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 bispyribac. To assess the occurrence of bispyribac residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC as well as the 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. All information required by the regulatory framework was present and a risk to consumers was not identified.

Keywords: bispyribac, bispyribac-sodium, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, herbicide

Requestor: European Commission

Question number: EFSA-Q-2011-00171

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Acknowledgement: EFSA wishes to thank the rapporteur Member State Italy for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2018. Reasoned Opinion on the review of the existing maximum residue levels for bispyribac according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(1):5142, 25 pp. https://doi.org/10.2903/j.efsa.2018.5142

ISSN: 1831-4732

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Summary

Bispyribac was included in Annex I to Directive 91/414/EEC on 1 August 2011 by Commission Implementing Regulation (EU) No 740/2011, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 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. To collect the relevant pesticide residues data, EFSA asked Italy, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 21 July 2017 and finalised on 21 September 2017. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 23 October 2017.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS and Member States, EFSA prepared in November 2017 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 6 December 2017 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The nature of residues of bispyribac was investigated in primary crops (cereals) and in rotational crops (cereals, root crops and pulses/oilseeds). Based on the primary crop studies, the parent compound is the major component of the residue. The confined rotational crop study showed that significant residues are not expected in succeeding crops. Therefore, the residue for enforcement and risk assessment was defined as the sum of bispyribac and its salts, expressed as bispyribac-sodium. This residue definition can be enforced in dry commodities as well as in other main matrices with limit of quantifications (LOQs) ranging from 0.005 to 0.02 mg/kg. The proposed residue definition is limited to cereal crops and applies to both grain and straw.

The available residue trials were sufficient to derive MRL proposals as well as risk assessment values for rice grain (only food commodity under assessment). A tentative MRL was also derived for rice straw in view of the future need to set MRLs in feed items. As residue levels in rice grain and straw are expected to remain below the LOQ and since the chronic exposure is expected to be far below 10% of the acceptable daily intake (ADI), no further investigation on the nature and magnitude of residues in processed commodities were required.

Livestock dietary burdens were calculated for different groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM) for all groups of livestock. Therefore, further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

Chronic consumer exposure resulting from the authorised use reported in the framework of this review was calculated using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The highest chronic exposure represented 0.2% of the ADI (PT, general population). Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.
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Background

Regulation (EC) No 396/20051 (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/EEC2 a reasoned opinion on the review of the existing MRLs for that active substance. As bispyribac was included in Annex I to Council Directive 91/414/EEC on 1 August 2011 by means of Commission Implementing Regulation (EU) No 740/20113, and has been deemed to be approved under Regulation (EC) No 1107/20094, in accordance with Commission Implementing Regulation (EU) No 540/20115, as amended by Commission Implementing Regulation (EU) No 541/20116, EFSA initiated the review of all existing MRLs for that active substance.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that, in the framework of Directive 91/414/EEC, 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 Directive 91/414/EEC 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.

Italy, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for bispyribac and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report were submitted to EFSA on 27 June 2012 (Italy, 2012) and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 21 July 2017 and finalised on 21 September 2017. Additional evaluation report was submitted by the European Union Reference Laboratories for Pesticide Residues (EURL, 2017). After having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 23 October 2017. No further clarifications were sought from Member States.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, and the additional information provided by the Member States, EFSA prepared in November 2017 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All

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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 740/2011 of 27 July 2011 approving the active substance bispyribac, 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 196, 28.7.2011, p. 6–10.
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.
comments received by 6 December 2017 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Italy, 2012) and the evaluation report submitted by European Union Reference Laboratories for Pesticide Residues (EURel, 2017) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2017a) and the Member States consultation report (EFSA, 2017b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) (excel file) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo(EU) 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;
- 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

Bispyribac is the ISO common name for 2,6-bis(4,6-dimethoxypyrimidin-2-yloxy)benzoic acid (IUPAC).

Bispyribac belongs to the group of pyrimidinylloxybenzoic acid compounds which are used as herbicide on rice to control principally grasses and sedges. The only other compound in this class is pyriminobac. Its mode of action is by branched chain amino acid synthesis inhibition. It is a selective, systemic post-emergence herbicide, absorbed by foliage and roots.

The chemical structure of the active substance and its main metabolite(s) are reported in Appendix F.

Bispyribac was evaluated in the framework of Directive 91/414/EEC with Italy designated as RMS. The representative use supported for the peer review process was a suspension concentrate post-emergence (up to GS BBCH 25) herbicide on rice. Following the peer review, which was carried out by EFSA (EFSA, 2010), a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Implementing Regulation (EU) No 740/2011, which entered into force on 1 August 2011. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, bispyribac is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses herbicide only. According with the annex of the approval Regulation a specific provision of the approval that the applicant was required to submit to the European Commission further studies in the area of environmental fate and behaviour by 31 July 2013.

The EU MRLs for bispyribac correspond to the default value of 0.01 mg/kg according to Art 18(1) (b) Reg 396/2005. No MRL changes occurred since the entry unto force of the Regulation mentioned above.

For the purpose of this MRL review, the critical uses of bispyribac currently authorised within the EU, have been collected by the RMS and reported in the PROFile. The additional good agricultural practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAP for bispyribac are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Italy, 2012), the draft assessment report (DAR) prepared under Council Directive 91/414/EEC (Italy, 2003), the conclusion on the peer review of the pesticide risk assessment
of the active substance bispyribac (EFSA, 2010), as well as the evaluation report submitted during the completeness check (EURL, 2017). 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, 1997a–g, European Commission, 2000, 2010a,b, European Commission, 2017 and OECD, 2011, 2013).

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

It is noted that the sodium salt, a variant of bispyribac, was used in the residue studies. Thus, the evaluated data belong to the variant bispyribac-sodium and the reported residue levels are expressed as bispyribac-sodium, unless otherwise explicitly specified.

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 behaviour and metabolism of bispyribac-sodium was investigated in dry-seeded and water-seeded rice using pyrimidine-labelled and benzene-labelled bispyribac-sodium applied at rates that were slightly exaggerated (1.3–1.9 N) compared to the critical GAP (cGAP) reported in this review.

The studies demonstrated that the metabolic pathway of bispyribac-sodium in rice is similar under the different cultivation conditions investigated. Metabolism in the plants was extensive, with a substantial part of the radioactivity recovered in the mature plant being incorporated into natural plant components such as starch, lignin, and cellulose. Residues in mature rice grain were very low (≤ 0.02 mg eq/kg), and therefore, no further analysis was conducted in this crop part. Upon analysis of immature plants and/or straw and roots bispyribac-sodium was always the major component of the total residue, amounting to 77% total radioactive residue (TRR) in the immature rice plant, to 8% TRR (0.01–0.04 mg/kg) in straw and 3% TRR in the roots. Similar metabolites were identified in the examined materials, with M02 (BX-180) (anion or associated to salts) being most prevalent in the mature crop (2–5%TRR in straw and roots; 0.01–0.02 mg/kg). None of the identified and unidentified metabolites was present in significant amounts in the plants.

A metabolic pathway could be established for bispyribac-sodium in rice plants that involves hydroxylation of a pyrimidine ring or O-demethylation of a methoxy group on a pyrimidine ring followed by glucoside conjugation at the demethylated position or hydrolytic cleavage of a pyrimidine ring from the benzyl moiety. All major metabolic steps observed in rice plants were common with those seen in the rodent metabolism studies.

1.1.2. Nature of residues in rotational crops

According to the soil degradation studies evaluated in the framework of the peer review, field DT90 values of bispyribac-sodium ranges between 20 and 30 days, which is lower than the trigger value of 100 days (EFSA, 2010). The same is expected for the main soil metabolites (M05 and M06 also referred to as ‘DesMe-2023’). According to the European guidelines on rotational crops (European Commission, 1997b), further investigation of residues in rotational crops is not required and, although the fields used for rice production can be rotated to other cereals, relevant residues in rotational crops are not expected.

The nature of residues in rotational crops was anyhow investigated in a confined rotational crop study. Pyrimidine-labelled bispyribac-sodium was applied on bare soil at the rate of 68 g a.s./ha, which is more than twice the application rate authorised by the cGAP reported in this review. Wheat, radish and soybean were planted 28, 46 and 120 days after treatment (Italy, 2003). The TRRs in all crops and matrices sampled after the first planting ranged between 0.001 and 0.005 mg/kg. Due to the low residue levels, no further quantification of metabolites in the samples was attempted and investigation of residues was not continued for crops with longer plant-back intervals. Based on these results and

7 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.
considering the exaggerated application rate compared to the authorised GAPs, no bispyribac residues are expected in rotational crops. Further studies, such as field rotational crop trials, are not necessary.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities are not available. However, such studies are not required under this review since residue levels in rice grain and straw are expected to remain below the enforcement limit of quantification (LOQ) of 0.02 mg/kg. Furthermore, the chronic exposure is expected to be far below 10% of the acceptable daily intake (ADI) (see Section 3).

1.1.4. Methods of analysis in plants

During the peer review, an analytical method using high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) and its independent laboratory validation (ILV) were validated in rice grain and rice straw for the analysis of bispyribac and its salts with the LOQ of 0.02 mg/kg (EFSA, 2010).

According to the EURLs, bispyribac residues can also be enforced using the QuEChERS method and liquid chromatography with tandem mass spectrometry (LC-MS/MS) in high water content, high acid content, high oil content and dry commodities with a LOQ of 0.01 mg/kg in each matrix (EURLs, 2017).

1.1.5. Stability of residues in plants

The potential degradation of residues during storage of the residue trials samples was assessed in the framework of the peer review. Storage stability of bispyribac-sodium was demonstrated for a period of 8 months at –18°C in dry commodities (rice grain) as well as in rice straw (EFSA, 2010).

1.1.6. Proposed residue definitions

Based on the studies conducted on rice under various cultivation conditions and with two different radiolabels, bispyribac-sodium is the major component of the residue. None of the observed metabolites are present in significant amounts and, according to the confined rotational crop study, the total residues in the succeeding crops do not exceed 0.01 mg/kg. Based on these results, the residue for enforcement and risk assessment was defined as the sum of bispyribac and its salts, expressed as bispyribac-sodium (EFSA, 2010). This residue definition can be enforced in dry commodities as well as in rice straw with a LOQ of 0.02 mg/kg. This proposal is still applicable in the framework of the present review as the cGAP identified for rice is identical to the one assessed during the peer review. The proposed residue definition is still limited to cereal crops and applies to both grain and straw.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of bispyribac residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Italy, 2012), including residue trials evaluated in the framework of the peer review (EFSA, 2010). It is noted that the residue trials were performed with bispyribac-sodium, a variant salt of bispyribac and that residue samples were also analysed for this variant. Therefore, the reported residue levels were expressed as bispyribac-sodium, in accordance with the residue definition. All residue trial samples considered in this framework were stored in compliance with the storage conditions for which the residues were demonstrated stable. Decline of residues during storage of the trial samples is therefore not expected.

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).

The available residue trials are sufficient to derive MRL and risk assessment values for all commodities under consideration (rice grain and rice straw). It is noted that the cGAP reported for rice is not expected to lead to significant residue levels in rice grain and straw. This is confirmed by 10 residue trials analysing residues in grain and straw (eight trials from the peer review plus two trials...
reported in the framework on this review). Therefore, MRLs and risk assessment values can be set at the enforcement LOQ.

1.2.2. Magnitude of residues in rotational crops

The confined metabolism studies allowed to conclude that no bispyribac residues are expected in rotational/succeeding crops grown on soil previously treated with bispyribac-sodium (see Section 1.1.2). Further studies are not required.

1.2.3. Magnitude of residues in processed commodities

There are no studies available on the magnitude of residues in processed commodities of rice grain and these data are not required in this review (see also Section 1.1.3).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for rice grain (only food commodity under assessment). A tentative MRL was also derived for rice straw in view of the future need to set MRLs in feed items.

2. Residues in livestock

Bispyribac is authorised for use on rice and rice straw might be fed to livestock according to the OECD guidance (OECD, 2013), which has now also been agreed upon at European level. Livestock dietary burdens were therefore calculated for different groups of livestock according to the above-mentioned guidance. The input values for all relevant commodities are summarised in Appendix D. It is noted that the default concentration factor usually considered for rice, bran/pollard was not taken into account in the calculation since residues expected in rice grain are expected to remain below the LOQ (see Section 1.2.1). The calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM). Therefore, further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

Although not required, studies investigating the nature of bispyribac residues in commodities of animal origin were assessed by the RMS and reported in the framework of the peer review (Italy, 2003). Reported metabolism studies include one study in lactating goats and one study in laying hens using pyrimidine-labelled and benzene-labelled bispyribac-sodium. It is noted that lactating goats and laying hens were dosed with rates corresponding to more than 1,000 times the calculated dietary burdens.

Studies demonstrate that the transfer of residues to milk, eggs and any tissues is expected to very low. Most of the TRR was found in urine, faeces and gastrointestinal tract. Liver is the only edible tissue where significant residues were observed (0.20 mg eq/kg in goat and 4.98 mg eq/kg in poultry). In all other edible tissues, only very low levels or insignificant levels were retrieved with a maximum of 0.02 mg eq/kg in egg yolks and poultry skin fat and TRR below or equal to 0.01 mg kg/kg in any other tissues.

Bispyribac-sodium is a predominant component of the TRR in all tissues of ruminants and poultry where significant residues were quantified. It represents 37–39% of the TRR in goat liver and kidney, 97% of the TRR in poultry liver, 54–71% of TRR in poultry fat and 15% of TRR in egg yolk. The only analyte found in significant proportions in edible tissues is a glucuronide conjugate of the parent compounds, reported as metabolite M21. It accounted for 40–52% of the TRR (0.08–0.11 mg eq/kg) in goat liver or 1.3% of the TRR (0.07 mg eq/kg) in poultry liver. All other identified or unidentified metabolites accounted for less than 0.05 mg eq/kg.

It is noted that a conclusion on the residue definitions is not required in the present review. However, if the dietary burden would trigger this need in the future, the parent compound would be a good option for enforcement purpose as it is present in all the tissues where significant residues were observed. For risk assessment purpose, however, further considerations should be given on the need to consider the conjugate(s) of the parent compound as the glucuronide conjugate may also contribute to the overall residues in liver tissues.

Since a residue definition is neither needed nor proposed, analytical methods for enforcement in food of animal origin as well as storage stability studies are not required.

Livestock feeding studies were not carried out for bispyribac and these data are not required in this review.
3. Consumer risk assessment

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for rice grain (only food commodity under assessment) where MRL and risk assessment values could be derived in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). These input values are reported in Appendix D. Acute exposure calculations were not carried out because an acute reference dose (ArfD) was not deemed necessary for this active substance.

The exposures calculated were compared with the toxicological reference value derived for bispyribac-sodium (also applicable to bispyribac), derived by EFSA (2010) under Directive 91/414/EEC. The highest chronic exposure was calculated for Portuguese general population, representing 0.2% of the ADI. Based on these calculations, EFSA concludes that the use of bispyribac on rice is acceptable with regard to consumer exposure.

Conclusions

The nature of residues of bispyribac was investigated in primary crops (cereals) and in rotational crops (cereals, root crops and pulses/oilseeds). Based on the primary crop studies, the parent compound is the major component of the residue. The confined rotational crop study showed that significant residues are not expected in succeeding crops. Therefore, the residue for enforcement and risk assessment was defined as the sum of bispyribac and its salts, expressed as bispyribac-sodium. This residue definition can be enforced in dry commodities as well as in other main matrices with LOQs ranging from 0.005 to 0.02 mg/kg. The proposed residue definition is limited to cereal crops and applies to both grain and straw.

The available residue trials were sufficient to derive MRL proposals as well as risk assessment values for rice grain (only food commodity under assessment). A tentative MRL was also derived for rice straw in view of the future need to set MRLs in feed items. As residue levels in rice grain and straw are expected to remain below the LOQ and since the chronic exposure is expected to be far below 10% of the ADI, no further investigation on the nature and magnitude of residues in processed commodities were required.

Livestock dietary burdens were calculated for different groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM) for all groups of livestock. Therefore, further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

Chronic consumer exposure resulting from the authorised use reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 0.2% of the ADI (PT, general population). Acute exposure calculations were not carried out because an ArfD was not deemed necessary for this active substance.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 1). The MRL value derived for the only food commodity under evaluation (rice grain) is listed as ‘Recommended’, meaning that this MRL is sufficiently supported by data and is therefore proposed for inclusion in Annex II to the Regulation. For all other commodities, where uses are not authorised, further consideration by risk managers is needed in order to decide whether the default MRL of 0.01 mg/kg still applies or if a specific LOQ should be considered (see Table 1 footnotes for details). No data gaps were identified.
Table 1: Summary table

| Code number | Commodity                  | Existing EU MRL (mg/kg) | Outcome of the review | Comment              |
|-------------|----------------------------|-------------------------|-----------------------|----------------------|
| 500060      | Rice grain                 | 0.01*                   | 0.02*                 | Recommended          |
|             | Other commodities of plant and animal origin | 0.01*                   | –                     | Further consideration needed |

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

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

(a): The default MRL of 0.01 mg/kg currently applies to all commodities according to Art 18(1)(b) Reg 396/2005.

(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 G-I in Appendix E).

(c): 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.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CF conversion factor for enforcement residue definition to risk assessment residue definition
cGAP critical GAP
CXL codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DB dietary burden
DM dry matter
DT90 period required for 90% dissipation (define method of estimation)
eq residue expressed as a.s. equivalent
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GS growth stage
HPLC–MS/MS high performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardization
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
LOQ limit of quantification
Mo monitoring
MRL maximum residue level
MS/MS tandem mass spectrometry detector
NEU northern European Union
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PF processing factor
PHI pre-harvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
PROFile (EFSA) Pesticide Residues Overview File
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RD residue definition
RMS rapporteur Member State
RPF relative potency factor
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
SEU southern European Union
| Abbreviation | Description |
|--------------|-------------|
| SMILES       | simplified molecular-input line-entry system |
| STMR         | supervised trials median residue |
| TRR          | total radioactive residue |
| WHO          | World Health Organization |
# Appendix A – Summary of authorised uses considered for the review of MRLs

| Crop and/or situation | NEU, SEU, MS or country | F, G or I<sup>(a)</sup> | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|-------------------------|--------------------------|-----------------------------------|--------------|-----------------|-----------------------------|-------------------|---------|
| Rice                  | IT, ES, PT, EL, BG, RO  | F                        | Mono and dicots weds annual and perennial | SC           | 408 g/L         | Foliar treatment – spraying | 13–25             | 1 to 1              | 30.6    | n.a.               |

NEU: northern European Union; SEU: southern European Union; MS: Member State; SC: suspension concentrate; a.s.: active substance.

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

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

(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.

To be added 0.6–1 L/ha of adjuvant Biopower
Appendix B – List of end points

It is noted that the sodium salt, a variant of bispyribac, was used in the residue studies. Thus, the evaluated data belong to the variant bispyribac-sodium and the reported residue levels are expressed as bispyribac-sodium, unless otherwise explicitly specified.

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) |
|----------------------------------|-------------|---------|----------------|---------------|
| Cereals                          | Rice (dry-seeded) | Foliar (BBCH 15), 56 g a.s./ha (pyrimidine-labelled) | 94 |
| Cereals                          | Rice (water-seeded) | Foliar (BBCH 16), 41 g a.s./ha (pyrimidine-labelled) | 96 |
| Cereals                          | Rice (dry-seeded) | Foliar (BBCH 15), 40 g a.s./ha (benzene-labelled) | 99 |

Source: Italy (2003)
Studies performed with either pyrimidine-labelled or benzene-labelled bispyribac-sodium. Different samplings were performed on grain, straw, hulls, stems and roots.

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|-------------------------------------|-------------|---------|----------------|-----------|
| Root/tuber crops                    | Radish      | Bare soil, 68 g a.s./ha | 28, 46, 120 |
| Cereal (small grain)                | Wheat       | Bare soil, 68 g a.s./ha | 28, 46, 120 |
| Pulses/oilseeds                     | Soya bean   | Bare soil, 68 g a.s./ha | 28, 46, 120 |

Source: Italy (2003)
Study performed with pyrimidine labelled bispyribac-sodium.

| Processed commodities (hydrolysis study) | Conditions                  | Investigated? |
|------------------------------------------|-----------------------------|---------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4) | No            |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | No            |
|                                          | Sterilisation (20 min, 120°C, pH 6) | No            |
|                                          | Hydrolysis studies are not needed and not required. |               |
Can a general residue definition be proposed for primary crops? | No
---|---
Rotational crop and primary crop metabolism similar? | Yes (no significant residues observed in rotational crops)
Residue pattern in processed commodities similar to residue pattern in raw commodities? | Not applicable
Plant residue definition for monitoring (RD-Mo) | Sum of bispyribac and its salts, expressed as bispyribac-sodium (only for cereals)
Plant residue definition for risk assessment (RD-RA) | Sum bispyribac and its salts, expressed as bispyribac-sodium (only for cereals)
Conversion factor (monitoring to risk assessment) | Not applicable
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | HPLC-MS/MS (EFSA, 2010):
- Validated for the analysis of bispyribac and its salts in dry commodities (rice grain) and complex matrices (rice straw).
- LOQ: 0.02 mg/kg
LC-MS/MS (EURLs, 2017):
- Validated for the analysis of bispyribac-sodium in high water content, acid content and high oil content commodities with a LOQ of 0.01 mg/kg.
- Validated for the analysis of bispyribac in dry commodities with a LOQ of 0.005 mg/kg.

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry; 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 (Months) |
|---|---|---|---|---|
| Dry/high starch | Rice grain | −18 | 8 |
| Other | Rice straw | −18 | 8 |

Source: Italy (2003)
Study performed with bispyribac-sodium
B.1.2. Magnitude of residues in plants

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

| Crop            | Region/indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)\(^{(b)}\) | STMR (mg/kg)\(^{(c)}\) |
|-----------------|--------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|----------------------|----------------------|
| Rice grain      | SEU                      | 10 × < 0.02                                                                                        | Trials compliant with GAP Italy (2003, 2012). MRL\(_{OECD}\) = 0.02 | 0.02*                 | < 0.02               | < 0.02               |
| Rice straw      | SEU                      | 10 × < 0.02                                                                                        | Trials compliant with GAP Italy (2003, 2012). MRL\(_{OECD}\) = 0.02 | 0.02* (tentative)\(^{(d)}\) | < 0.02               | < 0.02               |

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

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

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

\(^{(b)}\): Highest residue.

\(^{(c)}\): Supervised trials median residue.

\(^{(d)}\): Tentative MRLs are derived for feed items.
B.1.2.2. Residues in succeeding crops

| Confined rotational crop study (quantitative aspect) | Radioactivity in the 30-day replant is below 0.01 mg/kg in all tested crops/matrices. Thus, 120-day samples were not analysed and the originally scheduled 360 days re-plant was not carried out. No residues above 0.01 mg/kg are expected in rotational crops (EFSA, 2010) |
|---|---|
| Field rotational crop study | Not available and not needed |

B.1.2.3. Processing factors

| Processed commodity | Number of studies | Processing factor (PF) |
|---|---|---|
| | | Individual values | Median PF |

| | Dietary burden expressed in mg/kg bw per day mg/kg DM | Most critical diet(a) | Most critical commodity(a) | Trigger exceeded (Y/N) |
|---|---|---|---|---|
| Cattle (all diets) | 0.0002 | 0.0002 | 0.01 | 0.01 | Cattle (dairy) | Rice, straw | No |
| Cattle (dairy only) | 0.0002 | 0.0002 | 0.01 | 0.01 | Cattle (dairy) | Rice, straw | No |
| Sheep (all diets) | 0.0004 | 0.0004 | 0.01 | 0.01 | Sheep (lamb) | Rice, straw | No |
| Sheep (ewe only) | 0.0003 | 0.0003 | 0.01 | 0.01 | Sheep (ram/ewe) | Rice, straw | No |
| Swine (all diets) | 0.0001 | 0.0001 | 0.00 | 0.00 | – | – | No |
| Poultry (all diets) | 0.0002 | 0.0002 | 0.00 | 0.00 | – | – | No |
| Poultry (layer only) | 0.0001 | 0.0001 | 0.00 | 0.00 | – | – | No |

bw: body weight; DM: dry matter.
(a): Calculated for the maximum dietary burden.

B.2. Residues in livestock

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 per day) | Duration (days) | N rate/comment |
|---|---|---|---|---|
| Lactating goat | 0.43 | 4.5 | > 1,000N; the calculated DB is almost insignificant. Both pyrimidine-label and benzene-label were used |
| Laying hen | 0.96 | 4.5 | > 4,000N; the calculated DB is almost insignificant. Only the pyrimidine-label was used |

Source: Italy (2003)
Studies performed with pyrimidine-labelled and/or benzene-labelled bispyribac-sodium.
Time needed to reach a plateau concentration in milk and eggs (days) Not applicable (residues remain < 0.01 mg/kg in milk and eggs from the day 1 onwards)

Metabolism in rat and ruminant similar (Yes/No) Yes

Animal residue definition for monitoring (RD-Mo) No proposal (not triggered)

Animal residue definition for risk assessment (RD-RA) No proposal (not triggered)

Conversion factor (monitoring to risk assessment) Not applicable

Fat soluble residues (Yes/No) Not applicable

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) Not applicable

B.2.1.2. Stability of residues in livestock

Animal products

| Animal | Commodity | T (°C) | Stability (Months/years) |
|--------|-----------|--------|-------------------------|
| –      | –         | –      | –                       |

Not available and not required

B.2.2. Magnitude of residues in livestock

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

No studies available and not required.

B.3. Consumer risk assessment

ADI: 0.01 mg/kg bw per day (EFSA, 2010)

Highest IEDI, according to EFSA PRIMo: 0.2% ADI (PT, general population)

Assumptions made for the calculations: The calculation is based on the median residue level in raw rice grain. The contributions of commodities where no GAP was reported in the framework of this review, were not included in the calculation.

ARfD: Not needed (EFSA, 2010)

B.4. Proposed MRLs

| Code number | Commodity | Existing EU MRL (mg/kg) | MRL (mg/kg) | Comment |
|-------------|-----------|-------------------------|-------------|---------|
|             | Rice grain | 0.01*                   | 0.02*       | Recommended (b) |
|             | Other commodities of plant and animal origin | 0.01*       | –          | Further consideration needed (c) |

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

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

(a): The default MRL of 0.01 mg/kg currently applies to all commodities according to Art 18(1)(b) Reg 396/2005.

(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 G-I in Appendix E).

(c): 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).
### Bispyribac-sodium

| Status of the active substance: | Approved |
|--------------------------------|----------|
| LOQ (mg/kg bw) | Proposed LOQ |

| Toxicological endpoints | ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Source of ADI | Source of ARfD |
|-------------------------|------------------------|-----------------|--------------|---------------|
| ADI                     | 0.01                   | n.n.            | EFSA         | EFSA          |
| Year of evaluation      | 2010                   | 2010            |              |               |

| No of diets exceeding ADI: | TMDI (range) in % of ADI of MS Diet | Commodity/ group of commodities | 2nd contributor to MS diet in % of ADI | Commodity/ group of commodities | 3rd contributor to MS diet in % of ADI | Commodity/ group of commodities |
|----------------------------|-------------------------------------|---------------------------------|----------------------------------------|---------------------------------|----------------------------------------|---------------------------------|
| Highest calculated        | Minimum – Maximum                  | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |FRUIT (FRESH OR FROZEN)                  |FRUIT (FRESH OR FROZEN)              |
| TMDI values in % of ADI   |                                     |                                 |                                        |                                 |                                        |                                 |
| 0.2                       |                                     | PT General population            | 0.2                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.1                       |                                     | UK Infant                        | 0.1                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.1                       |                                     | UK Toddler                       | 0.1                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.1                       |                                     | WHO cluster diet D               | 0.1                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.1                       |                                     | WHO Cluster diet B               | 0.1                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.1                       |                                     | ES child                         | 0.1                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.1                       |                                     | SE general population 90th percentile | 0.1                                 | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.1                       |                                     | UK vegetarian                    | 0.1                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.1                       |                                     | UK Adult                         | 0.1                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.1                       |                                     | FR toddler                       | 0.1                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.1                       |                                     | NL child                         | 0.1                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.1                       |                                     | DE child                         | 0.1                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | ES adult                         | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | LT adult                         | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | WHO cluster diet E               | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | WHO Cluster diet E               | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | WHO regional European diet       | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | IT kids/toddler                  | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | IT adult                         | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | IT adult                         | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | IE adult                         | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | IE adult                         | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | NL general                       | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | NL general                       | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | FR all population                | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | FR all population                | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | FR infant                        | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | DK child                         | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | DK child                         | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |
| 0.0                       |                                     | PL general population            | 0.0                                    | Rice                            |FRUIT (FRESH OR FROZEN)                 |FRUIT (FRESH OR FROZEN)              |

### Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs, were below the ADI. A long-term intake of residues of bispyribac-sodium is unlikely to present a public health concern.
Acute risk assessment is not necessary.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD. No of critical MRLs (IESTI 1)

| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|---------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------|
| IESTI 1 | *) | **) | IESTI 1 | *) | **) | IESTI 1 | *) | **) | IESTI 2 | *) | **) | IESTI 2 | *) | **) |
| Highest % of ARfD/ADI | Commodities | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/threshold MRL (mg/kg) |

No of commodities for which ARfD/ADI is exceeded (IESTI 1): 

No of commodities for which ARfD/ADI is exceeded (IESTI 2):

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

No of critical MRLs (IESTI 1): 

No of critical MRLs (IESTI 2):

Conclusion:

As no ARfD was considered necessary, it is concluded that the short-term intake of bispyribac-sodium residues is unlikely to present a public health concern.

ACUTE RISK ASSESSMENT/CHILDREN – REFINED CALCULATIONS

ACUTE RISK ASSESSMENT/ADULTS/GENERAL POPULATION – REFINED CALCULATIONS

The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

*) pMRL: provisional temporary MRL.

**) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

As no ARfD was considered necessary, it is concluded that the short-term intake of bispyribac-sodium residues is unlikely to present a public health concern.
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                |
| Rice, bran/pollard    | 0.02* STMR           |                        | 0.02* STMR           |                        |
| Rice, straw           | 0.02* STMR           |                        | 0.02* HR             |                        |

*: Indicates that the input value is proposed at the limit of quantification. STMR: supervised trials median residue; HR: highest residue; PF processing factor.

(a): For rice bran, no default processing factor was applied because bispyribac is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

D.2. Consumer risk assessment

| Commodity   | Chronic risk assessment | Acute risk assessment |
|-------------|-------------------------|-----------------------|
|             | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Rice, grain | 0.02* STMR              |                        | 0.02* HR            |                        |

STMR: supervised trials median residue; HR: highest residue.

(a): Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations

1. **Evaluation of the GAPs and available residues data at EU level**
   - GAP or DB in 0.1 mg/kg to 1 mg/kg DM in EU?
     - Yes: MRL derived in Section 3.
     - No: GAP or DB in 1 mg/kg to 10 mg/kg DM in EU?
       - Yes: MRL likely supported by data?
         - Yes: MRL is recommended.
         - No: MRL fully supported by data?
           - Yes: MRL is recommended.
           - No: Risk identified?
             - Yes: Median/highest values are included in the RA.
             - No: Tentative median/highest values are included in the RA.
             - Not considered for the RA.
   - No: GAP or DB > 0.1 mg/kg to 1 mg/kg DM in EU?
     - Yes: MRL derived in Section 3.
     - No: GAP or DB > 1 mg/kg DM in EU?
       - Yes: MRL fully supported by data?
         - Yes: MRL is recommended.
         - No: Risk identified?
           - Yes: Median/highest values are included in the RA.
           - No: Tentative median/highest values are included in the RA.
           - Not considered for the RA.
   - No: GAP or DB > 1 mg/kg DM in EU?
     - Yes: MRL derived in Section 3.
     - No: MRL fully supported by data?
       - Yes: MRL is recommended.
       - No: Risk identified?
         - Yes: Median/highest values are included in the RA.
         - No: Tentative median/highest values are included in the RA.
         - Not considered for the RA.

2. **Consumer risk assessment for GAPs evaluated at EU level – EU scenarios**
   - Not considered for the RA.
   - Current EU MRL is included in the RA.
     - Risk identified?
       - Yes: Median/highest values are included in the RA.
       - No: Fall-back MRL available?
         - Yes: MRL is recommended.
         - No: Not considered for the RA.
   - Tentative median/highest values are included in the RA.
     - Risk identified?
       - Yes: Median/highest values are included in the RA.
       - No: Fall-back MRL available?
         - Yes: MRL is recommended.
         - No: Not considered for the RA.
   - Current EU MRL is included in the RA.
     - Risk identified?
       - Yes: Median/highest values are included in the RA.
       - No: Fall-back MRL available?
         - Yes: MRL is recommended.
         - No: Not considered for the RA.
   - Tentative median/highest values are included in the RA.
     - Risk identified?
       - Yes: Median/highest values are included in the RA.
       - No: Fall-back MRL available?
         - Yes: MRL is recommended.
         - No: Not considered for the RA.
   - Current EU MRL is included in the RA.
     - Risk identified?
       - Yes: Median/highest values are included in the RA.
       - No: Fall-back MRL available?
         - Yes: MRL is recommended.
         - No: Not considered for the RA.
   - Tentative median/highest values are included in the RA.
     - Risk identified?
       - Yes: Median/highest values are included in the RA.
       - No: Fall-back MRL available?
         - Yes: MRL is recommended.
         - No: Not considered for the RA.

3. **Recommendations resulting from EU authorisations and import tolerances**
   - Recommendations resulting from EU authorisations and import tolerances
     - (A) Specific LOQ or default MRL?
     - (B) Specific LOQ or default MRL?
     - (C) Maintain current EU MRL?
     - (D) Establish tentative EU MRL?
     - (F) Specific LOQ or default MRL?
     - (G) MRL is recommended.

Comparison with CXLs
Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes:
    - RD comparable?
      - Yes:
        - CXL higher?
          - Yes:
            - Maintain EU recommendation indicating CXL is not compatible.
          - No:
            - Input values for the RA remain unchanged.
      - No:
        - Input values for the RA remain unchanged.
  - No:
    - No:
      - No:
        - Input values for the RA remain unchanged.

Consumer risk assessment with consideration of the existing CXL

- CXL supported by data?
  - Yes:
    - CXL is included in the RA.
      - Risk identified?
        - Yes:
          - Input values for the RA remain unchanged.
        - No:
          - Codex median/highest residues are included in the RA.
  - No:
    - No:
      - No:
        - No:
          - No:
            - Risk identified?
              - Yes:
                - Input values for the RA remain unchanged.
              - No:
                - Codex median/highest residues are included in the RA.

Recommendations with consideration of the existing CXL

1. Maintain EU recommendation indicating that no CXL is available.
2. Maintain EU recommendation indicating CXL is not compatible.
3. Maintain EU recommendation indicating that CXL is covered.
4. Maintain current CXL or EU recommendation?
5. Maintain EU recommendation; higher CXL is not safe for consumer.
6. Maintain EU recommendation; higher CXL is not safe for consumer.
7. CXL recommended; EU recommendation is covered as well.
## Appendix F – Used compound bac codes

| Code/trivial name | Chemical name/SMILES notation | Structural formula |
|-------------------|-------------------------------|--------------------|
| Bispyribac        | 2,6-bis(4,6-dimethoxypyrimidin-2-yloxy)benzoic acid OC1nc(nc(OC)c1)OC3cccc(Oc2nc(cc(OC)n2)OC)c3C(=O)O | ![Image](image1.png) |
| Bispyribac-sodium | sodium 2,6-bis(4,6-dimethoxy pyrimidin-2-yloxy)benz oate [Na+].OC1nc(nc(OC)c1)OC3cccc(Oc2nc(cc(OC)n2)OC)c3C(=O)-O | ![Image](image2.png) |
| M02 (BX-180)      | 2-[(4,6-dimethoxypyrimidin-2-yl)oxygen]-6-hydroxybenz oic acid O=C(O)c2c(Oc1nc(cc(OC)n1)OC)c3cc2O | ![Image](image3.png) |
| M03               | 4,6-dimethoxypyrimidin-2-ol OC1cc(OC)nc(O)n1 | ![Image](image4.png) |
| M04               | 6-methoxypyrimidine-2,4-diol Oc1cc(OC)nc(O)n1 | ![Image](image5.png) |
| M06 (DesMe-2023)  | sodium 2-[(4,6-dimethoxy pyrimidin-2-yl)oxy]-6-[(4-h ydroxy-6-methoxypyrimidin-2-yl)oxy] benzoate [Na+].OC1nc(nc(OC)c1)OC3cccc(Oc2nc(cc(OC)n2)OC)c3C(=O)-O | ![Image](image6.png) |
| M21 (2023-glucoronic acid) | 1-O-2,6-bis(4,6-dimethoxypyrimidin-2-yl)oxy benzoyl-L-α-glucopyranuronic acid O=C(O)[C@H](1)O[C@H][C@H][O][C@H](O)[C@H](O)[C@H][C@H](1)C(=O)-O)c4c(Oc2nc(cc(OC)c2)c3cc4Oc3nc(OC)c3(OC)n3 | ![Image](image7.png) |

SMILES: simplified molecular-input line-entry system.