA798670 moiety, expressed as isopyrazam.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.005 mg/kg (0.0025 mg/kg anti- and syn-isomers) in all matrices is available. According to the EURLs, the LOQ of 0.01 mg/kg may be achievable based on screening data and the general analytical behaviour of isopyrazam in routine analyses.

Livestock feeding study on lactating cows was used to derive MRL and risk assessment values in milk and tissues of ruminants at the LOQ. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs.

For poultry, the metabolism study was sufficient to conclude that residue levels would remain below the enforcement LOQ of 0.01 mg/kg in muscle, fat, liver and eggs.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. The highest chronic exposure was calculated for the Dutch toddler, representing 14% of the ADI, and the highest acute exposure was calculated for peach, representing 19% of the ARfD. Including the existing CXLs in the calculations had no impact on the consumer exposure.

These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Therefore, these uses are unlikely to pose a risk to consumer’s health.

In addition, EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the enantiomer ratio of isopyrazam and further investigation on this matter would in principle be required. EFSA notes that in view of the large margin of safety in the exposure calculations, the potential change of isomer ratios in the final residues is not expected to be
of concern for the authorised uses reported in the framework of this review. In case future uses of isopyrazam would lead to a higher consumer exposure, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required.

**Recommendations**

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). One tentative MRL, not sufficiently supported by data, need to be confirmed by the following data:

- Four residue trials supporting the northern outdoor GAP on mustard seeds.

To inform further risk management discussions, it is noted that isopyrazam might no longer satisfy the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.

**Table 2:** Summary table

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|------------------------|----------------------|-----------------------|---------|
| 130010      | Apples    | 0.7                    | 0.4                  | Further consideration needed<sup>(a)</sup> |         |
| 130020      | Pears     | 0.7                    | 0.4                  | Further consideration needed<sup>(a)</sup> |         |
| 130030      | Quinces   | 0.7                    | 0.4                  | Further consideration needed<sup>(a)</sup> |         |
| 130040      | Medlar    | 0.7                    | 0.4                  | Further consideration needed<sup>(a)</sup> |         |
| 130050      | Loquat    | 0.7                    | 0.4                  | Further consideration needed<sup>(a)</sup> |         |
| 140030      | Peaches   | 1.5                    |                      | Further consideration needed<sup>(b)</sup> |         |
| 163020      | Bananas   | 0.05                   | 0.06                 | Further consideration needed<sup>(b)</sup> |         |
| 213010      | Beetroot  | 0.2                    |                      | Further consideration needed<sup>(b)</sup> |         |
| 213020      | Carrots   | 0.2                    | 0.15                 | Further consideration needed<sup>(a)</sup> |         |
| 213030      | Celeriac  | 0.2                    |                      | Further consideration needed<sup>(b)</sup> |         |
| 213040      | Horseradish | 0.2                |                      | Further consideration needed<sup>(b)</sup> |         |
| 213050      | Jerusalem artichokes | 0.2         |                      | Further consideration needed<sup>(b)</sup> |         |
| 213060      | Parsnips  | 0.2                    |                      | Further consideration needed<sup>(b)</sup> |         |
| 213070      | Parsley root | 0.2              |                      | Further consideration needed<sup>(b)</sup> |         |
| 213080      | Radishes  | 0.2                    |                      | Further consideration needed<sup>(b)</sup> |         |
| 213090      | Salsify   | 0.2                    |                      | Further consideration needed<sup>(b)</sup> |         |
| 213100      | Swedes    | 0.2                    |                      | Further consideration needed<sup>(b)</sup> |         |
| 213110      | Turnips   | 0.2                    |                      | Further consideration needed<sup>(b)</sup> |         |
| 231010      | Tomatoes  | 0.5                    | 0.4                  | Further consideration needed<sup>(b)</sup> |         |
| 231020      | Peppers   | 0.09                   | 0.09                 | Further consideration needed<sup>(a)</sup> |         |
| 231030      | Aubergines (egg plants) | 0.5     | 0.4                  | Further consideration needed<sup>(a)</sup> |         |
| 232010      | Cucumbers | 0.4                    | 0.06                 | Further consideration needed<sup>(a)</sup> |         |
| 232020      | Gherkins  | 0.4                    |                      | Further consideration needed<sup>(b)</sup> |         |
| 232030      | Courgettes | 0.4                |                      | Further consideration needed<sup>(b)</sup> |         |
| 233010      | Melons    | 0.3                    | 0.15                 | Further consideration needed<sup>(a)</sup> |         |
| 233020      | Pumpkins  | 0.3                    |                      | Further consideration needed<sup>(b)</sup> |         |
| 233030      | Watermelons | 0.3                  |                      | Further consideration needed<sup>(b)</sup> |         |
| 401020      | Peanuts   | 0.01*                  | 0.01*                | Further consideration needed<sup>(c)</sup> |         |
| 401060      | Rape seed | 0.4                    | 0.2                  | Further consideration needed<sup>(b)</sup> |         |
| 401080      | Mustard seed | 0.4                |                      | Further consideration needed<sup>(d)</sup> | data gap #1 |
| 500010      | Barley grain | 0.6             | 0.6                  | Further consideration needed<sup>(a)</sup> |         |
| 500050      | Oats grain | 0.6                    |                      | Further consideration needed<sup>(b)</sup> |         |
| Code number | Commodity       | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|------------|-----------------|-------------------------|----------------------|-----------------------|---------|
| 500070     | Rye grain       | 0.2                     | 0.03                 | 0.2                   | Further consideration needed<sup>(a)</sup> |
| 500090     | Wheat grain     | 0.2                     | 0.03                 | 0.2                   | Further consideration needed<sup>(a)</sup> |
| 1011010    | Swine meat      | 0.01*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1011020    | Swine fat       | 0.03                    | 0.03                 | 0.03                  | Further consideration needed<sup>(a)</sup> |
| 1011030    | Swine liver     | 0.02                    | 0.02                 | 0.02                  | Further consideration needed<sup>(e)</sup> |
| 1011040    | Swine kidney    | 0.02                    | 0.02                 | 0.02                  | Further consideration needed<sup>(e)</sup> |
| 1012010    | Bovine meat     | 0.01*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1012020    | Bovine fat      | 0.03                    | 0.03                 | 0.03                  | Further consideration needed<sup>(e)</sup> |
| 1012030    | Bovine liver    | 0.02                    | 0.02                 | 0.02                  | Further consideration needed<sup>(e)</sup> |
| 1012040    | Bovine kidney   | 0.02                    | 0.02                 | 0.02                  | Further consideration needed<sup>(e)</sup> |
| 1013010    | Sheep meat      | 0.01*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1013020    | Sheep fat       | 0.03                    | 0.03                 | 0.03                  | Further consideration needed<sup>(e)</sup> |
| 1013030    | Sheep liver     | 0.02                    | 0.02                 | 0.02                  | Further consideration needed<sup>(e)</sup> |
| 1013040    | Sheep kidney    | 0.02                    | 0.02                 | 0.02                  | Further consideration needed<sup>(e)</sup> |
| 1014010    | Goat meat       | 0.01*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1014020    | Goat fat        | 0.03                    | 0.03                 | 0.03                  | Further consideration needed<sup>(e)</sup> |
| 1014030    | Goat liver      | 0.02                    | 0.02                 | 0.02                  | Further consideration needed<sup>(e)</sup> |
| 1014040    | Goat kidney     | 0.02                    | 0.02                 | 0.02                  | Further consideration needed<sup>(e)</sup> |
| 1015010    | Horse meat      | 0.01*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1015020    | Horse fat       | 0.03                    | 0.03                 | 0.03                  | Further consideration needed<sup>(e)</sup> |
| 1015030    | Horse liver     | 0.02                    | 0.02                 | 0.02                  | Further consideration needed<sup>(e)</sup> |
| 1015040    | Horse kidney    | 0.02                    | 0.02                 | 0.02                  | Further consideration needed<sup>(e)</sup> |
| 1016010    | Poultry meat    | 0.01*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1016020    | Poultry fat     | 0.01*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1016030    | Poultry liver   | 0.01*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1020010    | Cattle milk     | 0.01*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1020020    | Sheep milk      | 0.01*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1020030    | Goat milk       | 0.01*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1020040    | Horse milk      | 0.01*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
| 1030000    | Birds’ eggs     | 0.01*                   | 0.01*                | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|            | Other commodities of plant and/or animal origin | See Reg. 552/2019 | – | – | Further consideration needed<sup>(f)</sup> |

MRL: maximum residue level; CXL: codex maximum residue limit.

*: Indicates that the MRL is set at the limit of quantification.

(F): The residue definition is fat soluble.

(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the derived MRL (combination H-III in Appendix E). It is noted that isopyrazam might no longer satisfy the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.

(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E). It is noted that isopyrazam might no longer satisfy the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.

(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E). It is noted that isopyrazam might no longer satisfy the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.

(d): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination F-I in Appendix E). It is noted that isopyrazam might no longer satisfy the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.

(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination H-VII in Appendix E). It is noted that isopyrazam might no longer satisfy the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.

(f): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
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**Abbreviations**

a.i. active ingredient  
as. active substance  
ADI acceptable daily intake  
AR applied radioactivity  
ARfD acute reference dose  
BBCH growth stages of mono- and dicotyledonous plants  
bw body weight  
CAC Codex Alimentarius Commission  
CCPR Codex Committee on Pesticide Residues  
CF conversion factor for enforcement residue definition to risk assessment residue definition  
CXL codex maximum residue limit  
DALA days after last application  
DAR draft assessment report  
DAT days after treatment  
DB dietary burden
### Appendix A – Summary of authorised uses considered for the review of MRLs

**A.1. Authorised outdoor uses in northern EU**

| Crop and/or situation | MS or country | Preparation | Method kind | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------------|-------------|-------------|-------------|--------------------------------|--------------------------|---------|
|                       |               | Type<sup>(b)</sup> | Conc. a.s. | Range of growth stages and season<sup>(c)</sup> | Number min–max | Interval between application (min) | a.s./hl min–max | Water L/ha min–max | Rate and unit |
| Apples                | CZ, DE, NL    | F SC        | 100 g/L    | 69–89       | 1–2             | –            | –            | 150 g a.i./ha | 21             |
| Pears                 | CZ, DE        | F SC        | 100 g/L    | 69–89       | 2               | –            | –            | 150 g a.i./ha | 21             |
| Quinces               | CZ, NL        | F SC        | 100 g/L    | 69–89       | 2               | –            | –            | 150 g a.i./ha | 21             |
| Medlars               | CZ, NL        | F SC        | 100 g/L    | 69–89       | 2               | –            | –            | 150 g a.i./ha | 21             |
| Loquats               | CZ, NL        | F SC        | 100 g/L    | 69–89       | 2               | –            | –            | 150 g a.i./ha | 21             |
| Beetroots             | IE, UK, BE, NL| F EC        | 125 g/L    | 14–49       | 1–2             | 14           | –            | 125 g a.i./ha | 14             |
| Carrots               | IE, UK, BE, NL| F EC        | 125 g/L    | 14–49       | 1–2             | 14           | –            | 125 g a.i./ha | 14             |
| Celeriacs             | IE, UK, BE, NL| F EC        | 125 g/L    | 14–49       | 1–2             | 14           | –            | 125 g a.i./ha | 14             |
| Horseradishes         | IE, BE, NL    | F EC        | 125 g/L    | 14–49       | 1–2             | 14           | –            | 125 g a.i./ha | 14             |
| Jerusalem artichokes  | NL            | F EC        | 125 g/L    | 40–49       | 1–2             | 14           | –            | 125 g a.i./ha | 14             |
| Parsnips              | IE, UK, BE, NL| F EC        | 125 g/L    | 14–49       | 1–2             | 14           | –            | 125 g a.i./ha | 14             |
| Parsley roots         | IE, BE, NL    | F EC        | 125 g/L    | 14–49       | 1–2             | 14           | –            | 125 g a.i./ha | 14             |
| Radishes              | IE, BE, NL    | F EC        | 125 g/L    | 14–49       | 1–2             | 14           | –            | 125 g a.i./ha | 14             |
| Crop and/or situation | MS or country | F G or T(a) | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|-------------|-------------|-------------------------------|--------------|---------|
|                       |               | Type(b) | Conc. a.s. | Method kind | Range of growth stages and season(c) | Number min-max | Interval between application (min) | a.s./hl min-max | Water L/ha min-max | Rate and unit |         |         |
| Salsifies             | IE, NL        | F EC     | 125 g/L    | Foliar treatment – spraying | 40–49 | 1–2 | 14 | – | – | 125 g a.i./ha | 14 |         |         |
| Swedes                | IE, UK, BE, NL| F EC     | 125 g/L    | Foliar treatment – spraying | 14–49 | 1–2 | 14 | – | – | 125 g a.i./ha | 14 |         |         |
| Turnips               | IE, UK, BE, NL| F EC     | 125 g/L    | Foliar treatment – spraying | 14–49 | 1–2 | 14 | – | – | 125 g a.i./ha | 14 |         |         |
| Gherkins              | BE, NL        | F EC     | 125 g/L    | Foliar treatment – spraying | 51–89 | 1–2 | 7 | – | – | 125 g a.i./ha | 1 |         |         |
| Courgettes            | BE, NL        | F EC     | 125 g/L    | Foliar treatment – spraying | 51–89 | 1–2 | 7 | – | – | 125 g a.i./ha | 1 |         |         |
| Pumpkins              | BE, NL        | F EC     | 125 g/L    | Foliar treatment – spraying | 51–89 | 1–2 | 7 | – | – | 125 g a.i./ha | 7 |         |         |
| Rapeseeds             | UK, PL, CZ, HU, DE | F SC | 125 g/L    | Foliar treatment – spraying | 61–69 | 1 | – | – | 125 g a.i./ha | n.a. |         |         |
| Mustard seeds         | PL            | F SC     | 125 g/L    | Foliar treatment – general | 61–69 | 1 | – | – | 125 g a.i./ha | n.a. |         |         |
| Barley                | AT, UK, PL, BE, IE, CZ, HU, NL | F SC | 125 g/L    | Foliar treatment – spraying | 31–69 | 1–2 | 14 | – | – | 125 g a.i./ha | n.a. | 21 days or min 14 days interval, 35 days or no PHI, depending on the formulation. Max 250 g/ha/12 months |
| Oat                   | HU            | F SC     | 125 g/L    | Foliar treatment – spraying | 30–59 | 2 | 14 | – | – | 125 g a.i./ha | 35 |         |         |
## A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|-------------|--------------------------------|---------------|---------|
|                       |               | Type(b) Conc. a.s. Method kind | Range of growth stages and season(c) Number min–max | Interval between application (min) a.s./hL min–max Water L/ha min–max Rate and unit |               |         |
| Rye                   | UK, PL, HU, BE, NL | F SC 125 g/L Foliar treatment – spraying | 30–69 1–2 | 14 | – | – | 125 g a.i./ha | n.a. | 21 days or min 14 days interval, 35 days or no PHI, depending on the formulation. Max 250 g/ha/12 months |
| Wheat                 | AT, UK, PL, BE, CZ, HU, NL, DE | F SC 125 g/L Foliar treatment – spraying | 30–69 1–2 | 14 | – | – | 125 g a.i./ha | n.a. | 21 days or min 14 days interval, 35 days or no PHI, depending on the formulation. Max 250 g/ha/12 months |
| Apples                | EL, IT, BG, PT | F SC 100 g/L Foliar treatment – spraying | 69–85 1–2 | – | – | 150 g a.i./ha | 21 |
| Pears                 | EL, IT, BG, PT | F SC 100 g/L Foliar treatment – spraying | 69–85 1–2 | – | – | 150 g a.i./ha | 21 |
| Quinces               | EL, IT, BG, PT | F SC 100 g/L Foliar treatment – spraying | 69–85 1–2 | – | – | 150 g a.i./ha | 21 |

MS: Member State; a.s.: active substance; a.i.: active ingredient; SC: suspension concentrate; EC: emulsiifiable 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.
| Crop and/or situation | MS or country | F G Type (a) | Conc. a.s. | Method kind | Range of growth stages and season (c) | Number min–max | Interval between application (min) | a.s./hL min–max | Water L/ha min–max | Rate and unit | PHI (days) (d) |
|-----------------------|----------------|-------------|-----------|--------------|---------------------------------|----------------|-------------------------------|----------------|-------------------|----------------|---------------|
| Medlars               | EL, IT, BG     | F SC        | 100 g/L   | Foliar treatment – spraying | 69–89             | 1–2                          | –               | –                      | 150 g a.i./ha | 21                |
| Loquats               | EL, IT, BG, PT | F SC        | 100 g/L   | Foliar treatment – spraying | 69–89             | 1–2                          | –               | –                      | 150 g a.i./ha | 21                |
| Peaches               | EL, IT, BG, PT | F SC        | 100 g/L   | Foliar treatment – spraying | 71–85             | 1–2                          | –               | –                      | 150 g a.i./ha | 7                |
| Carrots               | EL, ES, IT, BG, PT | F EC  | 125 g/L   | Foliar treatment – spraying | 14–49             | 1–2                          | –               | –                      | 125 g a.i./ha | 14                |
| Tomatoes              | EL, ES, BG, PT | F EC        | 125 g/L   | Foliar treatment – spraying | 51–89             | 1–2                          | –               | –                      | 125 g a.i./ha | 1                |
| Aubergines            | BG, PT         | F EC        | 125 g/L   | Foliar treatment – spraying | 51–89             | 2               | 7               | –                      | 125 g a.i./ha | 1                |
| Cucumbers             | EL, ES, IT, BG, PT | F EC  | 125 g/L   | Foliar treatment – spraying | 51–89             | 1–2                          | –               | –                      | 125 g a.i./ha | 1                |
| Courgettes            | EL, ES, IT, BG, PT | F EC  | 125 g/L   | Foliar treatment – spraying | 51–89             | 1–2                          | –               | –                      | 125 g a.i./ha | 1                |
| Melons                | EL, ES, IT, BG, PT | F EC  | 125 g/L   | Foliar treatment – spraying | 51–89             | 1–2                          | 7               | –                      | 125 g a.i./ha | 7                |
| Pumpkins              | EL, ES, IT, BG, PT | F EC  | 125 g/L   | Foliar treatment – spraying | 51–89             | 1–2                          | –               | –                      | 125 g a.i./ha | 7                |
| Watermelons           | EL, ES, IT, BG, PT | F EC  | 125 g/L   | Foliar treatment – spraying | 51–89             | 1–2                          | 7               | –                      | 125 g a.i./ha | 7                |
| Rapeseeds             | HR             | F SC        | 125 g/L   | Foliar treatment – spraying | 61–69             | 1–2                          | –               | –                      | 125 g a.i./ha | n.a.            |
| Barley                | EL, IT, BG     | F SC        | 125 g/L   | Foliar treatment – spraying | 31–59             | 1–2                          | –               | –                      | 125 g a.i./ha | n.a.            |
| Oat                   | BG             | F SC        | 100 g/L   | Foliar treatment – spraying | 31–65             | 2               | 14              | –                      | 100 g a.i./ha | 35               |
| Rye                   | BG             | F SC        | 100 g/L   | Foliar treatment – spraying | 31–65             | 2               | 14              | –                      | 100 g a.i./ha | 35               |
| Wheat                 | EL, IT, BG, HR | F SC        | 125 g/L   | Foliar treatment – spraying | 31–69             | 1–2                          | –               | –                      | 125 g a.i./ha | n.a.            |

**MS:** Member State; **a.s.:** active substance; **a.i.:** active ingredient; **SC:** suspension concentrate; **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.
### A.3. Authorised indoor uses in EU

| Crop and/or situation | MS or country | F G or I<sup>(d)</sup> | Preparation | Application | Application rate per treatment | PHI (days)<sup>(e)</sup> | Remarks |
|-----------------------|---------------|------------------------|-------------|-----------------|-------------------------------|----------------|---------|
| Tomatoes              | EL, ES, HR, BG, DE, PT, NL, IE, BE, UK | I | EC | 125 g/L | Foliar treatment – spraying | 51–89 | 1–2 | 125 g a.i./ha | 1 | 50 g/ha LWA × 2,5. Max 250 g/ha/12 months |
| Sweet peppers        | ES, HR, DE, PT, IE, UK | I | EC | 125 g/L | Foliar treatment – spraying | 51–90 | 1–2 | 125 g a.i./ha | 3 | Water volume 300–1,000 L/ha i.e. max 125 g a.s/ha |
| Aubergines            | EL, ES, IT, HR, BG, DE, PT, NL, IE, BE, UK | I | EC | 125 g/L | Foliar treatment – spraying | 51–89 | 1–2 | 125 g a.i./ha | 1 | 50 g/ha LWA × 2,5. Max 250 g/ha/12 months |
| Cucumbers             | EL, ES, IT, HR, BG, DE, PT, NL, IE, BE, UK | I | EC | 125 g/L | Foliar treatment – spraying | 51–92 | 1–2 | 125 g a.i./ha | 1 | 50 g/ha LWA × 2,5. Max 250 g/ha/12 months |
| Gherkins              | BE, DE | I | EC | 125 g/L | Foliar treatment – spraying | 51–89 | 1–2 | 125 g a.i./ha | 1 | 125 g/ha (horizontal crops) or 50 g/ha LWA × 1,9 (vertical crops). Max 250 g/ha/12 months |
| Courgettes            | EL, ES, IT, HR, BG, DE, PT, NL, IE, BE, UK | I | EC | 125 g/L | Foliar treatment – spraying | 51–93 | 1–2 | 125 g a.i./ha | 1 | 125 g/ha (horizontal crops) or 50 g/ha LWA × 1,9 (vertical crops). Max 250 g/ha/12 months |
| Melons                | EL, ES, IT, HR, BG, DE, PT, NL, IE, BE, UK | I | EC | 125 g/L | Foliar treatment – spraying | 51–94 | 1–2 | 125 g a.i./ha | 7 | 125 g/ha (horizontal crops) or 50 g/ha LWA × 2,5 (vertical crops). Max 250 g/ha/12 months |
## A.4. Import tolerance

| Crop and/or situation | MS or country | F G or I(a) | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|-------------|-------------|-------------------------------|---------------|---------|
|                       |               |             | Type(b) Conc. a.s. Method kind | Range of growth stages & season(c) Number min–max Interval between application (min) a.s./hL min–max Water L/ha min–max Rate and unit |               |         |
| Bananas | CR | F | EC | 125 g/L | Foliar treatment – spraying | 5–10 | – | 75 g a.i./ha | 1 | use assessed was from various central american countries via aerial application with a 0 day PHI |

MS: Member State; a.s.: active substance; a.i.: active ingredient; SC: suspension concentrate; 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                       | Grape       | Foliar, 400 g/ha | 21 | Radiolabelled active substance: pyrazole-5-14C-isopyrazam and phenyl-UL-14C-isopyrazam. EFSA (2012b) |
| Leafy crops                       | Lettuce     | Foliar, 3 x 125 g/ha | 3, 14 |
| Cereals/grass                     | Wheat       | Foliar, 3 x 125 g/ha | 13, 46-48 |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Turnips     | Bare soil, 360 g/ha | 30, 90, 300 | Radiolabelled active substance: pyrazole-5-14C-isopyrazam and phenyl-UL-14C-isopyrazam. EFSA (2012b) |
| Leafy crops                         | Lettuce     | Bare soil, 360 g/ha | 30, 90, 300 |
| Cereal (small grain)                | Wheat       | Bare soil, 360 g/ha | 30, 90, 300 |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Yes        | Radiolabelled active substance: pyrazole-5-14C-isopyrazam and phenyl-UL-14C-isopyrazam. EFSA (2012b) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes |
| Sterilisation (20 min, 120°C, pH 6)      | Yes |
| Other processing conditions             | --         | --      |
| Question                                                                 | Yes                                                                 |
|------------------------------------------------------------------------|----------------------------------------------------------------------|
| Can a general residue definition be proposed for primary crops?         | Yes                                                                 |
| Rotational crop and primary crop metabolism similar?                    | Yes \( \text{The metabolism was similar, noting that the relative contribution of the common metabolite CSCD465008 in residues in rotational crops were higher compared to primary crops.} \) |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes \( \text{EFSA (2012b)} \) |
| Plant residue definition for monitoring (RD-Mo)                         | Isopyrazam (sum of isomers) (EFSA, 2012b) |
| Plant residue definition for risk assessment (RD-RA)                    | Isopyrazam (sum of isomers) plus its metabolite CSCD459488 [syn– hydroxyl isopyrazam] (free and conjugated), expressed as isopyrazam (EFSA, 2012b) |
| Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs) | Matrices with high water (apple) content, high oil (rape seed) content, and dry matrices (wheat grain): LC–MS/MS, LOQ 0.01 mg/kg (0.005 mg/kg for syn- and anti- isomer respectively)  
Confimatory method available (2 different mass transitions). Method not enantioselective.  
ILV available for high water, high oil content and dry commodities.  
(EFSA, 2012b; Norway, 2020)  
Isopyrazam can be monitored in high water content, high acid content, dry and high fat content commodities with an LOQ of 0.01 mg/kg. In high water content and high acid content commodities, even lower levels down to 0.002 mg/kg were successfully validated. Dry and high fat content commodities were successfully validated down to 0.005 mg/kg (EURLs, 2020) |

DAT: days after treatment; PBI: plant- back interval; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; 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                                                                 |
|-----------------------------------|--------------------|------------------------------------|--------|------------------|-----------------------------------------------------------------------------------|
|                                   | High water content | Tomato, lentils, potato            | –18    | 24 Months        | isopyrazam                                                                        |
|                                   |                    | Apple, carrot, lentils, spinach    | –18    | 28 Months        | CSCD459488 and CSCD459489 (anti- and syn-hydroxy-isopyrazam, respectively)        |
|                                   |                    | Carrot, spinach                    | –18    | 12 Months        | CSCD465008 and CSAA798670                                                          |
|                                   | High oil content   | Rape seed                          | –18    | 24 Months        | isopyrazam                                                                        |
|                                   |                    | Rape seed                          | –18    | 28 Months        | CSCD459488 and CSCD459489 (anti- and syn-hydroxy-isopyrazam, respectively)        |
|                                   | High starch content| Cereal grain                        | –18    | 24 Months        | isopyrazam                                                                        |
|                                   |                    | Cereal grain                        | –18    | 28 Months        | CSCD459488 and CSCD459489 (anti- and syn-hydroxy-isopyrazam, respectively)        |
|                                   |                    | Cereal grain                        | –18    | 12 Months        | CSCD465008 and CSAA798670                                                          |
|                                   | High acid content  | Orange                             | –18    | 28 Months        | CSCD459488 and CSCD459489 (anti- and syn-hydroxy-isopyrazam, respectively)        |
|                                   | Others             | Straw, forage                       | –18    | 24 Months        | isopyrazam                                                                        |
|                                   |                    | straw                              | –18    | 28 Months        | CSCD459488 and CSCD459489 (anti- and syn-hydroxy-isopyrazam, respectively)        |
|                                   |                    | Straw, forage                       | –18    | 12 Months        | CSCD465008 and CSAA798670                                                          |

### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials – Primary crops

| Commodity | Region/Indoor(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) |
|-----------|------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|---------------|-----------------|-------|
| Pome fruits | NEU              | Mo: 0.026; 0.031; 0.092; 0.093; 0.117; 0.122; 0.189; 0.200; RA: 0.031; 0.036; 0.097; 0.098; 0.122; 0.127; 0.194; 0.205 | Trials on apples compliant with the GAP (Norway, 2020). Extrapolation to pome fruits is possible. MRL_{OECD} = 0.36 | 0.4                   | 0.20          | 0.11            | 1.00  |
| Commodity | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL<sup>(b)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-----------|-----------------------------|---------------------------------------------------------------|-----------------|------------------------------------|-----------------|-----------------|-------------|
| SEU       | Mo: 0.047; 0.050; 0.062; 0.111; 0.140; 0.153; 0.173; 0.235 RA: 0.052; 0.055; 0.067; 0.116; 0.145; 0.158; 0.178; 0.24 | Trials on apples compliant with the GAP (Norway, 2020). Extrapolation to pome fruits is possible. MRL<sub>OEC</sub> = 0.39 | 0.4 | 0.24 | 0.13 | 1.00 |
| Peaches   | SEU                          | Apricots: Mo: 0.11; 0.12; 0.17; 0.33; RA: 0.12; 0.125; 0.18; 0.34; Peaches: Mo: 0.08; 0.18; 0.25; 0.39 RA: 0.085; 0.18; 0.26; 0.395 | Trials on apricot and peaches compliant with the GAP (Norway, 2020). Extrapolation to peaches possible. MRL<sub>OEC</sub> = 0.65 | 0.7 | 0.39 | 0.18 | 1.00 |
| Bananas   | Import (CR)                  | Mo: < 0.01; < 0.01; 0.011; 0.012; 0.015; 0.016; 0.017; 0.022; 0.034; 0.04 RA: < 0.015; < 0.015; 0.016; 0.020; 0.021; 0.026; 0.026; 0.033; 0.049; 0.053 | Trials on bananas compliant with GAP (EFSA, 2011) MRL<sub>OEC</sub> = 0.06 | 0.06 | 0.04 | 0.02 | 1.50 |
| Root and tuber vegetables, except sugar beets | NEU                          | Mo: < 0.01; < 0.01; 0.01; 0.011; 0.015; 0.019; 0.054; 0.055 RA: < 0.015; < 0.015; 0.015; 0.02; 0.024; 0.059; 0.06 | Trials on carrots compliant with GAP (EFSA, 2013b). Extrapolation to root and tuber vegetables excluding sugar beets is applicable. MRL<sub>OEC</sub> = 0.1 | 0.1 | 0.06 | 0.01 | 1.40 |
| Carrots   | SEU                          | Mo: < 0.01; < 0.01; 0.01; 0.025; 0.029; 0.037; 0.075; 0.099 RA: < 0.015; < 0.015; 0.015; 0.03; 0.034; 0.042; 0.08; 0.104 | Trials on carrots compliant with GAP (EFSA, 2013b). Extrapolation to root and tuber vegetables excluding sugar beets is applicable. MRL<sub>OEC</sub> = 0.17 | 0.2 | 0.10 | 0.03 | 1.2 |
| Tomatoes  | SEU                          | Mo: 0.03; 0.04; 0.04; 0.04 RA: 0.035; 0.04; 0.05; 0.05 | Trials on tomatoes compliant with GAP (France, 2014). Extrapolation to aubergines applicable. Additional data not needed as the EU indoor GAP clearly more critical. MRL<sub>OEC</sub> = 0.11 | 0.15 | 0.04 | 0.04 | 1.2 |
| EU        | Mo: 0.017; 0.018; 0.025; 0.048; 0.049; 0.134; 0.191; 0.228 RA: 0.022; 0.023; 0.030; 0.053; 0.054; 0.139; 0.196; 0.233 | Trials on tomatoes compliant with GAP (EFSA, 2015). Extrapolation to aubergines is applicable. MRL<sub>OEC</sub> = 0.42 | 0.5 | 0.23 | 0.05 | 1.1 |
| Commodity                      | Region/Indoor | 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) |
|--------------------------------|---------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|---------------|-----------------|-------|
| Sweet peppers/bell peppers    | EU            | Mo: 0.012; 0.018; 0.019; 0.044; 0.049; 0.134(e); 0.183; 0.228 | Trials on cherry tomatoes compliant with GAP (France, 2014). Extrapolation to sweet peppers applicable. MRL<sub>OECD</sub> = 0.42 | 0.5                    | 0.23          | 0.16            | 1.1   |
| Cucumbers                      | NEU           | Mo: 0.017; 0.027; 0.048; 0.051; 0.072; 0.110; 0.122; 0.232 | Trials on cucumbers compliant with the GAP (EFSA, 2013a). Extrapolation to gherkins and courgettes possible. No use authorised in NEU on cucumbers. MRL<sub>OECD</sub> = 0.36 | 0.4                    | 0.23          | 0.06            | 1.1   |
| Courgettes                     | SEU           | Mo: < 0.01; < 0.01; 0.010; 0.014; 0.023; 0.028; 0.032; 0.049 | Trials on cucumbers compliant with GAP (EFSA, 2013a). Extrapolation to courgettes possible. No use authorised in SEU on gherkins. MRL<sub>OECD</sub> = 0.08 | 0.08                   | 0.05          | 0.02            | 1.5   |
| Melons                         | EU            | Mo: < 0.01; 0.010; 0.012; 0.013; 0.015; 0.017; 0.025; 0.036 | Trials on cucumbers compliant with GAP (EFSA, 2013a). Extrapolation to cucurbits with edible peel is applicable. MRL<sub>OECD</sub> = 0.05 | 0.06                   | 0.04          | 0.01            | 1.6   |
| Pumpkins                       | NEU           | Mo: 0.021; 0.024; 0.027; 0.030; 0.034; 0.082; 0.156; 0.162 | Trials on melons compliant with GAP. Residues in pulp were below the LOQ of 0.015 mg/kg in all trials (EFSA, 2013a). Extrapolation to pumpkins is applicable. No use authorised in NEU on melons and watermelons. MRL<sub>OECD</sub> = 0.31 | 0.3                    | 0.16          | 0.03            | 1.2   |
| Watermelons                    | SEU           | Mo: 0.011; 0.011; 0.012; 0.012; 0.015; 0.020; 0.026; 0.040 | Trials on melons compliant with GAP. Residues in pulp were below the LOQ of 0.015 mg/kg in all trials (EFSA, 2013a). Extrapolation to pumpkins and watermelons is applicable. MRL<sub>OECD</sub> = 0.06 | 0.06                   | 0.04          | 0.01            | 1.4   |
| Commodity                  | Region/Indoor(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) |
|---------------------------|------------------|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------------|----------------|-------|
| EU                        |                  | Mo: 0.019; 0.027; 0.029; 0.056; 0.058; 0.072; 0.105; 0.350       | Trials on melons compliant with GAP. Residues in pulp were below the LOQ of 0.015 mg/kg in all trials (EFSA, 2013a). Extrapolation to pumpkins and watermelons is applicable. MRL_{OECD} = 0.53 | 0.6                   | 0.35          | 0.06           | 1.1   |
| Rapeseeds/canola seeds    | NEU              | Mo: 0.033; 0.035; 0.038; 0.055; 0.068; 0.068; 0.086; 0.090       | Overdosed trials on rapeseeds performed with two applications instead of 1. No additional trials are needed as the SEU GAP is clearly more critical (EFSA, 2013b). MRL_{OECD} = 0.18 | 0.2                   | 0.09          | 0.06           | 1.10  |
| SEU                       |                  | Mo: < 0.01; 0.021; 0.029; 0.186; < 0.01; < 0.01; 0.012; 0.052     | Trials on rapeseeds compliant with GAP (EFSA 2013b; Norway, 2020). MRL_{OECD} = 0.28                                                                                                                        | 0.3                   | 0.19          | 0.02           | 1.65  |
| Mustard seeds             | NEU              | Mo: 0.033; 0.035; 0.038; 0.055; 0.068; 0.068; 0.086; 0.090       | Overdosed trials on rapeseeds, as two applications instead of 1 (EFSA, 2013b). Extrapolation to mustard seeds is applicable. MRL_{OECD} = 0.18                                                                 | 0.2 Tentative(f)      | 0.09          | 0.06           | 1.10  |
| Barley grains Oat grains  | NEU              | Mo: < 0.01; 0.014; 0.016; 0.017; 0.020; 0.024; 0.026; 0.035; 0.07; 0.19 | Trials on barley compliant with the GAP (EFSA, 2012b; Norway, 2020). Extrapolation to oat grains is applicable. MRL_{OECD} = 0.25                                                                 | 0.3                   | 0.19          | 0.03           | 1.60  |
| SEU                       |                  | Mo: < 0.01; < 0.01; 0.016; 0.024; 0.046; 0.17; 0.17; 0.23; 0.50  | Trials on barley compliant with GAP (EFSA, 2012b). Extrapolation to oat grains is applicable. MRL_{OECD} = 0.78                                                                                                   | 0.8                   | 0.50          | 0.05           | 1.60  |
| Commodity       | Region/ Indoor(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 grains    | NEU               | Mo: < 0.01; < 0.01; < 0.01; 0.011; 0.012; 0.014; 0.017 RA: < 0.015; < 0.015; < 0.015; 0.016; 0.019; 0.019; 0.026 | Wheat trials conducted with a total of 3 applications, instead of 2. However, the contribution of the 1st treatment to the final residue level was considered negligible (EFSA, 2012b). Extrapolation to rye is applicable. MRL_{OECD} = 0.02 | 0.03                   | 0.02          | 0.01            | 1.50  |
| Rye grains      |                   |                                                              |                                                                                                                                                                                                              |                        |               |                 |       |
| Barley straw    | NEU               | Mo: 0.076; 0.18; 0.12; 0.5; 0.47; 0.68; 1.1; 0.84; 2; 1.4; 0.45; 1.5 RA: 0.097; 0.25; 0.31; 0.59; 0.60; 0.71; 1.1; 1.3; 2.3; 1.57; 0.6; 1.64 | Trials on barley straw compliant with GAP (EFSA, 2012b; Norway, 2020). Extrapolation to oat straw is applicable. MRL_{OECD} = 3.21 | 4 (tentative)(g)       | 2.00          | 0.59            | 1.23  |
| Oat straw       |                   |                                                              |                                                                                                                                                                                                              |                        |               |                 |       |
| Wheat straw     | NEU               | Mo: 0.13; 0.26; 0.15; 0.45; 1.1; 2.5; 3.5; 5.9; 6.9 RA: 0.19; 0.31; 0.33; 0.59; 1.8; 3.0; 4.0; 6.7; 7.2 | Trials on wheat straw with 3 application instead of 2 acceptable, as first application is not expected to contribute (EFSA, 2012b). Extrapolation to rye straw is applicable. MRL_{OECD} = 12.71 | 15 (tentative)(g)      | 6.90          | 1.10            | 1.20  |
| Rye straw       |                   |                                                              |                                                                                                                                                                                                              |                        |               |                 |       |
| NEU             | Mo: < 0.01; 0.2; 1.3; 2.8; 5.1; 6.7; 7.1; 8.4 RA: < 0.015; 0.43; 1.7; 3.6; 7.2; 7.2; 7.6; 9.3 | Trials on wheat straw with 3 application instead of 2 acceptable, as first application is not expected to contribute (EFSA, 2012b). Extrapolation to rye straw is applicable. MRL_{OECD} = 17.18 | 20 (tentative)(g)      | 8.40          | 3.95            | 1.30  |
### Commodity Residues in rotational crops

#### a) Overall summary

| Commodity      | Region/Indoor\(^{(a)}\) | 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\(^{(d)}\) |
|----------------|--------------------------|---------------------------------------------------------------|-----------------|------------------------|----------------------|------------------------|------------|
| Turnip tops    | NEU                      | Mo: – RA: –                                                   | No trials are available. | –                      | –                    | –                      | –          |

**GAP:** Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.

\(^{(a)}\): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials, Country code: if non-EU trials.

\(^{(b)}\): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

\(^{(c)}\): Supervised trials median residue. The median residue for risk assessment (RA) 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 sample taken at PHI 1 day, instead of PHI 3 days, as samples at later PHI not available.

\(^{(f)}\): MRL tentative as trials overdosed (two applications instead of one).

\(^{(g)}\): Tentative MRLs are derived for feed commodities in view of the future need to set MRLs in these commodities.

**B.1.2.2. Residues in rotational crops**

**a) Overall summary**

Residues in rotational and succeeding crops expected based on confined rotational crop study?

| Yes |
|-----|

Confined rotational crop study conducted at 360 g/ha in turnip, lettuce and wheat. Isopyrazam was below the LOQ of 0.01 mg/kg in all edible part of crops. CSCD459488 (free and conjugated) was found in straw (0.06 - 0.13 mg eq/kg), CSCD465008 was found at 0.01 mg/kg in lettuce (PBI 60 days) and in turnip tops (0.01 - 0.02 mg eq/kg; at all PBI).

Residues in rotational and succeeding crops expected based on field rotational crop study?

| Yes |
|-----|

Wheat was treated with 3x250 g a.i./ha (0.9N), following last application the crops were plough in soil, and spinach, carrots and barley were planted at nominal PBIs of 30, 60 and 365 days (see table (b) below). Isopyrazam may be present in root crops at PBI 30 days at the LOQ, while CSCD459488 was detected at low levels in leafy crops and cereals (see table (b) below).

The common metabolite CSCD465008 may occur at low levels in leafy crops (up to 0.06 mg/kg in spinach, up to 0.15 mg/kg in carrot tops). CSAA798670 was below the LOQ of 0.01 mg/kg in all samples, at all PBIs.

**LOQ:** limit of quantification; **PBI:** plant-back interval; **a.i.:** active ingredients.
### b) Summary of residues data from the rotational crops residue trials

| Commodity       | Region/Indoor(a) | PBI (days)(b) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) |
|-----------------|------------------|---------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|----------------|
| Spinach         | NEU/SEU          | 30            | Isopyrazam (sum of isomers): 4 × < 0.01 CSD459488: 2 × < 0.005; 0.006; 0.01 | Rotational crops field trials conducted at a dose rate corresponding to 0.9N of the max PECsafety for parent (United Kingdom, 2012). | –                      | Mo: 0.01  RA: 0.02 | Mo: 0.01 RA: 0.015 |
| Carrot root     | NEU/SEU          | 30            | Isopyrazam (sum of isomers): 3 × < 0.01; 0.01 CSD459488: 4 × < 0.005 | Rotational crops field trials conducted at a dose rate corresponding to 0.9N of the max PECsafety for parent (United Kingdom, 2012). | –                      | Mo: 0.01 RA: 0.015 | Mo: 0.01 RA: 0.015 |
| Carrot tops     | NEU/SEU          | 30            | Isopyrazam (sum of isomers): 4 × < 0.01 CSD459488: 4 × < 0.005 | Rotational crops field trials conducted at a dose rate corresponding to 0.9N of the max PECsafety for parent (United Kingdom, 2012). | –                      | Mo: 0.01 RA: 0.015 | Mo: 0.01 RA: 0.015 |
| Barley grain    | NEU/SEU          | 30            | Isopyrazam (sum of isomers): 4 × < 0.01 CSD459488: 4 × < 0.005 | Rotational crops field trials conducted at a dose rate corresponding to 0.9N of the max PECsafety for parent (United Kingdom, 2012). | –                      | Mo: 0.01 RA: 0.015 | Mo: 0.01 RA: 0.015 |
| Commodity | Region/Indoor<sup>(a)</sup> | PBI (days)<sup>(b)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(c)</sup> (mg/kg) | STMR<sup>(d)</sup> (mg/kg) |
|-----------|---------------------|---------------------|-------------------------------------------------------------|------------------|----------------------|---------------------|---------------------|
| Barley straw | NEU/SEU | 30 | Isopyrazam (sum of isomers): 4 × < 0.01 CSD459488: 4 × < 0.005 | Rotational crops field trials conducted at a dose rate corresponding to 0.9N of the max PEC<sub>total</sub> for parent (United Kingdom, 2012). | – | Mo: 0.01 | Mo: 0.01 |
| | | 60 | Isopyrazam (sum of isomers): 4 × < 0.01 CSD459488: 0.017; 0.029; 0.036; 0.054 | | | Mo: 0.01 | Mo: 0.01 |
| | | 365 | Isopyrazam (sum of isomers): 4 × < 0.01 CSD459488: 0.008; 0.011; 0.034; 0.049 | | | Mo: 0.01 | Mo: 0.01 |

*: Indicates that the MRL is proposed at the limit of quantification.
Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Country code: if non-EU trials.
(b): Plant-back interval: The interval (days, months, years) between the final application of a pesticide product to a primary crop and the planting of a rotational crop.
(c): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(d): Supervised trials median residue.
### B.1.2.3. Processing factors

| Processed commodity    | Number of valid studies\(^{(a)}\) | Processing Factor (PF) | CF\(_P\)\(^{(b)}\) | Comment/Source |
|------------------------|------------------------------------|------------------------|-------------------|----------------|
|                        |                                    | Individual values      | Median PF         |                |
| Apples, juice          | 4                                  | 0.02; 0.02; 0.02; 0.03  |
| Apples, dry pomace     | 4                                  | 4.3; 5.6; 6.0; 6.3     |
| Apples, wet pomace     | 4                                  | 2.0; 2.3; 2.5; 3.3     |
| Apples, sauce          | 4                                  | 0.1; 0.18; 0.22; 0.26  |
| Bananas, peeled        | 9                                  | 2 × < 0.3; 4 × < 0.6; < 0.75; 2 × 2 × < 1 |
| Melons, peeled         | 24                                 | 2 × < 0.1; < 0.2; 2 × < 0.3; 4 × < 0.4; 3 × < 0.5; 2 × < 0.6; 2 × < 0.7; 2 × < 0.8; 4 × < 0.9; 2 × < 1 |
| Tomato juice           | 4                                  | 0.24; 0.25; 0.60; 0.86 |
| Tomato canned          | 4                                  | 0.07; 0.20; 0.24; 0.36; |
| Tomato puree           | 4                                  | 2.6; 4.9; 5.1; 7.9    |
| Tomato paste           | 4                                  | 3.3; 6.4; 7.6; 8.3    |
| Tomato ketchup         | 4                                  | 3.6; 3.6; 3.6; 6.2    |
| Tomato sun-dried       | 4                                  | 5.7; 11.8; 10.5; 14.4 |
| Barley, brewing malt  | 4                                  | 3 × 0.4; 0.5          |
| Barley, beer           | 4                                  | 4 × < 0.1             |
| Barley, pot/pearl      | 4                                  | 4 × 0.4               |
| Barley, dry brewer’s grain | 2                              | 2 × 0.8               |
| Wheat, whole-meal flour| 4                                  | 3 × 0.7; 0.8          |
| Wheat, whole-meal bread| 4                                | 3 × 0.5; 0.7          |
| Wheat, white flour     | 4                                  | 4 × 0.2               |

\(^{(a)}\) Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

\(^{(b)}\) Median of the individual conversion factors for each processing residues trial.

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### B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup\(^{(a)}\) | Most critical commodity\(^{(b)}\) | Trigger exceeded (Y/N) |
|-----------------------------|---------------------------------------------|---------------------------------|---------------------------------|-----------------------|
|                            | Median | Maximum | Median | Maximum |                      |                      |                      |                      |
| Cattle (all)               | 0.052  | 0.121   | 1.39   | 3.35     | Dairy cattle          | Barley straw         | Yes                   |
| Cattle (dairy only)        | 0.052  | 0.121   | 1.36   | 3.16     | Dairy cattle          | Barley straw         | Yes                   |
| Sheep (all)                | 0.108  | 0.257   | 2.54   | 6.04     | Lamb                 | Barley straw         | Yes                   |
| Sheep (ewe only)           | 0.085  | 0.201   | 2.54   | 6.04     | Ram/Ewe              | Barley straw         | Yes                   |
| Swine (all)                | 0.008  | 0.016   | 0.28   | 0.52     | Swine (finishing)     | Swede roots          | Yes                   |

PF: Processing factor (–Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo); CF\(_P\): Conversion factor for risk assessment in processed commodity (–Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo).

\(^{(a)}\) Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

\(^{(b)}\) Median of the individual conversion factors for each processing residues trial.
### Relevant groups (subgroups)

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup<sup>a</sup> | Most critical commodity<sup>b</sup> | Trigger exceeded (Y/N) |
|----------------------------|-----------------------------|----------------------------------|---------------------------------|-----------------------|
|                            | mg/kg bw per day | mg/kg DM | Median | Maximum | Median | Maximum |                   |                       |
| Poultry (all)              | 0.051           | 0.101   | 0.74   | 1.48    | Poultry layer | Wheat straw | Yes |
| Poultry (layer only)       | 0.051           | 0.101   | 0.74   | 1.48    | Poultry layer | Wheat straw | Yes |
| Fish                       | –               | –       | –      | –       | –      | –       | –               |

bw: body weight; DM: dry matter.

<sup>a</sup>: 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’.

<sup>b</sup>: 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                    | 0.82–0.89       | 14                | 14C-labelled isopyrazam with a ratio of syn- and anti-isomers of 70:30 and 95:5 (EFSA, 2012b). |
| Lactating ruminants           | 0.78–0.93       | 7                 | Goat 14C-labelled isopyrazam with a ratio of syn- and anti-isomers of 70:30 and 95:5 pyrazole and phenyl ring labelled [14C] isopyrazam and pyrazole ring labelled [14C] CSCD459488 (EFSA, 2012b). |
Time needed to reach a plateau concentration in milk and eggs (days)

| Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|--------|-----------|--------|------------------|-------------------|----------------|
| Milk: | 4 days | EFSA (2012b) |
| Eggs: | 4 days | EFSA (2012b) |

Metabolism in rat and ruminant similar

Can a general residue definition be proposed for animals?

Animal residue definition for monitoring (RD-Mo)

Animal residue definition for risk assessment (RD-RA)

Fat soluble residues

Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)

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

B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|------------------------------------|--------|-----------|--------|------------------|-------------------|----------------|
|                                    | Bovine | Muscle    | –18    | 14 Months        | Isopyrazam        | EFSA (2012b)   |
|                                    | Bovine | Fat       | –18    | 14 Months        |                   |                |
|                                    | Bovine | Liver     | –18    | 14 Months        |                   |                |
|                                    | Bovine | Kidney    | –18    | 14 Months        |                   |                |
|                                    | Bovine | Milk      | –18    | 14 Months        |                   |                |
|                                    | Poultry| Eggs      | –18    | 14 Months        |                   |                |
|                                    | Bovine | Muscle    | –18    | 20 Months        | CDCD656800 (syn- and anti-isomers) | EFSA (2012b) |
|                                    | Bovine | Fat       | –18    | 20 Months        |                   |                |
|                                    | Bovine | Liver     | –18    | 20 Months        |                   |                |
|                                    | Bovine | Kidney    | –18    | 20 Months        |                   |                |
|                                    | Bovine | Milk      | –18    | 20 Months        |                   |                |
|                                    | Poultry| Eggs      | –18    | 20 Months        |                   |                |
|                                    | Bovine | Muscle    | –18    | 12 Months        | Isopyrazam, and its metabolites determined as CSAA798670 | United Kingdom (2012) |
|                                    | Bovine | Fat       | –18    | 12 Months        |                   |                |
|                                    | Bovine | Liver     | –18    | 12 Months        |                   |                |
|                                    | Bovine | Kidney    | –18    | 12 Months        |                   |                |
|                                    | Bovine | Milk      | –18    | 12 Months        |                   |                |
|                                    | Poultry| Eggs      | –18    | 12 Months        |                   |                |
### B.2.2. Magnitude of residues in livestock

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

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF(c) |
|------------------|-----------------------------------------------|-----------------------|---------------------|-------|
|                  | Mean | Highest | STMR<sub>Mo</sub><sup>(a)</sup> (mg/kg) | HR<sub>Mo</sub><sup>(b)</sup> (mg/kg) |       |
| Cattle (all)     |      |         |                                      |                   |       |
| Muscle           | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* | 2    |
| Fat              | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* | 2    |
| Liver            | 0.01  | 0.01   | < 0.01 | < 0.01 | 0.01* | 22   |
| Kidney           | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* | 6    |
| Cattle (dairy only) |      |         |                                      |                   |       |
| Milk<sup>(e)</sup> | < 0.01 | n.a.   | < 0.01 | < 0.01 | 0.01* | 3    |
| Sheep (all)<sup>(f)</sup> |      |         |                                      |                   |       |
| Muscle           | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* | 2    |
| Fat              | < 0.01 | < 0.01 | < 0.01 | 0.01  | 0.015 | 2    |
| Liver            | 0.01  | 0.01   | < 0.01 | < 0.01 | 0.01* | 22   |
| Kidney           | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* | 6    |
| Sheep (ewe only)<sup>(f)</sup> |      |         |                                      |                   |       |
| Milk<sup>(e)</sup> | < 0.01 | n.a.   | < 0.01 | < 0.01 | 0.01* | 3    |
| Swine (all)<sup>(f)</sup> |      |         |                                      |                   |       |
| Muscle           | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* | 2    |
| Fat              | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* | 2    |
| Liver            | 0.01  | 0.01   | < 0.01 | < 0.01 | 0.01* | 22   |
| Kidney           | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* | 6    |
| Poultry (all)    |      |         |                                      |                   |       |
| Muscle           | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* | 1    |
| Fat              | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* | 1    |
| Liver            | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* | 1    |
| Poultry (layer only) |      |         |                                      |                   |       |
| Eggs<sup>(g)</sup> | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* | 1    |

bw: body weight; n.a.: not applicable; n.r.: not reported.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.
(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.
(c): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(d): Closest feeding level and N dose rate related to the maximum dietary burden.
(e): For milk, mean was derived from samplings performed from day D3 to day D28 (daily mean of 3 cows).
(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.
(g): For eggs, mean and highest residues were derived from samplings performed from day D1 to day D14 (daily mean or daily highest of 3 laying hens).
### B.3. Consumer risk assessment

#### B.3.1. Consumer risk assessment without or with consideration of the existing CXLs

| ARfD          | 0.2 mg/kg bw (European Commission, 2012) |
|---------------|----------------------------------------|
| Highest IESTI, according to EFSA PRIMo (rev.3.1) | **Scenario EU and CX:** Peaches: 19% of ARfD |
| NESTI (% ARfD) | Not assessed in this review. |

**Assumptions made for the calculations**

**Scenario EU:** The calculation is based on the highest residue levels expected in raw agricultural commodities, multiplied by the conversion factor for risk assessment, except for bananas and cucurbits with inedible peel for which the derived peeling factors were also applied.

**Scenario CX:** For those commodities having a CXL higher than the EU MRL proposal, highest residue levels applied in the EU scenario were replaced by the highest residue levels derived by JMPR. The same CFs were applied for CXLs as used for the EU MRL proposals. Considering that CXLs for meat were expressed on a fat basis, EFSA re-calculated the corresponding highest residue levels for meat.

| ADI          | 0.03 mg/kg bw per day (European Commission, 2012) |
|--------------|----------------------------------------|
| TMDI according to EFSA PRIMo | Not assessed in this review. |
| NTMDI, according to (to be specified) | Not assessed in this review. |
| Highest IEDI, according to EFSA PRIMo (rev.3.1) | **Scenario EU and CX:** 14% ADI (Dutch toddler) |
| NEDI (% ADI) | Not assessed in this review. |

**Assumptions made for the calculations**

**Scenario EU:** The calculation is based on the median residue levels derived for raw agricultural commodities, multiplied by the conversion factor for risk assessment, except for bananas and cucurbits with inedible peel for which the derived peeling factors were also applied. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

**Scenario CX:** For those commodities having a CXL higher than the EU MRL proposal, median residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR. The same CFs were applied for CXLs as used for the EU MRL proposals. Considering that CXLs for meat were expressed on a fat basis, EFSA re-calculated the corresponding median residue levels for meat.
Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003)

| Metabolite(s) | ADI (mg/kg bw per day) | Intake of groundwater metabolites (% ADI) |
|---------------|------------------------|------------------------------------------|
| Not assessed in this review. |
| Not assessed in this review. |
| Not assessed in this review. |

**B.4. Proposed MRLs**

| Code number | Commodity                        | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Outcome of the review                                      | Comment                  |
|-------------|----------------------------------|-------------------------|----------------------|-------------|-----------------------------------------------------------|--------------------------|
| 130010      | Apples                           | 0.7                     | 0.4                  | 0.4         | Further consideration needed (a)                          |                          |
| 130020      | Pears                            | 0.7                     | 0.4                  | 0.4         | Further consideration needed (a)                          |                          |
| 130030      | Quinces                          | 0.7                     | 0.4                  | 0.4         | Further consideration needed (a)                          |                          |
| 130040      | Medlar                           | 0.7                     | 0.4                  | 0.4         | Further consideration needed (a)                          |                          |
| 130050      | Loquat                           | 0.7                     | 0.4                  | 0.4         | Further consideration needed (a)                          |                          |
| 140030      | Peaches                          | 1.5                     | –                    | 0.7         | Further consideration needed (b)                          |                          |
| 163020      | Bananas                          | 0.05                    | 0.06                 | 0.06        | Further consideration needed (a)                          |                          |
| 213010      | Beetroot                         | 0.2                     | –                    | 0.1         | Further consideration needed (b)                          |                          |
| 213020      | Carrots                          | 0.2                     | 0.15                 | 0.2         | Further consideration needed (a)                          |                          |
| 213030      | Celeriac                         | 0.2                     | –                    | 0.1         | Further consideration needed (b)                          |                          |
| 213040      | Horseradish                      | 0.2                     | –                    | 0.1         | Further consideration needed (b)                          |                          |
| 213050      | Jerusalem artichokes             | 0.2                     | –                    | 0.1         | Further consideration needed (b)                          |                          |
| 213060      | Parsnips                         | 0.2                     | –                    | 0.1         | Further consideration needed (b)                          |                          |
| 213070      | Parsley root                     | 0.2                     | –                    | 0.1         | Further consideration needed (b)                          |                          |
| 213080      | Radishes                         | 0.2                     | –                    | 0.1         | Further consideration needed (b)                          |                          |
| 213090      | Salsify                          | 0.2                     | –                    | 0.1         | Further consideration needed (b)                          |                          |
| 213100      | Swedes                           | 0.2                     | –                    | 0.1         | Further consideration needed (b)                          |                          |
| 213110      | Turnips                          | 0.2                     | –                    | 0.1         | Further consideration needed (b)                          |                          |
| 231010      | Tomatoes                         | 0.5                     | 0.4                  | 0.5         | Further consideration needed (a)                          |                          |
| 231020      | Peppers                          | 0.09                    | 0.09                 | 0.5         | Further consideration needed (a)                          |                          |
| 231030      | Aubergines (egg plants)          | 0.5                     | 0.4                  | 0.5         | Further consideration needed (a)                          |                          |
| 232010      | Cucumbers                        | 0.4                     | 0.06                 | 0.08        | Further consideration needed (a)                          |                          |
| 232020      | Gherkins                         | 0.4                     | –                    | 0.4         | Further consideration needed (b)                          |                          |
| 232030      | Courgettes                       | 0.4                     | –                    | 0.4         | Further consideration needed (b)                          |                          |
| 233010      | Melons                           | 0.3                     | 0.15                 | 0.6         | Further consideration needed (a)                          |                          |
| 233020      | Pumpkins                         | 0.3                     | –                    | 0.6         | Further consideration needed (b)                          |                          |
| 233030      | Watermelons                      | 0.3                     | –                    | 0.6         | Further consideration needed (b)                          |                          |
| 401020      | Peanuts                          | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed (c)                          |                          |
| 401060      | Rape seed                        | 0.4                     | 0.2                  | 0.3         | Further consideration needed (a)                          |                          |
| 401080      | Mustard seed                     | 0.4                     | –                    | 0.2         | Further consideration needed (d) data gap #1              |                          |

**Review of the existing MRLs for isopyrazam**

**www.efsa.europa.eu/efsajournal 42 EFSA Journal 2021;19(7):6684**
| Code number | Commodity    | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                                      |
|-------------|--------------|-------------------------|----------------------|-------------|----------------------------------------------|
| 500010      | Barley grain | 0.6                     | 0.6                  | 0.8         | Further consideration needed\(^{(a)}\)      |
| 500050      | Oats grain   | 0.6                     | –                    | 0.8         | Further consideration needed\(^{(b)}\)      |
| 500070      | Rye grain    | 0.2                     | 0.03                 | 0.2         | Further consideration needed\(^{(a)}\)      |
| 500090      | Wheat grain  | 0.2                     | 0.03                 | 0.2         | Further consideration needed\(^{(a)}\)      |
| 1011010     | Swine meat   | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(a)}\)      |
| 1011020     | Swine fat    | 0.03                    | 0.03                 | 0.03        | Further consideration needed\(^{(e)}\)      |
| 1011030     | Swine liver  | 0.02                    | 0.02                 | 0.02        | Further consideration needed\(^{(e)}\)      |
| 1011040     | Swine kidney | 0.02                    | 0.02                 | 0.02        | Further consideration needed\(^{(e)}\)      |
| 1012010     | Bovine meat  | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(a)}\)      |
| 1012020     | Bovine fat   | 0.03                    | 0.03                 | 0.03        | Further consideration needed\(^{(a)}\)      |
| 1012030     | Bovine liver | 0.02                    | 0.02                 | 0.02        | Further consideration needed\(^{(e)}\)      |
| 1012040     | Bovine kidney| 0.02                    | 0.02                 | 0.02        | Further consideration needed\(^{(e)}\)      |
| 1013010     | Sheep meat   | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(a)}\)      |
| 1013020     | Sheep fat    | 0.03                    | 0.03                 | 0.03        | Further consideration needed\(^{(e)}\)      |
| 1013030     | Sheep liver  | 0.02                    | 0.02                 | 0.02        | Further consideration needed\(^{(e)}\)      |
| 1013040     | Sheep kidney | 0.02                    | 0.02                 | 0.02        | Further consideration needed\(^{(e)}\)      |
| 1014010     | Goat meat    | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(a)}\)      |
| 1014020     | Goat fat     | 0.03                    | 0.03                 | 0.03        | Further consideration needed\(^{(e)}\)      |
| 1014030     | Goat liver   | 0.02                    | 0.02                 | 0.02        | Further consideration needed\(^{(e)}\)      |
| 1014040     | Goat kidney  | 0.02                    | 0.02                 | 0.02        | Further consideration needed\(^{(e)}\)      |
| 1015010     | Horse meat   | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(a)}\)      |
| 1015020     | Horse fat    | 0.03                    | 0.03                 | 0.03        | Further consideration needed\(^{(e)}\)      |
| 1015030     | Horse liver  | 0.02                    | 0.02                 | 0.02        | Further consideration needed\(^{(e)}\)      |
| 1015040     | Horse kidney | 0.02                    | 0.02                 | 0.02        | Further consideration needed\(^{(e)}\)      |
| 1016010     | Poultry meat | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(a)}\)      |
| 1016020     | Poultry fat  | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(a)}\)      |
| 1016030     | Poultry liver| 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(a)}\)      |
| 1020010     | Cattle milk  | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(a)}\)      |
| 1020020     | Sheep milk   | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(a)}\)      |
| 1020030     | Goat milk    | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(a)}\)      |
| 1020040     | Horse milk   | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(a)}\)      |
| 1030000     | Birds' eggs  | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(a)}\)      |
| –           | Other        | See Reg. 552/2019       | –                    | –           | Further consideration needed \(^{(f)}\)    |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(F): The residue definition is fat soluble.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the derived MRL (combination H–III in Appendix E). It is noted that isopyrazam might no longer satisfy the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H–I in Appendix E). It is noted that isopyrazam might no longer satisfy the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.
(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A–VII in Appendix E). It is noted that isopyrazam might no longer satisfy the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.
(d): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination F–I in Appendix E). It is noted that isopyrazam might no longer satisfy the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.
(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination H-VII in Appendix E). It is noted that isopyrazam might no longer satisfy the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009.

(f): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
# Appendix C – Pesticide Residue Intake Model (PRIMo)

## Isopyrazam (F)

### Toxicological reference values

| Parameter               | Value (mg/kg) |
|-------------------------|---------------|
| LOQs                    | 0.01–0.02     |
| ADI (mg/kg bw per day)  | 0.03          |
| ARfD (mg/kg bw)         | 0.2           |

### Source of ADI and ARfD

- ADI: EC
- ARfD: EC

### EFSA PRIMo revision 3.1; 2019/03/19

### Year of evaluation

- 2012

### No of diets exceeding the ADI: ---

### Table: Calculated exposure (% of ADI)

| Commodity/group of commodities | 14% | 9% | 7% | 6% | 5% | 5% | 4% | 3% | 2% | 1% | 0.8% |
|--------------------------------|-----|----|----|----|----|----|----|----|----|----|------|
| MRLs set at the LOQ (in % of ADI) | 14% | 9% | 7% | 6% | 5% | 5% | 4% | 3% | 2% | 1% | 0.8% |
| Commodities not under assessment (in % of ADI) | 9% | 2% | 2% | 1% | 0.6% | 0.6% | 0.4% | 0.7% | 0.4% | 0.4% | 0.3% |

### Calculations

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

The long-term intake of residues of Isopyrazam (F) is unlikely to present a public health concern.

### Details – chronic risk assessment

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

### Details – acute risk assessment

Acute risk assessment/children

### Supplementary results – chronic risk assessment

Acute risk assessment/adults

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[Additional content as per the document]
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Unprocessed commodities

| 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) |
|-----------------------|-------------|--------------------------|---------------------|-----------------------|-------------|--------------------------|---------------------|
| 19%                   | Peaches     | 0.7/0.39                 | 37                  | 4%                    | Courgettes  | 0.4/0.37                 | 8.8                  |
| 17%                   | Pears       | 0.4/0.24                 | 33                  | 4%                    | Aubergines/egg plants | 0.5/0.28       | 7.5                  |
| 13%                   | Apples      | 0.4/0.24                 | 26                  | 4%                    | Peaches     | 0.7/0.39                 | 7.3                  |
| 8%                    | Tomatoes    | 0.5/0.28                 | 16                  | 3%                    | Apples      | 0.4/0.24                 | 6.7                  |
| 8%                    | Melons      | 0.6/0.11                 | 16                  | 2%                    | Tomatoes    | 0.5/0.28                 | 4.4                  |
| 8%                    | Sweet peppers/bell peppers | 0.5/0.25 | 15                  | 2%                    | Watermelons | 0.6/0.11    | 4.3                  |
| 6%                    | Watermelons | 0.6/0.11                 | 13                  | 2%                    | Sweet peppers/bell peppers | 0.5/0.25 | 4.1                  |
| 4%                    | Carrots     | 0.2/0.14                 | 8.9                 | 2%                    | Melons      | 0.6/0.11                 | 4.1                  |
| 3%                    | Aubergines/egg plants | 0.5/0.28 | 6.9                  | 2%                    | Quinces     | 0.4/0.24                 | 3.7                  |
| 3%                    | Quinces     | 0.4/0.24                 | 5.9                 | 1%                    | Swedes/tubabagies | 0.1/0.08 | 2.9                  |
| 3%                    | Cucumbers  | 0.08/0.08               | 5.2                 | 1%                    | Carrots     | 0.2/0.14                 | 2.8                  |
| 2%                    | Beetroots  | 0.1/0.08                | 4.8                 | 1%                    | Gherkins    | 0.4/0.37                 | 2.2                  |
| 2%                    | Celeries/turnip rooted | 0.1/0.08 | 4.6                  | 1%                    | Cucumbers   | 0.08/0.08              | 2.2                  |
| 2%                    | Salsifies/tubabagies | 0.1/0.08 | 4.3                  | 1.0%                   | Beetroots   | 0.1/0.08                | 1.9                  |

### Processed commodities

| 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) |
|-----------------------|------------------------|--------------------------|---------------------|-----------------------|------------------------|--------------------------|---------------------|
| 16%                   | Pumpkins/boiled       | 0.6/0.35                | 31                  | 10%                   | Pumpkins/boiled        | 0.6/0.35                | 19                  |
| 7%                    | Courgettes/boiled     | 0.4/0.37                | 13                  | 4%                    | Courgettes/boiled      | 0.4/0.37                | 8.4                  |
| 5%                    | Peaches/canned        | 0.7/0.39                | 10                  | 2%                    | Beetroots/canned       | 0.1/0.08                | 3.3                  |
| 4%                    | Gherkins/pickled      | 0.4/0.37                | 8.5                 | 2%                    | Peaches/canned         | 0.7/0.39                | 3.2                  |
| 2%                    | Tumips/boiled         | 0.1/0.08                | 4.3                 | 0.9%                   | Parsnips/boiled        | 0.1/0.08                | 1.8                  |
| 2%                    | Paranos/boiled        | 0.1/0.08                | 4.3                 | 0.8%                   | Tumips/boiled          | 0.1/0.08                | 1.6                  |
| 2%                    | Pears/juice           | 0.4/0.13                | 4.2                 | 0.8%                   | Celeries/boiled        | 0.1/0.08                | 1.5                  |
| 2%                    | Beetroots/boiled      | 0.1/0.08                | 3.7                 | 0.3%                   | Salises/boled          | 0.1/0.08                | 0.69                 |
| 1%                    | Peaches/juice         | 0.7/0.18                | 3.0                 | 0.3%                   | Jerusalem artichokes/  | 0.1/0.08                | 0.68                 |
| 1%                    | Salsifies/boiled      | 0.1/0.08                | 2.2                 | 0.3%                   | Beer               | 0.8/0.02                | 0.58                 |
| 1%                    | Jerusalem artichokes/boiled | 0.1/0.08 | 2.1                  | 0.2%                   | Tomatoes/sauce/puree   | 0.5/0.06                | 0.49                 |
| 0.8%                  | Carrots/juice        | 0.2/0.04                | 1.5                 | 0.2%                   | Carrots/canned        | 0.2/0.04                | 0.34                 |
| 0.6%                  | Tomatoes/juice        | 0.5/0.06                | 1.1                 | 0.10%                  | Wheat/bread/pizza      | 0.2/0.04                | 0.19                 |
| 0.3%                  | Tomatoes/sauce/puree  | 0.5/0.06                | 0.57                | 0.08%                  | Wheat/pasta          | 0.2/0.04                | 0.17                 |
| 0.2%                  | Quinces/jam           | 0.4/0.13                | 0.39                | 0.08%                  | Quinces/jam           | 0.4/0.13                | 0.16                 |

### Conclusion

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of isopyrazam (F) is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.
LOQs (mg/kg) range from: 0.01 to: 0.01

ADI (mg/kg bw per day): 0.03
ARfD (mg/kg bw): 0.2

Source of ADI: EC
Source of ARfD: EC

EFSA PRIMo revision 3.1; 2021/01/06
Year of evaluation: 2012

No of diets exceeding the ADI: ---

### Calculated exposure (% of ADI)

| MS Diet | Exposure (µg/kg bw per day) | Highest contributor to MS diet (%) of ADI | 2nd contributor to MS diet (%) of ADI | 3rd contributor to MS diet (%) of ADI |
|---------|-----------------------------|------------------------------------------|---------------------------------------|---------------------------------------|
|         |                             | Commodity/group of commodities | Commodity/group of commodities | Commodity/group of commodities |
| Indoor  |                             | Pears | Wheat | Wheat | Pears |
| Outdoor |                             | 14%   | 9%    | 7%    | 6%    |
| Indoor  |                             | 4.34  | 2.82  | 2.05  | 1.68  |
| Outdoor |                             | 6%    | 5%    | 4%    | 3%    |
| Indoor  |                             | 5%    | 2%    | 0.7%  | 0.6%  |
| Outdoor |                             | 5%    | 2%    | 0.7%  | 0.4%  |
| Indoor  |                             | 5%    | 1%    | 0.7%  | 0.8%  |
| Outdoor |                             | 5%    | 1%    | 0.7%  | 0.6%  |
| Indoor  |                             | 4%    | 0.6%  | 0.7%  | 0.6%  |
| Outdoor |                             | 4%    | 0.6%  | 0.6%  | 0.5%  |
| Indoor  |                             | 4%    | 0.6%  | 0.6%  | 0.6%  |
| Outdoor |                             | 3%    | 0.5%  | 0.3%  | 0.3%  |
| Indoor  |                             | 3%    | 0.3%  | 0.3%  | 0.3%  |
| Outdoor |                             | 3%    | 0.2%  | 0.2%  | 0.2%  |
| Indoor  |                             | 2%    | 0.2%  | 0.2%  | 0.2%  |
| Outdoor |                             | 2%    | 0.2%  | 0.2%  | 0.2%  |
| Indoor  |                             | 2%    | 0.2%  | 0.2%  | 0.2%  |
| Outdoor |                             | 1%    | 0.2%  | 0.2%  | 0.2%  |
| Indoor  |                             | 1%    | 0.2%  | 0.2%  | 0.2%  |
| Outdoor |                             | 1%    | 0.2%  | 0.2%  | 0.2%  |

### MRLs set at the LOQ (in % of ADI)

| Commodities | MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|-------------|-----------------------------------|-----------------------------------------------|
| Pears       | 14%                               |                                               |
| Wheat       | 9%                                |                                               |
| Wheat       | 7%                                |                                               |
| Wheat       | 6%                                |                                               |
| Wheat       | 5%                                |                                               |
| Rye         | 5%                                |                                               |
| Wheat       | 5%                                |                                               |
| Wheat       | 4%                                |                                               |
| Wheat       | 4%                                |                                               |
| Apples      | 3%                                |                                               |
| Wheat       | 3%                                |                                               |
| Apples      | 3%                                |                                               |
| Wheat       | 3%                                |                                               |
| Carrots     | 2%                                |                                               |
| Wheat       | 2%                                |                                               |
| Tomatoes    | 2%                                |                                               |
| Apples      | 2%                                |                                               |
| Rye         | 2%                                |                                               |
| Peaches     | 2%                                |                                               |
| Wheat       | 2%                                |                                               |
| Apples      | 1%                                |                                               |
| Rye         | 1%                                |                                               |
| Apples      | 1%                                |                                               |
| Wheat       | 1%                                |                                               |
| Oat         | 1%                                |                                               |
| Pears       | 1%                                |                                               |
| Apples      | 1%                                |                                               |
| Wheat       | 1%                                |                                               |
| Apples      | 0.8%                              |                                               |
| Apples      | 0.7%                              |                                               |
| Carrots     | 0.6%                              |                                               |

### Toxicological reference values

Normal mode

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

**Conclusion:** FI 3 yr

**Input values**

**Supplementary results – chronic risk assessment**

**Details – acute risk assessment/children**

**Details – acute risk assessment/adults**

**Comments:**

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

The long-term intake of residues of Isopyrazam (F) 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.

**Details – acute risk assessment**

**Details – chronic risk assessment**

**Details – normal mode**

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### Acute risk assessment /children

| Commodity                        | MRL/input | Exposure | Highest % of ARfD/ADI | Commodity                        | MRL/input | Exposure |
|----------------------------------|-----------|----------|-----------------------|----------------------------------|-----------|----------|
| Peaches                          | 0.7 / 0.39 | 37 µg/kg bw | 19%                  | Courgettes                       | 0.4 / 0.37 | 8.6 µg/kg bw |
| Pears                            | 0.4 / 0.24 | 33 µg/kg bw | 17%                  | Aubergines/egg plants            | 0.5 / 0.28 | 7.5 µg/kg bw |
| Apples                           | 0.4 / 0.24 | 26 µg/kg bw | 13%                  | Pears                            | 0.4 / 0.24 | 7.3 µg/kg bw |
| Courgettes                       | 0.4 / 0.37 | 17 µg/kg bw | 9%                   | Tomatoes                         | 0.5 / 0.28 | 6.7 µg/kg bw |
| Tomatoes                         | 0.5 / 0.28 | 16 µg/kg bw | 8%                   | Melons                           | 0.6 / 0.11 | 4.4 µg/kg bw |
| Sweet peppers/bell peppers      | 0.5 / 0.25 | 15 µg/kg bw | 8%                   | Sweet peppers/bell peppers       | 0.5 / 0.25 | 4.1 µg/kg bw |
| Carrots                          | 0.2 / 0.14 | 8.9 µg/kg bw | 4%                   | Melons                           | 0.6 / 0.11 | 4.1 µg/kg bw |
| Aubergines/egg plants            | 0.5 / 0.28 | 6.9 µg/kg bw | 3%                   | Quinces                          | 0.4 / 0.24 | 3.7 µg/kg bw |
| Quinces                          | 0.4 / 0.24 | 5.9 µg/kg bw | 3%                   | Cucumbers                        | 0.0 / 0.08 | 2.9 µg/kg bw |
| Cucumbers                        | 0.0 / 0.08 | 5.2 µg/kg bw | 3%                   | Beetroots                        | 0.1 / 0.08 | 2.8 µg/kg bw |
| Beetroots                        | 0.1 / 0.08 | 4.8 µg/kg bw | 2%                   | Celeriacs/turnip rooted          | 0.1 / 0.08 | 2.2 µg/kg bw |
| Celeriacs/turnip rooted          | 0.1 / 0.08 | 4.6 µg/kg bw | 2%                   | Cucumbers                        | 0.0 / 0.08 | 2.2 µg/kg bw |
| peeled                           | 0.1 / 0.08 | 4.3 µg/kg bw | 1%                   | Beetroots                        | 0.1 / 0.08 | 1.9 µg/kg bw |

### Acute risk assessment /adults/general population

| Commodity                        | MRL/input | Exposure | Highest % of ARfD/ADI | Commodity                        | MRL/input | Exposure |
|----------------------------------|-----------|----------|-----------------------|----------------------------------|-----------|----------|
| Pumpkins/boiled                  | 0.6 / 0.35 | 31 µg/kg bw | 16%                  | Pumpkins/boiled                  | 0.6 / 0.35 | 19 µg/kg bw |
| Courgettes/boiled                | 0.4 / 0.37 | 13 µg/kg bw | 7%                   | Courgettes/boiled                | 0.4 / 0.37 | 8.4 µg/kg bw |
| Peaches/canned                   | 0.7 / 0.39 | 10 µg/kg bw | 5%                   | Beetroots/canned                 | 0.1 / 0.08 | 3.3 µg/kg bw |
| Garlies/citrus/beer              | 0.4 / 0.37 | 8.5 µg/kg bw | 4%                   | Peaches/citrus/beer              | 0.7 / 0.39 | 3.2 µg/kg bw |
| Turnips/boiled                   | 0.1 / 0.08 | 4.3 µg/kg bw | 2%                   | Garlic                           | 0.4 / 0.37 | 1.8 µg/kg bw |
| Parsnips/boiled                  | 0.1 / 0.08 | 4.3 µg/kg bw | 2%                   | Turnips/boiled                   | 0.1 / 0.08 | 1.6 µg/kg bw |
| Beetroots/boiled                 | 0.1 / 0.08 | 4.3 µg/kg bw | 2%                   | Parsnips/boiled                  | 0.1 / 0.08 | 1.5 µg/kg bw |
| Beetroots/boiled/grounded         | 0.1 / 0.08 | 4.3 µg/kg bw | 2%                   | Beetroots/boiled/grounded         | 0.1 / 0.08 | 0.69 µg/kg bw |
| Beetroots/boiled/grounded         | 0.1 / 0.08 | 4.3 µg/kg bw | 2%                   | Beetroots/boiled/grounded         | 0.1 / 0.08 | 0.33 µg/kg bw |
| Beetroots/boiled/grounded         | 0.1 / 0.08 | 4.3 µg/kg bw | 2%                   | Beetroots/boiled/grounded         | 0.1 / 0.08 | 0.2 µg/kg bw |
| Beetroots/boiled/grounded         | 0.1 / 0.08 | 4.3 µg/kg bw | 2%                   | Beetroots/boiled/grounded         | 0.1 / 0.08 | 0.17 µg/kg bw |
| Beetroots/boiled/grounded         | 0.1 / 0.08 | 4.3 µg/kg bw | 2%                   | Beetroots/boiled/grounded         | 0.1 / 0.08 | 0.16 µg/kg bw |

**Conclusion:**

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Isopyrazam (F) 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

| Feed commodity | Median dietary burden | Maximum dietary burden |
|----------------|-----------------------|------------------------|
|                | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment                |
| Apple, pomace, wet | 0.30 STMR × PF (2.4) |                        | 0.30 STMR × PF (2.4) |                        |
| Carrot, culls   | 0.04 STMR × CF (1.4) |                        | 0.14 HR × CF (1.4)   |                        |
| Swede, roots    | 0.01 STMR × CF (1.4) |                        | 0.08 HR × CF (1.4)   |                        |
| Turnip, roots   | 0.01 STMR × CF (1.4) |                        | 0.08 HR × CF (1.4)   |                        |
| Canola (Rape seed), meal(a) | 0.20 STMR × default PF (2) × CF (1.65) |                        | 0.20 STMR × default PF (2) × CF (1.65) |                        |
| Rape, meal(a)   | 0.20 STMR × default PF (2) × CF (1.65) |                        | 0.20 STMR × default PF (2) × CF (1.65) |                        |
| Barley, grain   | 0.08 STMR × CF (1.6) |                        | 0.08 STMR × CF (1.6) |                        |
| Brewer's grain, dried | 0.06 STMR × PF (0.8) × CF (1.0) |                        | 0.06 STMR × PF (0.8) × CF (1.0) |                        |
| Oat, grain      | 0.08 STMR × CF (1.6) |                        | 0.08 STMR × CF (1.6) |                        |
| Rye, grain      | 0.04 STMR × CF (1.5) |                        | 0.04 STMR × CF (1.5) |                        |
| Triticale, grain | 0.04 STMR × CF (1.5) |                        | 0.04 STMR × CF (1.5) |                        |
| Wheat, grain    | 0.04 STMR × CF (1.5) |                        | 0.04 STMR × CF (1.5) |                        |
| Wheat, distiller's grain (dry)(a) | 0.14 STMR × default PF (3.3) × CF (1.5) |                        | 0.14 STMR × default PF (3.3) × CF (1.5) |                        |
| Wheat gluten, meal(a) | 0.08 STMR × default PF (1.8) × CF (1.5) |                        | 0.08 STMR × default PF (1.8) × CF (1.5) |                        |
| Wheat, milled by-pdts(a) | 0.30 STMR × default PF (7) × CF (1.5) |                        | 0.30 STMR × default PF (7) × CF (1.5) |                        |
| Barley, straw   | 1.35 STMR × CF (1.2) |                        | 8.47 HR × CF (1.2)   |                        |
| Oat, straw      | 0.72 STMR × CF (1.2) |                        | 2.46 HR × CF (1.2)   |                        |
| Rye, straw      | 5.14 STMR × CF (1.3) |                        | 10.92 HR × CF (1.3)  |                        |
| Triticale, straw | 5.14 STMR × CF (1.3) |                        | 10.92 HR × CF (1.3)  |                        |
| Wheat, straw    | 5.14 STMR × CF (1.3) |                        | 10.92 HR × CF (1.3)  |                        |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor for enforcement to risk assessment residue definition.

*: Indicates that the input value is proposed at the limit of quantification.

(a): In the absence of processing factors supported by data, a default processing factor was included in the calculation to consider the potential concentration of residues in these commodities.

### D.2. Consumer risk assessment without consideration of the existing CXLs

| Commodity       | Chronic risk assessment | Acute risk assessment |
|-----------------|-------------------------|-----------------------|
|                 | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| Pome fruits     | 0.13 STMR_Mo × CF (1.0) |                        | 0.24 HR_Mo × CF (1.0)   |                        |
| Peaches         | 0.18 STMR_Mo × CF (1.0) |                        | 0.39 HR_Mo × CF (1.0)   |                        |

**Risk assessment residue definition:** Isopyrazam (sum of isomers) plus its metabolite CSCD459488 [syn-hydroxyl isopyrazam] (free and conjugated), expressed as isopyrazam.
| Commodity                        | Input value (mg/kg) | Comment                           | Input value (mg/kg) | Comment                           |
|---------------------------------|--------------------|-----------------------------------|--------------------|-----------------------------------|
| Bananas                         | 0.01               | STMR<sub>Mo</sub> × PF (0.6) × CF (1.0) | 0.02               | HR<sub>Mo</sub> × PF (0.6) × CF (1.0) |
| Beetroots                       | 0.01               | STMR<sub>Mo</sub> × CF (1.4)       | 0.08               | HR<sub>Mo</sub> × CF (1.4)        |
| Carrots                         | 0.04               | STMR<sub>Mo</sub> × CF (1.4)       | 0.14               | HR<sub>Mo</sub> × CF (1.4)        |
| Celeriacs/turnip rooted celeries| 0.01               | STMR<sub>Mo</sub> × CF (1.4)       | 0.08               | HR<sub>Mo</sub> × CF (1.4)        |
| Horseradishes                   | 0.01               | STMR<sub>Mo</sub> × CF (1.4)       | 0.08               | HR<sub>Mo</sub> × CF (1.4)        |
| Jerusalem artichokes            | 0.01               | STMR<sub>Mo</sub> × CF (1.4)       | 0.08               | HR<sub>Mo</sub> × CF (1.4)        |
| Parsnips                        | 0.01               | STMR<sub>Mo</sub> × CF (1.4)       | 0.08               | HR<sub>Mo</sub> × CF (1.4)        |
| Parsley roots/Hamburg roots parsley| 0.01               | STMR<sub>Mo</sub> × CF (1.4)       | 0.08               | HR<sub>Mo</sub> × CF (1.4)        |
| Radishes                        | 0.01               | STMR<sub>Mo</sub> × CF (1.4)       | 0.08               | HR<sub>Mo</sub> × CF (1.4)        |
| Salsifies                       | 0.01               | STMR<sub>Mo</sub> × CF (1.4)       | 0.08               | HR<sub>Mo</sub> × CF (1.4)        |
| Swedes/rutabagas                | 0.01               | STMR<sub>Mo</sub> × CF (1.4)       | 0.08               | HR<sub>Mo</sub> × CF (1.4)        |
| Turnips                         | 0.01               | STMR<sub>Mo</sub> × CF (1.4)       | 0.08               | HR<sub>Mo</sub> × CF (1.4)        |
| Tomatoes                        | 0.06               | STMR<sub>Mo</sub> × CF (1.2)       | 0.28               | HR<sub>Mo</sub> × CF (1.2)        |
| Sweet peppers/bell peppers      | 0.16               | STMR<sub>Mo</sub> × CF (1.1)       | 0.23               | HR<sub>Mo</sub> × CF (1.1)        |
| Aubergines/egg plants           | 0.06               | STMR<sub>Mo</sub> × CF (1.2)       | 0.28               | HR<sub>Mo</sub> × CF (1.5) × PF (0.6) |
| Cucumbers                       | 0.03               | STMR<sub>Mo</sub> × CF (1.6)       | 0.08               | HR<sub>Mo</sub> × CF (1.6)        |
| Gherkins                        | 0.1                | STMR<sub>Mo</sub> × CF (1.6)       | 0.37               | HR<sub>Mo</sub> × CF (1.6)        |
| Courgettes                      | 0.1                | STMR<sub>Mo</sub> × CF (1.6)       | 0.37               | HR<sub>Mo</sub> × CF (1.6)        |
| Melons                          | 0.02               | STMR<sub>Mo</sub> × PF (0.6) × CF (1.0) | 0.11               | HR<sub>Mo</sub> × PF (0.6) × CF (1.0) |
| Pumpkins                        | 0.02               | STMR<sub>Mo</sub> × PF (0.6) × CF (1.0) | 0.11               | HR<sub>Mo</sub> × PF (0.6) × CF (1.0) |
| Watermelons                     | 0.02               | STMR<sub>Mo</sub> × PF (0.6) × CF (1.0) | 0.11               | HR<sub>Mo</sub> × PF (0.6) × CF (1.0) |
| Rapesseeds/canola seeds         | 0.1                | STMR<sub>Mo</sub> × CF (1.0)       | 0.1                | STMR<sub>Mo</sub> × CF (1.0)      |
| Mustard seeds                   | 0.07               | STMR<sub>Mo</sub> × CF (1.1) (tentative) | 0.07               | STMR<sub>Mo</sub> × CF (1.1) (tentative) |
| Barley                          | 0.08               | STMR<sub>Mo</sub> × CF (1.6)       | 0.08               | STMR<sub>Mo</sub> × CF (1.6)      |
| Oat                             | 0.08               | STMR<sub>Mo</sub> × CF (1.6)       | 0.08               | STMR<sub>Mo</sub> × CF (1.6)      |
| Rye                             | 0.04               | STMR<sub>Mo</sub> × CF (1.5)       | 0.04               | STMR<sub>Mo</sub> × CF (1.5)      |
| Wheat                           | 0.04               | STMR<sub>Mo</sub> × CF (1.5)       | 0.04               | STMR<sub>Mo</sub> × CF (1.5)      |

**Risk assessment residue definition:** isopyrazam (sum of isomers) and all metabolites containing the CSAA798670 moiety, expressed as isopyrazam.

---

**Review of the existing MRLs for isopyrazam:**

- Swine, ruminant, equine meat
  - 0.02 (0.8 × STMR<sub>Mo</sub> muscle + 0.2 × STMR<sub>Mo</sub> fat) × CF (2)
  - 0.02 (0.8 × HR<sub>Mo</sub> muscle + 0.2 × HR<sub>Mo</sub> fat) × CF (2)
- Swine, ruminant, equine fat
  - 0.02 STMR<sub>Mo</sub> × CF (2)
  - 0.02 HR<sub>Mo</sub> × CF (2)
- Swine, ruminant, equine liver
  - 0.22 STMR<sub>Mo</sub> × CF (22)
  - 0.22 HR<sub>Mo</sub> × CF (22)
- Swine, ruminant, equine, kidney
  - 0.06 STMR<sub>Mo</sub> × CF (6)
  - 0.06 HR<sub>Mo</sub> × CF (6)
- Poultry meat, fat, liver
  - 0.01* STMR
  - 0.01* HR
- Ruminant and horse milk
  - 0.03 STMR<sub>Mo</sub> × CF (3)
  - 0.03 STMR<sub>Mo</sub> × CF (3)
- Birds eggs
  - 0.01* STMR
  - 0.01* HR
STMR: supervised trials median residue; HR: highest residue; Mo: monitoring; CF: conversion factor for enforcement to risk assessment residue definition.

*: Indicates that the input value is proposed at the limit of quantification.

D.3. Consumer risk assessment with consideration of the existing CXLs

| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|------------------------------------------------|-------------------------|-----------------------|
|                                                | Input value (mg/kg)     | Comment               |
|                                                | Comment                 | Input value (mg/kg)   | Comment               |
| Risk assessment residue definition: Isopyrazam (sum of isomers) plus its metabolite CSCD459488 \[syn-hydroxyl isopyrazam\] (free and conjugated), expressed as isopyrazam |
| Pome fruits                                    | 0.13                    | STMR<sub>Mo</sub> × CF (1.0) | 0.24          | HR<sub>Mo</sub> × CF (1.0) |
| Peaches                                        | 0.18                    | STMR<sub>Mo</sub> × CF (1.0) | 0.39          | HR<sub>Mo</sub> × CF (1.0) |
| Bananas                                        | 0.01                    | STMR<sub>Mo</sub> × PF (0.6) × CF (1.0) | 0.02 | HR<sub>Mo</sub> × PF (0.6) × CF (1.0) |
| Beetroots                                       | 0.01                    | STMR<sub>Mo</sub> × CF (1.4) | 0.08          | HR<sub>Mo</sub> × CF (1.4) |
| Carrots                                        | 0.04                    | STMR<sub>Mo</sub> × CF (1.4) | 0.14          | HR<sub>Mo</sub> × CF (1.4) |
| Celeriacs/turnip rooted celeries               | 0.01                    | STMR<sub>Mo</sub> × CF (1.4) | 0.08          | HR<sub>Mo</sub> × CF (1.4) |
| Horseradishes                                  | 0.01                    | STMR<sub>Mo</sub> × CF (1.4) | 0.08          | HR<sub>Mo</sub> × CF (1.4) |
| Jerusalem artichokes                           | 0.01                    | STMR<sub>Mo</sub> × CF (1.4) | 0.08          | HR<sub>Mo</sub> × CF (1.4) |
| Parsnips                                       | 0.01                    | STMR<sub>Mo</sub> × CF (1.4) | 0.08          | HR<sub>Mo</sub> × CF (1.4) |
| Parsley roots/ Hamburg roots parsley           | 0.01                    | STMR<sub>Mo</sub> × CF (1.4) | 0.08          | HR<sub>Mo</sub> × CF (1.4) |
| Radishes                                       | 0.01                    | STMR<sub>Mo</sub> × CF (1.4) | 0.08          | HR<sub>Mo</sub> × CF (1.4) |
| Salsifies                                      | 0.01                    | STMR<sub>Mo</sub> × CF (1.4) | 0.08          | HR<sub>Mo</sub> × CF (1.4) |
| Swedes/ rutabagas                              | 0.01                    | STMR<sub>Mo</sub> × CF (1.4) | 0.08          | HR<sub>Mo</sub> × CF (1.4) |
| Turnips                                        | 0.01                    | STMR<sub>Mo</sub> × CF (1.4) | 0.08          | HR<sub>Mo</sub> × CF (1.4) |
| Tomatoes                                       | 0.06                    | STMR<sub>Mo</sub> × CF (1.2) | 0.28          | HR<sub>Mo</sub> × CF (1.2) |
| Sweet peppers/ bell peppers                    | 0.16                    | STMR<sub>Mo</sub> × CF (1.1) | 0.23          | HR<sub>Mo</sub> × CF (1.1) |
| Aubergines/egg plants                          | 0.06                    | STMR<sub>Mo</sub> × CF (1.2) | 0.28          | HR<sub>Mo</sub> × CF (1.5) × PF (0.6) |
| Cucumbers                                      | 0.03                    | STMR<sub>Mo</sub> × CF (1.6) | 0.08          | HR<sub>Mo</sub> × CF (1.6) |
| Gherkins                                       | 0.1                     | STMR<sub>Mo</sub> × CF (1.6) | 0.37          | HR<sub>Mo</sub> × CF (1.6) |
| Courgettes                                     | 0.1                     | STMR<sub>Mo</sub> × CF (1.6) | 0.37          | HR<sub>Mo</sub> × CF (1.6) |
| Melons                                         | 0.02                    | STMR<sub>Mo</sub> × PF (0.6) × CF (1.0) | 0.11 | HR<sub>Mo</sub> × PF (0.6) × CF (1.0) |
| Pumpkins                                       | 0.02                    | STMR<sub>Mo</sub> × PF (0.6) × CF (1.0) | 0.11 | HR<sub>Mo</sub> × PF (0.6) × CF (1.0) |
| Watermelons                                    | 0.02                    | STMR<sub>Mo</sub> × PF (0.6) × CF (1.0) | 0.11 | HR<sub>Mo</sub> × PF (0.6) × CF (1.0) |
| Peanuts                                        | 0.02*                   | STMR<sub>Mo</sub> (CXL) × CF (1.5) | 0.02* | HR<sub>Mo</sub> (CXL) × CF (1.5) |
| Rapeseeds/canola seeds                         | 0.1                     | STMR<sub>Mo</sub> × CF (1.0) | 0.1           | STMR<sub>Mo</sub> × CF (1.0) |
| Mustard seeds                                  | 0.07                    | STMR<sub>Mo</sub> × CF (1.1) (tentative) | 0.07 | STMR<sub>Mo</sub> × CF (1.1) (tentative) |
| Barley                                         | 0.08                    | STMR<sub>Mo</sub> × CF (1.6) | 0.08          | STMR<sub>Mo</sub> × CF (1.6) |
| Oat                                            | 0.08                    | STMR<sub>Mo</sub> × CF (1.6) | 0.08          | STMR<sub>Mo</sub> × CF (1.6) |
| Rye                                            | 0.04                    | STMR<sub>Mo</sub> × CF (1.5) | 0.04          | STMR<sub>Mo</sub> × CF (1.5) |
| Wheat                                          | 0.04                    | STMR<sub>Mo</sub> × CF (1.5) | 0.04          | STMR<sub>Mo</sub> × CF (1.5) |
| Commodity                          | Chronic risk assessment                                                                 | Acute risk assessment                                                                 |
|-----------------------------------|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
|                                  | Comment                                                                                 | Comment                                                                                 |
|                                  | Input value (mg/kg)                                                                     | Input value (mg/kg)                                                                     |
|                                  |                                                                                         |                                                                                         |
| Risk assessment residue definition: | Isopyrazam (sum of isomers) and all metabolites containing the CSAA798670 moiety, expressed as isopyrazam |                                                                                         |
|                                  |                                                                                         |                                                                                         |
| Swine, ruminant, equine meat      | 0.02 (0.8 × STMR<sub>Mo</sub> muscle + 0.2 × STMR<sub>Mo</sub> fat) × CF (2)              | 0.02 (0.8 × HR<sub>Mo</sub> muscle + 0.2 × HR<sub>Mo</sub> fat) × CF (2)                 |
| Swine, ruminant, equine, fat      | 0.02 STMR<sub>Mo</sub> (CXL) × CF (2)                                                   | 0.04 HR (CXL)<sub>Mo</sub> × CF (2)                                                    |
| Swine, ruminant, equine, liver    | 0.22 STMR<sub>Mo</sub> (CXL) × CF (22)                                                  | 0.22 HR (CXL)<sub>Mo</sub> × CF (22)                                                   |
| Swine, ruminant, equine, kidney   | 0.06 STMR<sub>Mo</sub> (CXL) × CF (6)                                                   | 0.12 HR (CXL)<sub>Mo</sub> × CF (6)                                                    |
| Poultry meat, fat, liver          | 0.01* STMR                                                                             | 0.01* HR                                                                              |
| Ruminant and horse milk           | 0.03 STMR<sub>Mo</sub> × CF (3)                                                        | 0.03 STMR<sub>Mo</sub> × CF (3)                                                        |
| Birds eggs                        | 0.01* STMR                                                                             | 0.01* HR                                                                              |

STMR: supervised trials median residue; HR: highest residue; Mo: monitoring; CF: conversion factor for enforcement to risk assessment residue definition; CXL: codex maximum residue limit.

*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations
# Appendix F – Used compound codes

| Code/trivial name | IUPAC name/SMILES notation/InChiKey(a) | Structural formula(b) |
|-------------------|----------------------------------------|-----------------------|
| isopyrazam (mixture of isomers) | syn-isomers | 3-(difluoromethyl)-1-methyl-N-[(1R,4S,9R)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]-1H-pyrazole-4-carboxamide<br>FC(F)c1nn(C)cc1C(=O)Nc1cccc2[C@H]3CC[C@H][C@H]3C(C)C21<br>XTDZGXBTXBEZDN-HEHG2KQESA-N | ![Structural formula](attachment:image1.png) |
| | anti-isomers | 3-(difluoromethyl)-1-methyl-N-[(1S,4R,9S)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]-1H-pyrazole-4-carboxamide<br>FC(F)c1nn(C)cc1C(=O)Nc1cccc2[C@H]3CC[C@H][C@H]3C(C)C21<br>XTDZGXBTXBEZDN-IOASZLSFSA-N | ![Structural formula](attachment:image2.png) |
| hydroxy-isopyrazam (mixture of isomers) | hydroxy-isopyrazam (syn-isomers) | 3-(difluoromethyl)-N-[(1R,4S,9R)-9-(2-hydroxypropan-2-yl)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-1-methyl-1H-pyrazole-4-carboxamide<br>FC(F)c1nn(C)cc1C(=O)Nc1cccc2[C@H]3CC[C@H][C@H]3C(C)C21<br>HGWDTMJPJLLNY-HWWQOWPSSA-N | ![Structural formula](attachment:image3.png) |
| Code/trivial name                      | IUPAC name/SMILES notation/InChiKey**(a)** | Structural formula**(b)** |
|---------------------------------------|------------------------------------------|--------------------------|
| CSCD459489 hydroxy-isopyrazam (anti-isomers) | 3-(difluoromethyl)-N-[(1R,4S,9S)-9-(2-hydroxypropan-2-yl)-1,2,3,4-tetrahydro,1,4-methanonaphthalen-5-yl]-1-methyl-1H-pyrazole-4-carboxamide | ![](https://example.com/structure1.png) |
|                                       | FC(F)c1nn(C)cc1C(-O)Nc1ccc2[C@@H] 3CC[C@@H][([C@H]3C(C)(C)O)c21 | ![](https://example.com/structure2.png) |
|                                       | HCWDTMDPJLLNY-OZVIIMIRSA-N | |
|                                       | 3-(difluoromethyl)-N-[(1S,4R,9R)-9-(2-hydroxypropan-2-yl)-1,2,3,4-tetrahydro,1,4-methanonaphthalen-5-yl]-1-methyl-1H-pyrazole-4-carboxamide | ![](https://example.com/structure3.png) |
|                                       | FC(F)c1nn(C)cc1C(-O)Nc1ccc2[C@H] 3CC[C@H][([C@H]3C(C)(C)O)c21 | ![](https://example.com/structure4.png) |
|                                       | HCWDTMDPJLLNY-BFQNTYOBSA-N | |
| CSCD465008                            | 3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid | ![](https://example.com/structure5.png) |
|                                       | OC(-O)c1c[NH]nc1(F)F | |
|                                       | IGQNDARULCASRN-UHFFFAOYSA-N | |
| CSAA798670                            | 3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxylic acid | ![](https://example.com/structure6.png) |
|                                       | FC(F)c1nn(C)cc1C(-O)O | |
|                                       | RLOHOBNEYHZID-UHFFFAOYSA-N | |
| CDCD656800                            | 3-(difluoromethyl)-N-[(1R,4S)-2-hydroxy-9-(2-hydroxypropan-2-yl)-1,2,3,4-tetrahydro,1,4-methanonaphthalen-5-yl]-1-methyl-1H-pyrazole-4-carboxamide | ![](https://example.com/structure7.png) |
|                                       | FC(F)c1nn(C)cc1C(-O)Nc1ccc2[C@@H] 3CC(O)C[C@@H][([C@H]3C(C)(C)O)c21 | ![](https://example.com/structure8.png) |
|                                       | GYFHNRRNZXZFFR-IUHPWCTPSA-N | |
|                                       | 3-(difluoromethyl)-N-[(1S,4R)-2-hydroxy-9-(2-hydroxypropan-2-yl)-1,2,3,4-tetrahydro,1,4-methanonaphthalen-5-yl]-1-methyl-1H-pyrazole-4-carboxamide | ![](https://example.com/structure9.png) |
|                                       | FC(F)c1nn(C)cc1C(-O)Nc1ccc2[C@H]3C(O)C[C@H][([C@H]3C(C)(C)O)c21 | ![](https://example.com/structure10.png) |
|                                       | GYFHNRRNZXNZFFR-YQORHSBSFSA-N | |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

(a): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).
(b): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).