Evaluation of confirmatory data following the Article 12 MRL review for paclobutrazol

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Abstract

The applicant Proplan Plant Protection Company submitted a request to the competent national authority in Austria (originally the United Kingdom) to evaluate the confirmatory data that were identified for paclobutrazol in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the data gaps, two new metabolism studies performed on apples were submitted. In addition, two studies on the magnitude of residues in apples and pears providing data for triazole derivative metabolites were also submitted. The data gaps were considered satisfactorily addressed. The new information provided did not require a revision of the existing MRLs for pome fruits, apricots and peaches. An update of the risk assessment was performed for paclobutrazol and for the triazole derivative metabolites in light of the new data submitted and did not indicate any consumer intake concerns.

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Keywords: paclobutrazol, confirmatory data, pesticide, MRL review, risk assessment

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Summary

In 2017, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for paclobutrazol according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) a representative study investigating primary crop metabolism in fruit crops;
2) residue trials supporting the southern outdoor good agricultural practice (GAP) on table olives/olives for oil production, table/wine grapes and plums;
3) a representative study investigating the metabolism in ruminants and, eventually, livestock feeding studies (data gap relevant also for the authorisations on apples).

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 2019/89, including footnotes related to data gap number 1, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 24 January 2021. Data gap numbers 2 and 3 were not implemented in the MRL regulation, because for table olives, olives for oil production, tables and wine grapes and plums as well as for food commodities of animal origin, risk managers decided to set the MRLs at the LOQ for enforcement.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, Proplan Plant Protection Company submitted an application to the competent national authority in Austria (rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review. It is noted that after the withdrawal of the United Kingdom from the Union on 1 February 2020, the application was reallocated to the RMS, Austria. The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to the EFSA on 7 April 2022. When assessing the evaluation report, EFSA identified data gaps. On 3 August 2022, the evaluating Member State (EMS) submitted a revised evaluation report which replaced the previously submitted evaluation report.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EC) No 396/2005.

| Code(a) | Commodity | Existing MRL(b) | Data gap(s) Art.12 Review | Proposed MRL | Conclusion/recommendation |
|---------|-----------|----------------|----------------------------|--------------|----------------------------|
| 0130010 | Apples    | 0.05 (ft 1)    | Footnote related to data gap No 1. [representative study investigating primary crop metabolism in fruit crops] | 0.05         | The data gap identified by EFSA concerning the metabolism study in fruit crops has been addressed. The new GAP and new residue trials submitted in this application confirmed the existing MRL. The updated consumer risk assessment for paclobutrazol and TDMs did not indicate any consumer intake concerns. |
| 0130020 | Pears     | 0.05 (ft 1)    | Footnote related to data gap No 1. [representative study investigating primary crop metabolism in fruit crops] | 0.05         | The data gap identified by EFSA concerning the metabolism study in fruit crops has been addressed. The MRL is confirmed. The updated consumer risk assessment for paclobutrazol did not indicate any consumer intake concerns. In the absence of data for TDMs, on these commodities, no consumer intake concerns. |
| 0130030 | Quinces   | 0.05 (ft 1)    | Footnote related to data gap No 1. [representative study investigating primary crop metabolism in fruit crops] | 0.05         | The data gap identified by EFSA concerning the metabolism study in fruit crops has been addressed. The MRL is confirmed. The updated consumer risk assessment for paclobutrazol did not indicate any consumer intake concerns. In the absence of data for TDMs, on these commodities, no consumer intake concerns. |
| 0130040 | Medlars   | 0.05 (ft 1)    | Footnote related to data gap No 1. [representative study investigating primary crop metabolism in fruit crops] | 0.05         | The data gap identified by EFSA concerning the metabolism study in fruit crops has been addressed. The MRL is confirmed. The updated consumer risk assessment for paclobutrazol did not indicate any consumer intake concerns. In the absence of data for TDMs, on these commodities, no consumer intake concerns. |
| Code<sup>(a)</sup> | Commodity            | Existing MRL<sup>(b)</sup> | Data gap(s) Art.12 Review                                                                 | Proposed MRL | Conclusion/recommendation                              |
|-------------------|----------------------|-----------------------------|------------------------------------------------------------------------------------------|--------------|-------------------------------------------------------|
| 0130050           | Loquats/ Japanese medlars | 0.05 (ft 1)                | Footnote related to data gap No 1. [representative study investigating primary crop metabolism in fruit crops] | 0.05         | risk assessment could be performed for the TDMs.      |
| 0140010           | Apricots             | 0.15 (ft 1)                | Footnote related to data gap No 1. [representative study investigating primary crop metabolism in fruit crops] | 0.15         |                                                       |
| 0140030           | Peaches              | 0.15 (ft 1)                | Footnote related to data gap No 1. [representative study investigating primary crop metabolism in fruit crops] | 0.15         |                                                       |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice; TDMs: triazole derivative metabolites.

<sup>(a)</sup>: Commodity code number according to Annex I of Regulation (EC) No 396/2005.

<sup>(b)</sup>: Existing EU MRL and corresponding footnote on confirmatory data.

<sup>(ft 1)</sup>: The European Food Safety Authority identified some information on crop metabolism as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 24 January 2021, or, if that information is not submitted by that date, the lack of it.
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Assessment

The review of existing MRLs for the active substance paclobutrazol according to Article 12 of Regulation (EC) No 396/2005¹ (MRL review) has been performed in 2017 (EFSA, 2017). EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified. The list of GAPs assessed in the framework of the MRL review that were not fully supported by data and for which confirmatory data were requested are listed in Appendix A.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 2019/89², including footnotes for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 24 January 2021.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2020a), the applicant, Proplan Plant Protection Company, on 20 January 2021 submitted an application to the competent national authority in Austria (designated rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review. To address the data gaps identified by EFSA, the applicant provided two new metabolism studies performed on apples. In addition, two new studies on the magnitude of residues (including data for paclobutrazol and for triazole derivative metabolites) in apples and pears were also submitted.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 7 April 2022 (Austria, 2021). EFSA assessed the application as requested by the European Commission in accordance with Article 10 of Regulation (EC) No 396/2005. It is noted that after the withdrawal of the United Kingdom from the Union on 1 February 2020, the application was reallocated to the RMS, Austria. During the detailed assessment, EFSA identified points which needed further clarifications. On 3 August 2022, the RMS submitted a revised evaluation report which replaced the previously submitted evaluation report (Austria, 2021).

EFSA based its assessment on the evaluation report submitted by the RMS and the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005.

For this application, the data requirements established in Regulation (EU) No 544/2011³ and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 2019/89 are applicable. The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁴.

An updated list of end points, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix B.

The evaluation report submitted by the RMS (Austria, 2021) is considered a supporting document to this reasoned opinion and, thus, is made publicly available as a background document to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

In order to address data gap number 1,⁵ two new studies investigating the nature of residues in fruit crops were provided by the applicant. Both studies were performed on apples with foliar applications (4 × 200 g a.s./ha). One study was carried out with paclobutrazol radiolabelled on the

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¹ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, pp. 1–16.
² Commission Regulation (EU) 2019/89 of 18 January 2019 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bromadiolone, etofenprox, paclobutrazol and penconazole in or on certain products. C/2019/141.OJ L 22, 24.1.2019, pp. 13–51.
³ Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, pp. 1–66.
⁴ 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, pp. 127–175.
⁵ A representative study investigating primary crop metabolism in fruit crops.
phenyl moiety and one study with paclobutrazol radiolabelled on the triazole moiety. Details of the study design are presented in Appendix B. Both studies were considered valid and did not present deviations against the OECD Test Guideline No. 501 (Austria, 2021).

All authorised GAPs on fruit crops reported in the MRL review and the GAPs on apples and pears reported in the current application are covered by the parameters tested in the new metabolism studies, noting that the tested application rate is higher (4N) compared to the authorised practices.

In both studies, samplings were done at PHI 47–48 days and analysis was performed on washed apple samples and rinsing water separately. The total radioactive residues (TRR) found in apples ranged between 0.10 and 0.20 mg eq/kg. The residues remained significant in the fruit (58%–66% TRR) while the rest was retrieved in the washing solution.

The total extracted residues after conventional extraction and additional sequential treatments ranged between 84.5% and 91.4%. The unextractable residues (post extraction solids) remained in the range of 8.6%–15.5% (0.016–0.017 mg eq./kg).

Sufficient characterisation and identification of the TRR were achieved in both studies. The parent compound was the only component retrieved in the washing solution (34%–42% TRR). In washed fruit, it accounted for only 7% of the TRR (triazole study) and 16.6% TRR (phenyl study). Overall, the parent compound is significantly present in apple fruit (total washed + washing solution) at levels of 0.05–0.10 mg/kg.

In the triazole study, two main metabolites were identified: triazole alanine (TA) accounting for 19.0% TRR (0.038 mg eq./kg) and triazole lactic acid (TLA) accounting for 9.9% TRR (0.014 mg eq./kg). The other triazole derivative metabolites (TDM) were not identified in this study, indicating that 1,2,4-triazole (1,2,4-T) and triazole acetic acid (TAA) may not be expected in significant amounts in fruit crops after treatment with paclobutrazol.

In the phenyl study, along with parent paclobutrazol, one additional metabolite was identified under the common name 1A/1B (19.9% TRR; 0.02 mg eq./kg). This metabolite was identified as two possible O-glucoside conjugates of a hydroxylated paclobutrazol derivative (hydroxy-Paclobutrazol ((2RS, 3RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4 triazol-1-yl) pentan-1,3-diol)).

In both studies, subsequent extractions and characterisation revealed a number of unknown metabolites, all individually below 0.01 mg eq/kg, except one metabolite in the triazole study (5.4% of the TRR; 0.011 mg eq./kg).

The findings of the new two submitted studies are consistent with the results found in the rapeseed metabolism study (the only other valid metabolism study for paclobutrazol). The parent compound is present at significant levels in treated fruits (being a potential good marker) but part of it degrades leading to a potential occurrence of triazole derivative metabolites in harvested commodities at levels requiring further consideration.

All authorised GAPs on fruit crops reported in the MRL review are covered by the new studies. For the GAPs under assessment, the metabolite 1A/1B (max 0.02 mg eq./kg) is not expected to be a significant residue.

EFSA concluded that the data gap number 1 identified in the framework of the MRL review was addressed.

1.1.2. Nature of residues in rotational crops

Not relevant for the current assessment.

1.1.3. Nature of residues in processed commodities

Not relevant for the current assessment.

1.1.4. Analytical methods for enforcement purposes in plant commodities

Not relevant for the current assessment.

1.1.5. Stability of residues in plants

Not relevant for the current assessment.

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6 This is the name proposed by the study authors in the metabolism study and reported in the ER (Austria, 2021). However, the structural formula represented in the study report corresponded to O-glucoside conjugates of hydroxy-Paclobutrazol ((2RS, 3RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4 triazol-1-yl) pentan-3,5-diol). EFSA relied on the name proposed by the study authors (1,3-diol) and represented the molecule accordingly; see Appendix E.
1.1.6. Proposed residue definitions

The two new studies performed on apples confirm that the parent compound is a good marker for enforcement in fruit crops. Therefore, the residue definitions for enforcement and risk assessment previously derived on a tentative basis for fruit crops are now confirmed as paclobutrazol (sum of constituent isomers). These residue definitions are limited to oilseeds and fruit crops.

In addition, the new studies provided evidence of degradation of the parent compound leading to potential occurrence of TDM such as TA and TLA in fruit commodities after foliar treatments. Therefore, the set of additional residue definitions for the risk assessment derived in the conclusion of the peer review of the pesticide risk assessment of the TDM in light of confirmatory data (EFSA, 2018b) is also confirmed for paclobutrazol in fruit crops. In line with the EFSA conclusion, the residue definitions for risk assessment are as followed:

1) paclobutrazol (sum of constituent isomers);
2) triazole alanine (TA) and triazole lactic acid (TLA) [since these compounds share the same toxicity];
3) triazole acetic acid (TAA);
4) 1,2,4-triazole (1,2,4-T).

1.2. Magnitude of residues in plants

In the framework of the MRL review, no major data gaps related to residue trials in pome fruits, apricots and peaches, which would be expected to impact the validity of the MRLs derived, were identified. However, EFSA noted a lack of residue trials supporting southern GAPs on pome fruits, apricots, peaches and plums (EFSA, 2017), which might only have an impact on national authorisations.

In the context of the present assessment, the applicant provided new southern GAPs on apples and pears and a series of residue trials supporting these GAPs. EFSA assessed whether these new data might affect the existing MRL and risk assessment values.

For both apples and pears, the new GAP is a foliar treatment up to growth stage BBCH 73, with four applications at 50 g a.s./ha, PHI 60 days. Two studies performed in two consecutive years (2012, 2013) in different sites of southern Europe were submitted by the applicant. The parameters used in these experiments are in line with the GAP. A total of eight GAP-compliant trials (five on apples and three on pears) is available. In all trials, analyses were performed for paclobutrazol and for the four TDMs (1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid). The analytical methods used to analyse residue trial samples were sufficiently validated and the details of validation are presented in the evaluation report prepared by the EMS (Austria, 2021).

The available data indicate paclobutrazol levels ranging between the limit of quantification (LOQ) (<0.01 mg/kg) and 0.03 mg/kg, which was not found to trigger any increase of the existing MRL of 0.05 mg/kg for apples and pears. The MRL calculation was performed in accordance with the uniform principle defined by OECD (OECD, 2011).

The analysis of TDMs indicates significant residue levels found in untreated control samples, suggesting the use of triazole pesticide active substances in previous seasons. In line with the conclusion of the peer review of the pesticide risk assessment of the triazole derivative metabolite in light of confirmatory data (EFSA, 2018b), and despite these uncertainties, when the values from the positive control samples were higher than the levels found in treated samples, these values were considered in the assessment. For metabolite 1,2,4-T, the levels were found to remain below the LOQ of 0.01 mg/kg in all trials. The metabolite TA was the most predominant TDM (HR = 0.22 mg/kg), followed by metabolite TLA (HR = 0.19 mg/kg) and metabolite TAA (HR = 0.02 mg/kg).

EFSA concluded that the new GAP and data on apples and pears do not trigger any modifications of the existing MRLs for these crops. However, the new risk assessment values derived for paclobutrazol and for the triazole derivatives metabolites were used to assess the impact of this GAP on the livestock dietary burden and on the consumer dietary exposure.

It is noted that for the authorised uses of paclobutrazol on quinces, medlars, loquats, apricots and peaches, which were reported during the MRL review, no residue trials analysing the TDMs are available and these data were not required at the time of the MRL review. Consequently, uncertainty remains regarding the possible occurrence of TDMs in these commodities as they belong to the categories of fruit crops.
2. Residues in livestock

The existing MRLs on commodities of animal origin are at the LOQ of 0.01* mg/kg and are not tentative (no footnote in the MRL Regulation).

For paclobutrazol, the supervised trials median residue (STMR) (0.015 mg/kg) derived for apples in the present assessment is lower than the value derived in the framework of the MRL review (0.05 mg/kg). Therefore, the confirmatory data assessed in the present evaluation do not have an impact on the existing livestock exposure to paclobutrazol residues and the previous assessment of residues in livestock (EFSA, 2017) remains valid.

Regarding the TDMs, the STMR values derived for apples in the present assessment (0.015 mg/kg for TA; 0.01 mg/kg for TLA; < 0.01 mg/kg for TAA and 1,2,4-T) are lower than the ones derived in the framework of the pesticide risk assessment of the TDMs in light of confirmatory data (0.039 mg/kg for TA; 0.03 mg/kg for TLA; 0.03 mg/kg for TAA; 0.01 mg/kg for 1,2,4-T, following the use of paclobutrazol on apples). Therefore, the confirmatory data assessed in the present evaluation do not have an impact on the residues of the TDMs expected in livestock.

3. Consumer risk assessment

3.1. Paclobutrazol

Since the STMR and HR derived for apples and pears in the present assessment are lower than the ones derived in the framework of the MRL review (most recent assessment of paclobutrazol), and since the newly submitted metabolism studies do not change the residue definition for risk assessment, it is concluded that the confirmatory data submitted in the context of the present application are not expected to trigger a modification of previous consumer dietary exposure calculations.

Nevertheless, the dietary exposure calculations derived in the MRL review were updated to consider the revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019) and to consider the risk management decisions taken after the MRL review. In particular, the EU MRLs on plums, table and wine grapes, table olives, olives for oil production and commodities of animal origin were set at the enforcement LOQ. Therefore, the contributions of these commodities shall no longer be included in the calculation.

The revision 3.1 of the EFSA PRIMo assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological profile of paclobutrazol was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.022 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.1 mg/kg bw (EFSA, 2010). The derived toxicological reference values were confirmed after the finalisation of the confirmatory data of the EU pesticides peer review (European Commission, 2020b).

The input values used to perform the exposure assessment are reported in Appendix D.1. The outcome of the calculations is reported in Appendix B.3. The highest calculated chronic intake accounted for 4% of the ADI (NL toddler). The short-term exposure did not exceed the ARfD for the crops under consideration. It is concluded that the calculated consumer exposure to paclobutrazol is unlikely to pose a concern for public health.

3.2. Triazole derivative metabolites (TDMs)

The toxicological profile for each TDM was assessed in the framework of the pesticide risk assessment of the TDMs in light of confirmatory data (EFSA, 2018b). The ADI value was derived as 0.3 mg/kg bw day for TA, 0.3 mg/kg bw day for TLA, 1 mg/kg bw day for TAA and 0.023 mg/kg bw day for 1,2,4-T. An ARfD was derived as 0.3 mg/kg bw for TA, 0.3 mg/kg bw for TLA, 1 mg/kg bw for TAA and 0.1 mg/kg bw for 1,2,4-T.

Regarding the chronic exposure, EFSA compared the STMR values derived for apples and pears in the present assessment (0.015 mg/kg for TA; 0.01 mg/kg for TLA; < 0.01 mg/kg for TAA and 1,2,4-T) with the highest STMRs7 derived for pome fruits in the framework of the pesticide risk assessment of the TDMs in light of confirmatory data (0.039 mg/kg for TA; 0.03 mg/kg for TLA; 0.03 mg/kg for TAA; 0.01 mg/kg for 1,2,4-T, following the use of paclobutrazol on apples). Therefore, the confirmatory data assessed in the present evaluation do not have an impact on the residues of the TDMs expected in livestock.

7 In the framework of the pesticide risk assessment of the TDMs in light of confirmatory data, STMRs for TA, TLA, TAA, 1-2-4-T for apples and pears were derived from different active substances (EFSA, 2018b). For each TDM, the highest STMR from all substances was used to assess the chronic exposure.
0.01 mg/kg for 1,2,4-T). Since the STMR values derived in the present assessment are lower than the ones previously considered in the TDM assessment, it is concluded that the new data assessed in the present evaluation are not expected to trigger a modification of previous consumer dietary exposure calculations. Therefore, the conclusion of the peer review of the assessment of the pesticide risk assessment of the TDMs in light of confirmatory data remains unchanged. Using the EFSA PRIMo rev.3, the previous assessment concluded that the IEDI accounted for 93% of the ADI (NL toddler) for 1,2,4-T, 6% of the ADI (NL toddler) for TA, 1% of the ADI (NL toddler) for TAA and 1% of the ADI (NL toddler) for TLA (EFSA, 2018b).

Regarding the acute exposure, EFSA assessed potential risks associated with the acute intake of apples and pears containing TDMs at the highest estimated levels according to the submitted residue trials (0.22 mg/kg for TA; 0.19 mg/kg for TLA; 0.02 mg/kg for TAA and < 0.01 mg/kg for 1,2,4-T) using the revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019).

The outcome of the calculations is reported in Appendix B.3. For apples and pears, the short-term exposure did not exceed the ARfD for any TDMs. The highest calculated acute exposure accounted for 10% of the ARfD for the combination pears/TA. It is concluded that the calculated acute exposures to TDMs in light of the newly submitted data on apples and pears are unlikely to pose a concern for public health.

However, it should be noted that there are authorised uses of paclobutrazol on quinces, medlar, loquat, apricots and peaches (reported in the MRL review) for which no residue trials analysing the TDMs are available and were not requested at the time of the MRL review. For these crops, the data gap for metabolism studies has been addressed; since the new metabolism studies indicate the potential presence of TDMs in fruit crops, uncertainty remains regarding the possible occurrence of TDMs. The risk assessment related to TDMs in these crops could not be assessed.

4. Conclusion and recommendations

To address data gaps identified in the framework of the MRL review (EFSA, 2017), the applicant provided two new metabolism studies performed on apples. In addition, two studies on the magnitude of residues in apples and pears providing data for triazole derivative metabolites were also submitted. EFSA concluded that the data gaps were sufficiently addressed.

Consequently, the tentative MRLs for pome fruits, apricots and peaches are confirmed. No consumer intake concerns are associated with paclobutrazol in these commodities. EFSA also assessed the risks associated with the presence of TDMs in apples and pears on the basis of the new data submitted under the present assessment and concluded that no consumer intake concerns were identified. However, for the other authorised uses on fruit crops reported during the MRL review (quinces, medlars, loquats, apricots and peaches), the risk assessment related to TDMs could not be assessed in the absence of data. For these crops, the data gap for metabolism studies has been addressed, but uncertainty remains regarding the possible occurrence of TDMs.

The overview of the assessment of confirmatory data and the recommended MRLs are summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
EMS evaluating Member State
Eq residue expressed as a.s. equivalent
EUURL EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO Food and Agriculture Organisation of the United Nations
GAP Good Agricultural Practice
GC gas chromatography
GC-ECD gas chromatography with electron capture detector
GC-MS gas chromatography with mass spectrometry
GC-NPD gas chromatography with nitrogen/phosphorous detector
GCPF Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
GLP Good Laboratory Practice
GR granule
GS growth stage
HPLC-MS/MS high performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LC liquid chromatography
LOQ limit of quantification
MRL maximum residue level
MS mass spectrometry detector
| Abbreviation | Definition |
|--------------|------------|
| MS           | Member States |
| MS/MS        | tandem mass spectrometry detector |
| MW           | molecular weight |
| NEU          | northern Europe |
| NOAEL        | no observed adverse effect level |
| NPD          | nitrogen/phosphorous detector |
| OECD         | Organisation for Economic Co-operation and Development |
| PAFF         | Standing Committee on Plants, Animals, Food and Feed |
| PBI          | plant back interval |
| PF           | processing factor |
| PHI          | pre-harvest interval |
| P<sub>ow</sub> | partition coefficient between n-octanol and water |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| QuEChERS     | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA           | risk assessment |
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SC           | suspension concentrate |
| SEU          | southern Europe |
| STMR         | supervised trials median residue |
| TRR          | total radioactive residue |
| WG           | water-dispersible granule |
| WHO          | World Health Organisation |
## Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data

| Crop and/or situation | NEU, SEU, MS or country | F, G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|--------------|-----------------------------------|-------------|-------------|--------------------------------|---------------|---------|
|                       |                         |              |                                   |             | Method      | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./hl min-max | Water L/ha min-max | Rate | Unit |
| MRL review GAP (authorised uses) (EFSA, 2017) |                        |              |                                   |             | kind        |                                  |               |                                     |                  |                     |      |      |
| Apples                | SEU (ES)                | F            | Growth regulator                   | SC          | Foliar treatment | BBCH 71          | 1                           | –                      | –                           | 38 g a.s./ha      | 45      |      |      |
|                       |                         |              | Pears                             | SEU (ES)    | Foliar treatment | BBCH 71          | 1                           | –                      | –                           | 38 g a.s./ha      | 45      |      |      |
|                       |                         |              |                                    |             |              |                                  |               |                                     |                  |                     |      |      |
|                       |                         |              |                                    |             |              |                                  |               |                                     |                  |                     |      |      |
| New adjusted GAP (confirmatory data) (Austria, 2021) |                        |              |                                   |             | Method      | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./hl min-max | Water L/ha min-max | Rate | Unit |
| Apples                | SEU (IT, ES, PT, EL)   | F            | Growth regulator                   | SC          | Foliar treatment | BBCH 73          | 4                           | 7 days                | 0.005–0.01        | 500–1,000        | 50 g a.s./ha | 60   | –    |
|                       |                         |              | Pears                             | SEU (IT, ES, PT, EL) | Foliar treatment | BBCH 73          | 4                           | 7 days                | 0.005–0.01        | 500–1,000        | 50 g a.s./ha | 60   | –    |

NEU: northern European Union; SEU: southern European Union; MS: Member State, SC: suspension concentrate.
(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 formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
### Appendix B – List of end points

#### B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/source |
|-----------------------------------|-------------|---------|----------------|----------------|---------------|
| Fruit crops                       | Apples      |         | 4 × 200 g a.s./ha (at BBCH 73–74) | 48             | Study performed with paclobutrazol labelled on the triazole moiety (Austria, 2021). |
|                                   | Apples      |         | 4 × 200 g a.s./ha (at BBCH 73–76) | 47             | Study performed with paclobutrazol labelled on the phenyl moiety (Austria, 2021). |
| Pulses/oilseeds                   | Rapeseed    | Foliar, 1 × 62.5 g a.s./ha or 1 × 187.5 g a.s./ha | 90 (whole plant) 117–125 (mature seeds) | Study performed with paclobutrazol labelled on the phenyl and triazole moieties (EFSA, 2017). |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|-------------------------------------|-------------|---------|----------------|-----------|---------------|
| Root/tuber crops                   | Root/tuber crops | Radish | Bare soil, 100 g a.s./ha | 30, 120, 365 | (EFSA, 2017) |
| Leafy crops                        | Leafy crops | Mustard | Bare soil, 100 g a.s./ha | 30, 120, 365 | (EFSA, 2017) |
| Cereal (small grain)               | Cereal (small grain) | Wheat | Bare soil, 100 g a.s./ha | 30, 120, 365 | (EFSA, 2017) |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Not triggered |         | Studies not available and not required. |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Not triggered |         | Studies not available and not required. |
| Sterilisation (20 min, 120°C, pH 6)      | Not triggered |         | Studies not available and not required. |
Can a general residue definition be proposed for primary crops?

| No | Only 2 different crop groups investigated. |
|----------------|------------------------------------------|

Rotational crop and primary crop metabolism similar?

| Yes | – |
|----------------|----------------|

Residue pattern in processed commodities similar to residue pattern in raw commodities?

| Not triggered | Hydrolysis study not available and not required. |
|----------------|-----------------------------------------------|

Plant residue definition for monitoring (RD-Mo)

| Paclobutrazol (sum of constituent isomers) | [limited to oilseeds and fruit crops] |
|--------------------------------------------|----------------------------------------|

Plant residue definition for risk assessment (RD-RA)

| RD – risk assessment 1: paclobutrazol (sum of constituent isomers) | [limited to oilseeds and fruit crops] |
|---------------------------------------------------------------------|----------------------------------------|

RD – risk assessment 2: triazole derivative metabolites (TDMs):

- triazole alanine (TA) and triazole lactic acid (TLA)
- triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-T)

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

| LC–MS/MS (EFSA, 2017): | Validated in high oil content commodities | LOQ: 0.01 mg/kg |
|----------------------|------------------------------------------|----------------|

HPLC–MS/MS (EFSA, 2017):

- Validated in high water and high acid content commodities
- LOQ: 0.01 mg/kg

LC–MS/MS (EFSA, EURL, 2017):

- Method EN 15662:2008 validated in high water and high acid content commodities
- QuEChERS-method (EN 15662:2008) validated in dry commodities
- QuOil method (BVL L 13.04-5:2013-08) validated in high oil content commodities
- LOQ: 0.01 mg/kg

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; LOQ: limit of quantification; GC-MS: gas chromatography with mass spectrometry; LC-MS/MS: liquid chromatography with tandem mass spectrometry; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | $T$ (°C) | Stability period | Compounds covered | Comment/source |
|-----------------------------------|----------|-----------|----------|------------------|-------------------|---------------|
| **High water content**            |          |           |          |                  |                   |               |
| Apples                            |          |           | –18      | 12 Months        | paclobutrazol     | EFSA (2017)   |
| Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces |          |           | –20      | 53 Months        | TA                | EFSA (2018b) |
|                                   |          |           | –20      | 48<sup>(a)</sup> Months | TLA              | EFSA (2018b) |
|                                   |          |           | –20      | 53 Months        | TAA               | EFSA (2018b) |
|                                   |          |           | –20      | 6 Months         | 1,2,4-T           | EFSA (2018b) |
| **High oil content**              |          |           |          |                  |                   |               |
| Rapeseed                         |          |           | –18      | 27 Months        | paclobutrazol     | EFSA (2017)   |
| Rapeseed, soya beans             |          |           | –20      | 26<sup>(b)</sup> Months | TA                | EFSA (2018b) |
|                                   |          |           | –20      | 48 Months        | TLA               | EFSA (2018b) |
|                                   |          |           | –20      | 53 Months        | TAA               | EFSA (2018b) |
|                                   |          |           | –20      | 12<sup>(b)</sup> Months | 1,2,4-T           | EFSA (2018b) |
| **High protein content**         |          |           |          |                  |                   |               |
| Dry peas, navy beans             |          |           | –20      | 15 Months        | TA                | EFSA (2018b) |
|                                   |          |           | –20      | 48 Months        | TLA               | EFSA (2018b) |
|                                   |          |           | –20      | 25 Months        | TAA               | EFSA (2018b) |
|                                   |          |           | –        | –                | 1,2,4-T           | No data       |
| **Dry/high starch**              |          |           |          |                  |                   |               |
| Barley, wheat                    |          |           | –20      | 26 Months        | TA                | EFSA (2018b) |
|                                   |          |           | –20      | 48 Months        | TLA               | EFSA (2018b) |
|                                   |          |           | –20      | 26 Months        | TAA               | EFSA (2018b) |
|                                   |          |           | –20      | 12 Months        | 1,2,4-T           | EFSA (2018b) |
| **High acid content**            |          |           |          |                  |                   |               |
| Grapes                           |          |           | –18      | 12 Months        | paclobutrazol     | EFSA (2017)   |
| Oranges                          |          |           | –        | –                | TA                | No data       |
|                                   |          |           | –20      | 48 Months        | TLA               | EFSA (2018b) |
|                                   |          |           | –        | –                | TAA               | No data       |
|                                   |          |           | –        | –                | 1,2,4-T           | No data       |

**Legend:**
- TA: triazole alanine
- TLA: triazole lactic acid
- TAA: triazole acetic acid
- 1,2,4-T: 1,2,4-triazole
- HR-RAC: highest residue in raw agricultural commodity.

(a): Lettuce only.
(b): Soya bean only; not stable in rape seed.
### B.1.2. Magnitude of residues in plants

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

| 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) |
|-----------------|--------------------------|----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|----------------------|-----------------------|
| **Residue definition for enforcement and for risk assessment 1:** paclobutrazol |                          |                                                                  |                                                                              |                        |                      |                       |
| Apples, Pears   | SEU                      | 3 × < 0.01; 0.01; 3 × 0.02; 0.03                                  | Residue trials performed on apples (5) and pears (3) compliant with new adjusted GAP (Austria, 2021). The risk assessment values derived for pome fruits for the authorised use assessed in the MRL review were higher: 0.05 mg/kg both the STMR and HR (EFSA, 2017). | 0.05                   | 0.03                 | 0.015                 |
| **Residue definition for risk assessment 2:** triazole alanine (TA) and triazole lactic acid (TLA) |                          |                                                                  |                                                                              |                        |                      |                       |
| **Residue definition for risk assessment 3:** triazole acetic acid (TAA) |                          |                                                                  |                                                                              |                        |                      |                       |
| **Residue definition for risk assessment 4:** 1,2,4-triazole (1,2,4-T) |                          |                                                                  |                                                                              |                        |                      |                       |

| 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) |
|-----------------|--------------------------|----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|----------------------|-----------------------|
| Apples, Pears   | SEU                      | TA: 2 × < 0.01; 2 × 0.01; 0.02; 0.07; 0.16; 0.22\(^{(d)}\) | Residue trials performed on apples (5) and pears (3) compliant with new adjusted GAP (Austria, 2021). No data on the TDMs were available in apples and pears for the authorised uses assessed in the MRL review (EFSA, 2017). | n.r.                   | 0.22                 | 0.015                 |
|                 |                          | TLA: 4 × < 0.01; 0.01; 0.03; 0.09; 0.19\(^{(d)}\)               |                                                                              |                        |                      |                       |
|                 |                          | TAA: 5 × < 0.01; 0.01; 0.02\(^{(d)}\); 0.02                  |                                                                              |                        |                      |                       |
|                 |                          | 1,2,4-T: 8 × < 0.01                                            |                                                                              |                        |                      |                       |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment; n.r.: not relevant.

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

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

\(^{(c)}\): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

\(^{(d)}\): Higher residues found in untreated samples; residue levels in the corresponding treated samples were 0.17 mg/kg (TA), 0.12 mg/kg (TLA) and 0.02 (TAA).
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Inconclusive |

No relevant for the uses under assessment in the present opinion (apples and pears).

According to the results from the confined rotational crop studies, no significant residues (with the exception of the triazole derivative metabolites) are expected to occur in rotational crops, provided that paclobutrazol is applied according to the authorised GAPs considered in the MRL review (EFSA, 2017).

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant for the current assessment.

B.3. Consumer risk assessment

B.3.1. Paclobutrazol

| ARfD | 0.1 mg/kg bw (EC, 2020) |
| Highest IESTI, according to EFSA PRIMo | Peaches: 8% of ARfD  
Pears: 7% of ARfD  
Apples: 5% of ARfD |

Assumptions made for the calculations

The acute exposure assessment which was performed in the MRL review using rev. 2 of EFSA PRIMo was now updated, considering the new residue data on apples and pears submitted under the present assessment and considering the risk management decisions taken after the MRL review on the MRLs for various commodities. The calculation is based on the highest residue levels expected in raw agricultural commodities, except for oilseeds where the median values were considered. For apples and pears, a new GAP and new residue trials were submitted in the present assessment. Since the risk assessment values derived in the framework of the MRL review are higher than the ones derived from the new GAP, the median values derived in the MRL review are still considered in the consumer risk assessment. For plums, table and wine grapes, table olives and olives for oil production and for commodities of animal origin, the MRLs assessed during the MRL review were not supported by data and were set at the LOQs and therefore the contributions of these commodities were not included in the calculation.

Calculations performed using rev.3.1 of the EFSA PRIMo.
B.3.2. Triazole derivative metabolites

**ADI**

|                | 0.022 mg/kg bw per day (EC, 2020) |
|----------------|----------------------------------|

**Highest IEDI, according to EFSA PRIMo**

|                | 4% ADI (NL toddler) |
|----------------|---------------------|
| Contribution of crops assessed: |  |
| Apples: 2.84% of ADI (DE child) |  |
| Pears: 0.99% of ADI (NL toddler) |  |
| Quinces: 0.01% of ADI (RO general) |  |
| Medlar: 0.02% of ADI (GEMS/Food G15) |  |
| Loquat: 0.01% of ADI (GEMS/Food G10) |  |
| Apricot: 0.03% of ADI (DE child) |  |
| Peaches: 0.03% of ADI (IT adult) |  |

**Assumptions made for the calculations**

The chronic exposure assessment which was performed in the MRL review using rev. 2 of EFSA PRIMo was now updated, considering the new residue data on apples and pears submitted under the present assessment and considering the risk management decisions taken after the MRL review on the MRLs for various commodities. The calculation is based on the median residue levels derived for raw agricultural commodities. For apples and pears, a new GAP and new residue trials were submitted in the present assessment. Since the risk assessment values derived in the framework of the MRL review are higher than the ones derived from the new GAP the highest values derived in the MRL review are still considered in the consumer risk assessment. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation. For plums, table and wine grapes, table olives and olives for oil production and for commodities of animal origin the MRLs assessed during the MRL review were not supported by data and were set at the LOQs, therefore the contributions of these commodities were not included in the calculation.

Calculations performed using rev.3.1 of the EFSA PRIMo.

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**Assumptions made for the calculations**

The calculation is based on the highest residue levels derived from the newly submitted trials performed on apples and pears in the framework of the present application. The contributions of fruits commodities other than apples and pears on which the uses of paclobutrazol are authorized according to the MRL review - peaches, apricots, quinces, medlars, loquats - were not included in the calculation as for these crops no data were made available in the present application. Therefore, for these...
B.4. **Recommended MRLs**

| Code<sup>(a)</sup> | Commodity | Existing MRL<sup>(b)</sup> | Data gap(s) | Proposed MRL | Conclusion/recommendation |
|----------------------|-----------|---------------------------|-------------|--------------|---------------------------|
| 0130010              | Apples    | 0.05 (ft 1)              | Footnote related to data gap No. 1. [representative study investigating primary crop metabolism in fruit crops] | 0.05 | The data gap identified by EFSA concerning the metabolism study in fruit crops has been addressed. The new GAP and new residue trials submitted in this application confirmed the existing MRL. The updated consumer risk assessment for paclobutrazol and TDMs did not indicate any consumer intake concerns. |
| 0130020              | Pears     | 0.05 (ft 1)              | Footnote related to data gap No. 1. [representative study investigating primary crop metabolism in fruit crops] | 0.05 | |
| 0130030              | Quinces   | 0.05 (ft 1)              | Footnote related to data gap No. 1. [representative study investigating primary crop metabolism in fruit crops] | 0.05 | The data gap identified by EFSA concerning the metabolism study in fruit crops has been addressed. The MRL is confirmed. The updated consumer risk assessment for paclobutrazol did not indicate any consumer intake concerns. In the absence of data for TDMs, on these commodities, no consumer risk assessment could be performed for the TDMs. |
| 0130040              | Medlars   | 0.05 (ft 1)              | Footnote related to data gap No. 1. [representative study investigating primary crop metabolism in fruit crops] | 0.05 | |
| 0130050              | Loquats/ Japanese medlars | 0.05 (ft 1) | Footnote related to data gap No. 1. [representative study investigating primary crop metabolism in fruit crops] | 0.05 | |

**Enforcement residue definition:** Paclobutrazol (sum of constituent isomers)

The new data assessed in the present evaluation are not expected to trigger a modification of previous consumer dietary exposure calculations. Therefore, the conclusion of the peer review of the assessment of the pesticide risk assessment of the TDMs in light of confirmatory data remains unchanged (EFSA, 2018b).
| Code<sup>(a)</sup> | Commodity | Existing MRL<sup>(b)</sup> | Data gap(s) Art.12 Review | Proposed MRL | Conclusion/recommendation |
|------------------|-----------|-----------------------------|---------------------------|--------------|--------------------------|
| 0140010          | Apricots  | 0.15 (ft 1)                 | Footnote related to data gap No 1. [representative study investigating primary crop metabolism in fruit crops] | 0.15         |                          |
| 0140030          | Peaches   | 0.15 (ft 1)                 | Footnote related to data gap No 1. [representative study investigating primary crop metabolism in fruit crops] | 0.15         |                          |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice; TDMs: triazole derivative metabolites.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(b): Existing EU MRL and corresponding footnote on confirmatory data.

(ft 1): The European Food Safety Authority identified some information on crop metabolism as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 24 January 2021, or, if that information is not submitted by that date, the lack of it.
Appendix C – Pesticide Residue Intake Model (PRIMo)

### Toxicological reference values

| Toxicological reference | LOQs (mg/kg) | ADI (mg/kg bw per day) | Source of ADI | ARfD (mg/kg bw) | Source of ARfD |
|-------------------------|-------------|------------------------|---------------|----------------|---------------|
|                         | 0.01 to 0.05 | 0.022                  | EC            | 0.1            | EC            |

**EFSA PRIMo revision 3.1; 2021/01/06**

**Year of evaluation:** 2020

### Comments

- **FI adult** Apples
- **ES child** Apples
- **DE child** Apples
- **UK toddler** Apples
- **FR infant** Pears
- **UK adult** Pears
- **IO child** Pears
- **DE women 14-50 yr** Pears
- **PL general** Pears
- **FR child 3 15 yr** Pears
- **LT adult** Pears
- **NO general** Pears
- **RO general** Pears
- **PT general** Pears
- **GEMS/Food G08** Pears
- **GEMS/Food G06** Pears
- **GEMS/Food G07** Pears
- **IE adult** Pears
- **DK adult** Pears
- **GEMS/Food G10** Pears
- **FI 3 yr** Pears
- **FI 6 yr** Pears
- **FI adult** Pears
- **UK vegetarian**

### Calculated exposure (% of ADI)

| Commodity/group of commodities | MS Diet Exposure (% of ADI) | Highest contributor to MS diet (% of ADI) | 2nd contributor to MS diet (% of ADI) | 3rd contributor to MS diet (% of ADI) |
|-------------------------------|-----------------------------|----------------------------------------|------------------------------------|------------------------------------|
| Rapeseeds/canola seeds        | 4%                          | 0.77                                   | 2%                                 | 0.0%                               |
| Apricots                      | 3%                          | 0.67                                   | 3%                                 | 0.1%                               |
| Rapeseeds/canola seeds        | 2%                          | 0.36                                   | 1%                                 | 0.0%                               |
| Apricots                      | 0.8%                        | 0.18                                   | 3%                                 | 0.1%                               |
| Peaches                       | 0.7%                        | 0.15                                   | 0.1%                               | 0.0%                               |
| Peaches                       | 0.7%                        | 0.10                                   | 0.0%                               | 0.0%                               |
| Peaches                       | 0.6%                        | 0.09                                   | 0.0%                               | 0.0%                               |
| Peaches                       | 0.5%                        | 0.09                                   | 0.0%                               | 0.0%                               |
| Peaches                       | 0.5%                        | 0.08                                   | 0.0%                               | 0.0%                               |
| Quinces                       | 0.4%                        | 0.08                                   | 0.0%                               | 0.0%                               |
| Apricots                      | 0.4%                        | 0.07                                   | 0.0%                               | 0.0%                               |
| Peaches                       | 0.3%                        | 0.07                                   | 0.0%                               | 0.0%                               |
| Medlar                        | 0.3%                        | 0.07                                   | 0.0%                               | 0.0%                               |
| Peaches                       | 0.2%                        | 0.06                                   | 0.0%                               | 0.0%                               |
| Loquats/Japanese medlars       | 0.2%                        | 0.06                                   | 0.0%                               | 0.0%                               |

**Conclusion:**

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of paclobutrazol 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.
The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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

### Show results for all crops

#### Unprocessed commodities

| Highest % of ARfD/ADI | Commodity      | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodity      | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|----------------|--------------------------|---------------------|-----------------------|----------------|--------------------------|---------------------|
| 8%                    | Peaches       | 0.150/0.09              | 8.4                 | 2%                    | Peaches       | 0.150/0.09              | 1.6                 |
| 7%                    | Pears         | 0.050/0.05              | 6.9                 | 2%                    | Pears         | 0.050/0.05              | 1.5                 |
| 5%                    | Apples        | 0.050/0.05              | 5.4                 | 1%                    | Apples        | 0.050/0.05              | 1.4                 |
| 3%                    | Apricots      | 0.150/0.09              | 3.1                 | 1.0%                  | Apricots      | 0.150/0.09              | 0.96                |
| 1%                    | Quinces       | 0.050/0.05              | 1.2                 | 0.8%                  | Quinces       | 0.050/0.05              | 0.76                |
| 0.7%                  | Medlar        | 0.050/0.05              | 0.69                | 0.3%                  | Medlar        | 0.050/0.05              | 0.34                |
| 0.01%                 | Sesame seeds  | 0.010/0.01              | 0.01                | 0.01%                 | Sesame seeds  | 0.010/0.01              | 0.01                |
| 0.01%                 | Linseeds      | 0.010/0.01              | 0.01                | 0.01%                 | Linseeds      | 0.010/0.01              | 0.01                |
| 0.01%                 | Mustard seeds | 0.010/0.01              | 0.01                | 0.01%                 | Mustard seeds | 0.010/0.01              | 0.01                |
| 0.00%                 | Hemp seeds    | 0.010/0.01              | 0.00                | 0.00%                 | Hemp seeds    | 0.010/0.01              | 0.00                |

#### 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) |
|-----------------------|-----------------------|--------------------------|---------------------|-----------------------|-----------------------|--------------------------|---------------------|
| 3%                    | Apples/juice          | 0.050/0.05              | 2.7                 | 2%                    | Apples/juice          | 0.050/0.05              | 1.7                 |
| 2%                    | Peaches/canned        | 0.150/0.09              | 2.3                 | 0.7%                  | Peaches/canned        | 0.150/0.09              | 0.72                |
| 2%                    | Pears/juice           | 0.050/0.05              | 1.6                 | 0.06%                 | Pears/juice           | 0.050/0.05              | 0.06                |
| 0.3%                  | Peaches/juice         | 0.150/0.02              | 0.26                |                       |                       |                          |                     |
| 0.2%                  | Quinces/jam           | 0.050/0.05              | 0.15                |                       |                       |                          |                     |
| 0.0%                  | Rapeseeds/canola      | 0.010/0.02              | 0.01                |                       |                       |                          |                     |

#### Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of paclobutrazol is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.
### Appendix D – Input values for the exposure calculations

#### D.1. Consumer risk assessment (paclobutrazol)

| Commodity                  | Existing/proposed MRL (mg/kg) | Source         | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------------|----------------|-------------------------|-----------------------|
|                            |                               |                | Input value (mg/kg)     | Comment              | Input value (mg/kg) | Comment<sup>(a)</sup> |
| Apples                     | 0.05<sup>(b)</sup>            | EFSA (2017)    | 0.05<sup>(c)</sup>      | STMR-RAC             | 0.05<sup>(c)</sup>  | HR-RAC                  |
| Pears                      | 0.05<sup>(b)</sup>            | EFSA (2017)    | 0.05<sup>(c)</sup>      | STMR-RAC             | 0.05<sup>(c)</sup>  | HR-RAC                  |
| Quinces                    | 0.05<sup>(b)</sup>            | EFSA (2017)    | 0.05                    | STMR-RAC             | 0.05              | HR-RAC                  |
| Medlar                     | 0.05<sup>(b)</sup>            | EFSA (2017)    | 0.05                    | STMR-RAC             | 0.05              | HR-RAC                  |
| Loquats/Japanese medlars   | 0.05<sup>(b)</sup>            | EFSA (2017)    | 0.05                    | STMR-RAC             | 0.05              | HR-RAC                  |
| Apricots                   | 0.15<sup>(b)</sup>            | EFSA (2017)    | 0.02                    | STMR-RAC             | 0.09              | HR-RAC                  |
| Peaches                    | 0.15<sup>(b)</sup>            | EFSA (2017)    | 0.02                    | STMR-RAC             | 0.09              | HR-RAC                  |
| Linseeds                   | 0.01                          | EFSA (2017)    | 0.01                    | STMR-RAC             | 0.01              | STMR-RAC                |
| Sesame seeds               | 0.01                          | EFSA (2017)    | 0.01                    | STMR-RAC             | 0.01              | STMR-RAC                |
| Rapeseeds/canola seeds     | 0.01                          | EFSA (2017)    | 0.01                    | STMR-RAC             | 0.01              | STMR-RAC                |
| Mustard seeds              | 0.01                          | EFSA (2017)    | 0.01                    | STMR-RAC             | 0.01              | STMR-RAC                |
| Borage seeds               | 0.01                          | EFSA (2017)    | 0.01                    | STMR-RAC             | 0.01              | STMR-RAC                |
| Gold of pleasure seeds     | 0.01                          | EFSA (2017)    | 0.01                    | STMR-RAC             | 0.01              | STMR-RAC                |
| Hemp seeds                 | 0.01                          | EFSA (2017)    | 0.01                    | STMR-RAC             | 0.01              | STMR-RAC                |

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity.

<sup>(a)</sup>: Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

<sup>(b)</sup>: The existing MRL was derived on tentative basis during the MRL review (EFSA, 2017) because of the lack of metabolism studies on fruit crops. This data gap was addressed in the current assessment and the existing MRL was confirmed.

<sup>(c)</sup>: For apples and pears, a new GAP and new residue trials were submitted in the present assessment. It confirmed the existing MRL. The risk assessment values derived in the framework of the MRL review are higher than the STMR and HR derived from the new GAP (STMR = 0.02 mg/kg; HR = 0.03 mg/kg) and are therefore considered in the consumer risk assessment.

#### D.2. Acute consumer risk assessment (triazole derivative metabolites)

| Commodity     | TA (HR-RAC) (mg/kg) | TLA (HR-RAC) (mg/kg) | TAA (HR-RAC) (mg/kg) | 1,2,4-T (HR-RAC) (mg/kg) |
|---------------|---------------------|----------------------|----------------------|--------------------------|
| Apples        | 0.22                | 0.19                 | 0.02                 | 0.01                     |
| Pears         | 0.22                | 0.19                 | 0.02                 | 0.01                     |

TA: triazole alanine; TLA: triazole lactic acid; TAA: triazole acetic acid; 1,2,4-T: 1,2,4-triazole. HR-RAC: highest residue in raw agricultural commodity.
### Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-------------------------------------------------|---------------------------------|
| paclobutrazol                  | (2R,3S)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pentan-3-ol | ![Structure](image1) |
|                                | (2,5,3 S)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pentan-3-ol | ![Structure](image2) |
|                                | RMOGWMKXYWRTKW-UONOGXRCSA-N 0[C@H]([C@H](Cc1ccc(Cl)cc1)n1cncn1)C(C)C | ![Structure](image3) |
|                                | RMOGWMKXYWRTKW-KGLIPLIRSA-N 0[C@@H]([C@@H](Cc1ccc(Cl)cc1)n1cncn1)C(C)C | ![Structure](image4) |
| 1,2,4-triazole 1,2,4-T         | 1H-1,2,4-triazole c1ncnn1 NSPMIYGKQJPBQR-UHFFFAOYSA-N | ![Structure](image5) |
| Triazole alanine TA            | 3-(1H-1,2,4-triazol-1-yl)-D,L-alanine NC(Cn1cncn1)C(=O)O XVWFTQJHOHJMQ-UHFFFAOYSA-N | ![Structure](image6) |
| Triazole acetic acid TAA       | 1H-1,2,4-triazol-1-ylacetic acid O=C(O)Cn1cncn1 RXDBSQXFIWBJSR-UHFFFAOYSA-N | ![Structure](image7) |
| Triazole lactic acid or Triazole hydroxy propionic acid TLA | (2RS)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propanoic acid OC(Cn1cncn1)C(=O)O KJRGHGWETVMENC-UHFFFAOYSA-N | ![Structure](image8) |
| Metabolite 1A/1B               | O-glucoside conjugates of hydroxy-Paclobutrazol ((2RS, 3RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4 triazol-1-yl) pentan-1,3-diol)<sup>(d)</sup> The structure given is only one example of several possible glucosides. IREJOPUEDQYL-KBRYRDLCSA-N ClC1ccc(cc1)C(O)(O)(C(OC1O[C@@H][C@H][O][C@@H]](O)[C@@H](O))n1cncn1 | ![Structure](image9) |

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

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123,232, 07 Jul 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123,835, 28 Aug 2021).
(d): The name proposed by the study authors in the metabolism study is O-glucoside conjugates of hydroxy-Paclobutrazol ((2RS, 3RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4 triazol-1-yl) pentan-1,3-diol). However, the structural formula represented in the study report corresponded to O-glucoside conjugates of hydroxy-Paclobutrazol ((2RS, 3RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4 triazol-1-yl) pentan-3,5-diol). Therefore, EFSA relied on the name proposed by the study authors (1,3-diol) and represented the molecule accordingly. The structure given is only one example of several possible glucosides.