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

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Abstract
According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance thiencarbazone-methyl. To assess the occurrence of thiencarbazone-methyl residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011 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.

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

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Summary

Thiencarbazone-methyl was approved on 1 July 2014 by means of Commission Implementing Regulation (EU) No 145/2014 in the framework of Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 541/2011.

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

As the basis for the MRL review, on 19 November 2018, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 19 December 2018 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the rapporteur Member State (RMS) France to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 28 February 2019. On the basis of all the data submitted by Member States and by the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations and updated GAP overview file were provided by the RMS to EFSA on 29 April 2019. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURLs, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011, EFSA prepared in September 2019 a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure. Comments received by 17 October 2019 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of thiencarbazone-methyl in plants was investigated in primary and rotational crops. According to the results of the metabolism studies on cereals and root and tuber vegetables, the residue definition for enforcement can be proposed as parent thiencarbazone-methyl only. For risk assessment, the residue definition is proposed as the sum of thiencarbazone-methyl, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside, expressed as thiencarbazone-methyl. These residue definitions are also applicable to rotational crops. For the current authorised uses, a residue definition is not needed for processed commodities.

Fully validated analytical methods are available for the enforcement of the proposed residue definition in cereals and root and tuber vegetables at the limit of quantification (LOQ) of 0.01 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses. All compounds included in the risk assessment residue definition were demonstrated to be stable for at least 26 months in the relevant plant matrices.

No residues above the LOQ were found in edible parts from rotational crops. However, a field rotational crop study performed at an exaggerated dose, covering the plateau concentration calculated for the persistent metabolite BYH 18636-carboxylic acid, is still required to confirm that no significant residues of thiencarbazone-methyl are expected following multiannual applications according to the most critical GAP assessed in this review.

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

Thiencarbazone-methyl is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated were found to be below the trigger value of 0.1 mg/kg dry matter for each group and further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary. Nevertheless, the metabolism of thiencarbazone-methyl residues in livestock was investigated and a general residue definition for enforcement and risk assessment was proposed as thiencarbazone-methyl and BYH 18636-MMT, expressed as thiencarbazone-methyl.

Considering the authorised uses reported, a residue definition for livestock commodities is not required in the framework of this review. However, these residue definitions would be considered valid if in the future dietary burdens were to be triggered.
An analytical method for the enforcement of the proposed residue definition at the combined LOQ of 0.04 mg/kg in all animal matrices is available. According to the EURLs the LOQ of 0.01 mg/kg for each compound individually, is achievable by using the QuEChERS method in routine analyses.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3 of the EFSA PRIMo. The highest chronic exposure was calculated for NL toddler, representing 0.1% of the acceptable daily intake (ADI). This calculation indicates that the uses assessed under this review are unlikely to pose a risk to consumer’s health. 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 396/2005\(^1\) (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC\(^2\) a reasoned opinion on the review of the existing MRLs for that active substance.

As thiencarbazone-methyl was approved on 1 July 2014 by means of Implementing Regulation (EU) No 145/2014\(^2\) in the framework of Regulation (EC) No 1107/2009\(^3\) as amended by Commission Implementing Regulations (EU) No 540/2011\(^5\) and 541/2011\(^6\), EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EU) No 188/2011\(^7\) thiencarbazone-methyl was evaluated by the United Kingdom, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2013).

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC\(^2\) repealed by Regulation (EC) No 1107/2009. It should be noted, however, that in the framework of Regulation (EC) No 1107/2009, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

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

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

As the basis for the MRL review, on 19 November 2018 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 19 December 2018 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation 16 Member States provided feedback on their national authorisations of thiencarbazone-methyl. Based on the GAP data submitted, the re-assigned RMS France was asked to identify the critical GAPs (cGAPs) to be further considered in the

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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 145/2014 of 14 February 2014 approving the active substance thiencarbazone, 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 45, 15.2.2014, p. 12–16.

\(^4\) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

\(^5\) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

\(^6\) Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.

\(^7\) Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51–55.
assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States were requested to provide residue data supporting the cGAPs by 28 February 2019.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked France to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMO) calculations and updated GAP overview file, were submitted to EFSA on 29 April 2019. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, EFSA prepared in September 2019 a draft reasoned opinion, which was circulated to Member States and EURLs for commenting via a written procedure. All comments received by 17 October 2019 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (France, 2019), taking into account also the information provided by Member States during the collection of data, and the EURLs report on analytical methods (EURLs, 2019) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2019a) and the Member States consultation report (EFSA, 2019b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMO) and the PROFile as well as the GAP overview file listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMO is presented in Appendix C.

Terms of Reference

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

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

Thiencarbazone-methyl is the modified ISO name for methyl 4-{[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonylsulfamoyl]-5-methylthiophene-3-carboxylate (IUPAC).

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

For thiencarbazone-methyl, default MRL of 0.01 mg/kg is established according to Art 18(1)(b) of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for thiencarbazone-methyl are not available. There are no MRL changes occurred since the entry into force of the Regulation mentioned above.

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

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (France, 2019);
- the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2012, 2013);
- the conclusion on the peer review of the pesticide risk assessment of the active substance thiencarbazone-methyl (EFSA, 2013).
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\(^8\) and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a-g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

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

1. **Residues in plants**

1.1. **Nature of residues and methods of analysis in plants**

1.1.1. **Nature of residues in primary crops**

The metabolism of thiencarbazone-methyl was investigated after foliar and soil treatment in cereals (maize and wheat) and assessed in the framework of the peer review (United Kingdom, 2012; EFSA, 2013). New metabolism studies in tuber and root vegetables (sugar beet) were provided in the framework of this Article 12 review and, although not peer reviewed, were considered for the current assessment (France, 2019). In all studies thiencarbazone-methyl was radiolabelled either in the dihydrotriazole or the thiophene ring of the molecule.

In maize, three different application patterns were investigated which cover possible routes of uptake, i.e. via soil and leaves, namely: a single pre-emergence application, an early post-emergence application, and a split-application with a post-emergence foliar treatment followed by a soil treatment (see details in Appendix B.1.1).

The studies performed with these three different patterns showed similar results and similar metabolic profile. In general, very low total radioactive residues (TRR) levels were detected (0.001–0.083 mg eq/kg); therefore, in all maize matrices, many metabolites were identified but all at very low levels below the limit of quantification (LOQ) (< 0.01 mg/kg). BYH 18636-MMT-glucoside was always found to be the major metabolite in the dihydrotriazole label, while parent thiencarbazone-methyl was a very minor residue detected only in maize forage and stover at a maximum level of 0.007 mg eq/kg (EFSA, 2013).

Following the pre-emergence application pattern (48 g a.s./ha), BYH 18636-MMT-glucoside represented up to 65% TRR in maize forage and stover (0.003–0.01 mg eq/kg) in the dihydrotriazole label. In the thiophene label, the significant metabolites were BYH 18636-hydroxy-sulfonamide-carboxylic acid and conjugates present at 23% TRR (0.003 mg eq/kg) in maize forage, and BYH 18636-hydroxy-sulfonamide-carboxylic acid and BYH 18636-hydroxy-thienosaccharine and their conjugates accounting together for 32% TRR (0.001 mg eq/kg) in maize forage. After the early post-emergence application pattern (12 g a.s./ha at stage BBCH 13-16, equivalent to a field treatment at 48 g a.s./ha), BYH 18636-MMT-glucoside was still the major metabolite in maize forage and stover (up to 17% TRR; 0.009 mg eq/kg). BYH 18636-N-desmethyl-hydroxy was also significant, representing up to 12.5% TRR (0.006 mg eq/kg) in maize forage. Finally, in the split-application pattern (post-emergence application of 32 g a.s./ha at BBCH 16 and an additional soil treatment of 16 g a.s./ha at BBCH 19), the main metabolite BYH 18636-MMT-glucoside accounted for up to 63% TRR in maize forage and stover. Other metabolites just above 10% TRR were identified but at very low absolute levels (United Kingdom, 2012).

In wheat, a single early post-emergence application of 16–17 g a.s./ha at stage BBCH 13–15 was studied. Following this application, higher TRR levels were observed in wheat, up to 0.014 mg eq/kg in grain and 0.39 mg eq/kg in the other matrices. Parent thiencarbazone-methyl was detected in significant proportions and levels (up to 17% TRR; 0.05 mg eq/kg) only in forage samples with both labels. Metabolite BYH 18636-N-desmethyl was the major component in all matrices and for both labels, representing up to 47% TRR (0.17 mg eq/kg) in forage, 14% TRR (0.06 mg eq/kg) in straw and 31% TRR (0.003 mg eq/kg) in grain, while BYH 18636-MMT-glucoside was present at up to 22% TRR (0.06 mg eq/kg) in straw (EFSA, 2013). Other metabolites were found above 10% TRR, however absolute levels were always below 0.05 mg eq/kg in feed items and below 0.01 mg eq/kg in grain.

A similar metabolic profile was observed in maize and wheat, noting that in maize, metabolites result from the cleavage of the parent molecule, whereas in wheat the metabolism is dominated by the compounds (specially BYH 18636-N-desmethyl) containing the entire structure of the parent (EFSA, 2013).

\(^8\) 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.
Review of the existing MRLs for thiencarbazone-methyl

1.1.2. Nature of residues in rotational crops

Thiencarbazone-methyl is authorised on crops that may be grown in rotation. The field DT\textsubscript{90} values reported in the soil degradation studies evaluated in the framework of the peer review were above 100 days both for parent (148 days) and metabolite BYH 18636-carboxylic acid (644 days) (EFSA, 2013). Therefore, the assessment of residues in rotational crops is triggered.

It is noted that with a maximum field DT\textsubscript{90} of 148 days (< 365 days), accumulation of thiencarbazone-methyl in soil does not need to be accounted for. Considering the reported GAPs that have only one application per crop and a single crop being grown in a field in a single year, with an application rate for thiencarbazone-methyl of 40 g a.s./ha, the predicted environmental concentration in soil (PEC\textsubscript{soil}) assuming a soil bulk density of 1.5 g/cm\textsuperscript{3}, a soil mixing depth of 20 cm and no crop interception, is 0.013 mg/kg soil immediately after application. The metabolite BYH 18636-carboxylic acid-glucoside, being the major compound accounting for 39–41% TRR (0.046–0.083 mg eq/kg). In the thiophene label, the major metabolites in roots and leaves were BYH 18636-hydroxy-sulfonamide-glucoside and BYH 18636-hydroxy-sulfonamide-carboxylic acid-glucoside, representing up to 16% TRR (0.02 mg eq/kg) and 29% TRR (0.10 mg eq/kg), respectively (France, 2019). No new metabolites were identified with respect to the ones found in the metabolism studies performed in cereals.

The metabolic pathway of thiencarbazone-methyl was sufficiently elucidated, and it is concluded that the metabolic pattern of tuber and root vegetables (sugar beet) is covered by that in cereals (wheat and maize).
chards, the parent compound and BYH 18636-MMT were significant representing respectively up to 30% TRR and 22% TRR, however, with low absolute levels (< 0.001 mg eq/kg). For all application rates of 15, 30 and 45 g a.s./ha, residues were generally decreasing over time in all raw agricultural commodities and no individual compound exceeded the LOQ of 0.01 mg/kg in edible parts of the crops for both labels, nor 0.05 mg/kg in feed commodities (EFSA, 2013). The metabolic pathway as observed in primary crops and in rotational crops consists in the N-depmethylation of the parent compound and several hydrolysis steps. It can be concluded that the metabolism and distribution of thiencarbazone-methyl in rotational crops is similar to the metabolic pathway observed in primary crops.

1.1.3. Nature of residues in processed commodities

In all commodities residues were below 0.1 mg/kg and the total theoretical maximum daily intake is below 10% of the acceptable daily intake (ADI). Therefore, the investigation of the nature of residues in processed commodities is in principle not required. Although not needed, a study investigating the nature of residues of thiencarbazone-methyl in processed commodities was provided and assessed in the framework of this review (France, 2019). This study were conducted with radiolabelled thiencarbazone-methyl on the dihydrotriazole or thiophene ring simulating standard hydrolysis conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5), sterilisation (20 min at 120°C, pH 6) as well as sugar refining (120 min at 95°C, pH 9).

The studies demonstrated that thiencarbazone-methyl is readily degraded when subject to hydrolytic conditions. The highest recovery of the parent was 40% TRR, under conditions representing pasteurisation, whereas under all other tested conditions, hydrolytic cleavage of the parent was almost complete (< 3.8% TRR, or even not detected).

With the dihydrotriazole label, the main degradation product was BYH 18636-MMT (64–99% TRR) under all food processing conditions. With the thiophene label, BYH 18636-sulfonamide was the major compound under standard hydrolysis conditions (59–96% TRR), while BYH 18636-sulfonamide-carboxylic acid and BYH 18636-thienosaccharine were significant (67% and 31% TRR, respectively) under the alkaline conditions representing sugar refining.

1.1.4. Methods of analysis in plants

During the peer review, a hyphenated analytical method based on high performance liquid chromatography (HPLC) coupled to tandem mass spectrometry (MS/MS), detection was validated for the determination of thiencarbazone-methyl, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside in high water, high acid, high oil and dry commodities, with a LOQ of 0.01 mg/kg. Two MRM transitions (in HPLC-MS/MS) for quantification and confirmation were monitored for each analyte and in each matrix tested. This primary method is considered highly specific and supported by an independent laboratory validation (ILV) validated for maize forage, maize grain and wheat straw (United Kingdom, 2012; EFSA, 2013). During the completeness check, the EURs provided a QuEChERS multi-residue method using HPLC-MS/MS, for the routine analysis of thiencarbazone-methyl with a LOQ of 0.01 mg/kg in commodities with high water and high acid content, and of 0.005 mg/kg in dry commodities. A QuOil method using HPLC-MS/MS was also provided with a LOQ of 0.01 mg/kg in high oil content commodities (EURs, 2019).

1.1.5. Stability of residues in plants

The storage stability of thiencarbazone-methyl and its metabolites was investigated in high water content commodities (maize forage, tomato, potato, lettuce), high oil content commodities (soybean seeds), dry commodities (maize grain) and maize stover, and assessed in the framework of the peer review (EFSA, 2013; United Kingdom, 2013). The available studies demonstrated that thiencarbazone-methyl, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside were stable in plant matrices covering the relevant crops assessed under this review for a period of 26 months when stored at –18°C.
1.1.6. Proposed residue definitions

The metabolism of thiencarbazone-methyl was similar in all crops assessed. The metabolism in rotational crops is similar to the metabolism observed in primary crops. A residue definition for processed commodities is not required.

As the parent compound was found to be a sufficient marker in cereals and tuber and root vegetables, the residue definition for enforcement is proposed as thiencarbazone-methyl only.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all four main plant matrices is available (EFSA, 2013). According to the EURs, the LOQ of 0.01 mg/kg, and even 0.005 mg/kg for dry commodities, is achievable by using the QuEChERS method in routine analyses (EURs, 2019).

For risk assessment, during the peer review, the metabolites BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside were observed in significant proportions and levels in cereals, and parent thiencarbazone-methyl was considered the only toxicologically relevant compound. Therefore, the residue definition for risk assessment was proposed as the sum of thiencarbazone-methyl, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside, expressed as thiencarbazone-methyl (EFSA, 2013).

Regarding the new metabolism study on sugar beet, parent thiencarbazone-methyl and metabolite BYH 18636-MMT-glucoside were the most significant compounds identified (see Section 1.1.1). Considering that the metabolic profile described in sugar beet is covered by the one observed in cereals, the above-mentioned residue definition was found to be applicable to cereals and tuber and root vegetables.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of thiencarbazone-methyl residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (France, 2019) as well as the residue trials evaluated in the framework of the peer review (United Kingdom, 2012; EFSA, 2013). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected.

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).

For all crops assessed during this review, available residue trials were sufficient to derive MRLs and risk assessment values.

1.2.2. Magnitude of residues in rotational crops

A field rotational crop study performed in the United States was available and previously assessed during the peer review (United Kingdom, 2012; EFSA, 2013).

In the provided US field study, thiencarbazone-methyl was applied to maize at 45 g a.s./ha (just above 1N the application rate of the cGAP). Within 50–61 days after the last application, maize was destroyed by tillage. Then, rotational crops (soybean seeds and wheat) were planted 2 months after and 3 months after, respectively. Samples of rotated crops were analysed for parent and metabolites BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside. Residues in the soil tested were not analysed.

In all matrices, parent thiencarbazone-methyl and BYH 18636-N-desmethyl residues were found to be lower than 0.01 mg/kg. BYH 18636-MMT-glucoside was also below LOQ in wheat matrices and soybean seeds, while it occurred up to 0.02 mg/kg in soya forage and up to 0.07 mg/kg in soya hay (United Kingdom, 2012; EFSA, 2013). Residue levels above LOQ were only found in non-edible parts of soybean.

EFSA verified whether this study was covering the plateau concentration estimated for the persistent metabolite BYH 18636-carboxylic acid. To this end, the accumulated PECsoil of BYH 18636-carboxylic acid was calculated as 0.0092 mg/kg soil as the peak following the application of thiencarbazone-methyl at the cGAP, falling to 0.0023 mg/kg soil one year later. This calculation was performed considering the degradation rate of BYH 18636-carboxylic acid (see Section 1.1.2), the maximum amount of 53.6% of this metabolite formed in soil, the maximum application rate of 40 g a.s./ha per year assessed in this review (treatment authorised on maize and common millet), a soil bulk density of 1.5 g/cm³, a soil mixing depth of 20 cm and no crop interception.
Residues in the treated soil and in the rotated crops were not analysed for metabolite BYH 18636-carboxylic acid, therefore it was not possible to verify whether this metabolite was formed in the soil and taken up by the plants. Moreover, the study was performed at the seasonal application rate of the most cGAP, hence is not expected to cover the accumulation of BYH 18636-carboxylic acid following multiple years of consecutive applications.

Consequently, a field rotational crop study performed at an exaggerated dose covering the plateau concentration calculated for BYH 18636-carboxylic acid and analysing for this metabolite in the soil, is still required. In the meanwhile, Member States granting authorisations for thiencarbazone-methyl should take the appropriate risk mitigation measures in order to avoid the presence of significant residues in rotational crops.

1.2.3. Magnitude of residues in processed commodities

In the framework of this review, no studies investigating the magnitude of thiencarbazone-methyl residues in processed commodities were provided and are not considered necessary (see Section 1.1.3). This may need to be reconsidered in the context of future authorised uses and if robust processing factors were to be required by risk managers, particularly for enforcement purposes.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation.

MRLs were also calculated for feed crops (cereal straw, maize for forage, fodder beets) in view of the future need to set MRLs in feed items.

Specific MRLs for rotational crops are not needed, provided that Member States will take adequate risk mitigation measures in order to avoid significant residues to occur in rotational crops.

2. Residues in livestock

Thiencarbazone-methyl is authorised for use on crops that might be fed to livestock (cereals, sugar and fodder beets). Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D.

Since 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), further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

Although not required, metabolism studies were available and assessed in the framework of the peer review (United Kingdom, 2012; EFSA, 2013). The metabolism of thiencarbazone-methyl residues in livestock was investigated in lactating goats and laying hens at a dose rate of 2 mg/kg body weight (bw) per day, covering largely the maximum dietary burdens calculated in this review (France, 2019).

In both studies, thiencarbazone-methyl was radiolabelled in the dihydrotriazole or thiophene ring of the molecule. The studies performed with the dihydrotriazole label showed that the parent is extensively metabolised in all livestock matrices and, when detected, present in low proportions (< 8% TRR; 0.06 mg eq/kg). Whereas with the thiophene label, parent thiencarbazone-methyl accounted for 83% TRR (0.004 mg eq/kg) in eggs and 80% TRR (0.102 mg eq/kg) in milk. The main metabolites identified in all matrices were BYH 18636-MMT (49–70% TRR in poultry; 23–49% TRR in goat) and methyl carbamate (13–23% TRR in poultry; 27–54% TRR in goat). In lactating goats, significant levels of BYH 18636-sulfonamide were found up to 85% TRR (3.1 mg eq/kg) in liver, as well as BYH 18636-sulfonamide carboxylic acid up to 52% TRR (0.35 mg eq/kg) in fat (United Kingdom, 2012).

The metabolism in lactating goats and laying hens is very similar and residues result from the cleavage of the parent compound, oxidative N-demethylation and hydrolysis steps.

Parent thiencarbazone-methyl and BYH 18636-MMT were found to be the most relevant compounds in livestock commodities. Therefore, during the peer review, a residue definition for enforcement and for risk assessment was proposed as thiencarbazone-methyl and BYH 18636-MMT, expressed as thiencarbazone-methyl (EFSA, 2013). Even if not required in the framework of this review, these residue definitions as derived from the available metabolism studies would still be valid if in the future, the dietary burdens were to be triggered.

The storage stability of parent thiencarbazone-methyl and BYH 18636-MMT was not investigated and such data were not required. Nevertheless, a study to demonstrate the storage stability of BYH
18636-sulfonamide for a period of two months at –18°C in fat and milk is available (United Kingdom, 2012; EFSA, 2013). A fully validated high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) analytical method for the parent and metabolite BYH 18636-MMT individually at the LOQ of 0.01 mg/kg is available in all animal matrices (United Kingdom, 2012; EFSA, 2013; France, 2019). The enforcement LOQ of the proposed residue definition was calculated as a combined LOQ of 0.04 mg/kg, considering the molecular weights of each compound. According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses for the determination of the parent in muscle and liver, and of BYH 18636-MMT in muscle, liver and eggs (EURLs, 2019).

The metabolism studies in poultry and ruminants performed at an exaggerated dose rate (i.e. 1,100–2,200N rate compared to the maximum dietary burdens) is sufficient to conclude that residue levels would remain below the enforcement LOQ of 0.04 mg/kg in edible tissues, from the dietary burden resulting from the authorised uses of thiencarbazone-methyl. No feeding study was required in the framework of the peer review and of this review. However, a US feeding study on lactating cows is available. The results of this study performed at a dose rate equivalent to 8N confirmed that no residues are expected in animal matrices (United Kingdom, 2012; EFSA, 2013).

3. Consumer risk assessment

In the framework of this review, only the uses of thiencarbazone-methyl reported by the RMS in Appendix A were considered.

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 3 of the EFSA PRIMo (EFSA, 2018). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). All input values included in the exposure calculations are summarised 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 exposure values calculated were compared with the toxicological reference value for thiencarbazone-methyl, derived by EFSA (2013). The highest chronic exposure was calculated for NL toddler, representing 0.1% ADI. This calculation indicates that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Therefore, these uses are unlikely to pose a risk to consumer’s health.

Conclusions

The metabolism of thiencarbazone-methyl in plants was investigated in primary and rotational crops. According to the results of the metabolism studies on cereals and root and tuber vegetables, the residue definition for enforcement can be proposed as parent thiencarbazone-methyl only. For risk assessment the residue definition is proposed as the sum of thiencarbazone-methyl, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside, expressed as thiencarbazone-methyl. These residue definitions are also applicable to rotational crops. For the current authorised uses, a residue definition is not needed for processed commodities.

Fully validated analytical methods are available for the enforcement of the proposed residue definition in cereals and root and tuber vegetables at the LOQ of 0.01 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses. All compounds included in the risk assessment residue definition were demonstrated to be stable for at least 26 months in the relevant plant matrices.

No residues above the LOQ were found in edible parts from rotational crops. However, a field rotational crop study performed at an exaggerated dose, covering the plateau concentration calculated for the persistent metabolite BYH 18636-carboxylic acid, is still required to confirm that no significant residues of thiencarbazone-methyl are expected following multiannual applications according to the most cGAP assessed in this review.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. Specific MRLs for rotational crops are not needed, provided that Member States will take adequate risk mitigation measures in order to avoid significant residues to occur in rotational crops.
Thiencarbazone-methyl is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated were found to be below the trigger value of 0.1 mg/kg DM for each group and further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary. Nevertheless, the metabolism of thiencarbazone-methyl residues in livestock was investigated and a general residue definition for enforcement and risk assessment was proposed as thiencarbazone-methyl and BYH 18636-MMT, expressed as thiencarbazone-methyl. Considering the authorised uses reported, a residue definition for livestock commodities is not required in the framework of this review. However, these residue definitions would be considered valid if in the future dietary burdens were to be triggered.

An analytical method for the enforcement of the proposed residue definition at the combined LOQ of 0.04 mg/kg in all animal matrices is available. According to the EURLs the LOQ of 0.01 mg/kg for each compound individually, is achievable by using the QuEChERS method in routine analyses.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3 of the EFSA PRIMo. The highest chronic exposure was calculated for NL toddler, representing 0.1% of the ADI. This calculation indicates that the uses assessed under this review are unlikely to pose a risk to consumer’s health. 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). All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 1 footnotes for details).

EFSA identified the following data gap which might have an impact on national authorisations:

- a representative field rotational crop study covering the plateau concentration of metabolite BYH 18636-carboxylic acid and analysing for this metabolite in the soil.

Pending the submission of this study, Member States granting authorisations for thiencarbazone-methyl should take the appropriate risk mitigation measures or modify the relevant authorisations in order to avoid the presence of significant residues in rotational crops.

### Table 1: Summary table

| Code number | Commodity                        | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | MRL (mg/kg) | Comment |
|-------------|----------------------------------|-------------------------|----------------------|-----------------------|-------------|---------|
| 234000      | Sweet corn                       | 0.01*                   | –                    | 0.01*                 | Recommended(a) |
| 500010      | Barley grain                     | 0.01*                   | –                    | 0.01*                 | Recommended(a) |
| 500030      | Maize grain                      | 0.01*                   | –                    | 0.01*                 | Recommended(a) |
| 500040      | Millet grain                     | 0.01*                   | –                    | 0.01*                 | Recommended(a) |
| 500070      | Rye grain                        | 0.01*                   | –                    | 0.01*                 | Recommended(a) |
| 500080      | Sorghum grain                    | 0.01*                   | –                    | 0.01*                 | Recommended(a) |
| 500090      | Wheat grain                      | 0.01*                   | –                    | 0.01*                 | Recommended(a) |
| 900010      | Sugar beet (root)                | 0.01*                   | –                    | 0.01*                 | Recommended(a) |
| –           | Other commodities of plant and/or animal origin | See Art.18(1)(b) of Reg 396/2005 | – | – | Further consideration needed(b) |

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

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

(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).

(b): 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
DT_{90}  period required for 90% dissipation (define method of estimation)
eq  residue expressed as a.s. equivalent
EUROs  European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO  Food and Agriculture Organization of the United Nations
GAP  Good Agricultural Practice
HPLC–MS/MS  high-performance liquid chromatography with tandem mass spectrometry
HR  highest residue
IEDI  international estimated daily intake
ILV  independent laboratory validation
InChIKey  International Chemical Identifier Key
ISO  International Organisation for Standardization
IUPAC  International Union of Pure and Applied Chemistry
LC  liquid chromatography
LC–MS/MS  liquid chromatography with tandem mass spectrometry
LOQ  limit of quantification
Mo  monitoring
MRL  maximum residue level
MS/MS  tandem mass spectrometry detector
NEDI  national estimated daily intake
NEU  northern European Union
NTMDI  national theoretical maximum daily intake
OD  oil dispersion
OECD  Organisation for Economic Co-operation and Development
PBI  plant-back interval
PF  processing factor
PHI  preharvest interval
P_{ow}  partition coefficient between n-octanol and water
PRIMo  (EFSA) Pesticide Residues Intake Model
PROFile  (EFSA) Pesticide Residues Overview File
QuEChERS  Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
QuOil  variation of QuEChERS method for fat and oil content commodities
RA  risk assessment
RD  residue definition
RMS  rapporteur Member State
SANCO  Directorate-General for Health and Consumers
SC  suspension concentrate
SEU  southern European Union
SMILES  simplified molecular-input line-entry system
STMR  supervised trials median residue
TMDI  theoretical maximum daily intake
TRR  total radioactive residue
WG  water-dispersible granule
WHO  World Health Organization
## Appendix A – Summary of authorised uses considered for the review of MRLs

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

| Crop and/or situation | MS or country | FG or Y(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|------------|------------------------------------|-------------|----------------|------------------|--------------|---------|
|                       |               |            |                                    |             |               |                                |              |         |
| Sweet corn            | NL            | F          | Weeds                              | SC 68 g/L   | Foliar treatment – broadcast spraying | 12–16           | 1            | 19.72 g a.s./ha | n.a.     |
| Barley                | AT            | F          | Annual monocotyledous and dicotyledonous weeds, *Bromus* sp., *Lolium* sp., *Avena* fatua, *Apera* spica-venti, *Poa* sp., *Alopecurus myosuroides* | WG 37.2 g/kg | Foliar treatment – broadcast spraying | 13–32          | 1            | 7.2 g a.s./ha | n.a.     |
| Maize                 | FR            | F          | Broad-leaved weeds and grasses      | SC 90 g/L   | Foliar treatment – broadcast spraying | 0–13            | 1            | 40 g a.s./ha | n.a.     |
| Common millet         | FR            | F          | Broad-leaved weeds and grasses      | SC 90 g/L   | Foliar treatment – broadcast spraying | 0–13            | 1            | 40 g a.s./ha | n.a.     |
| Rye                   | NL            | F          | Annual weeds                       | WG 37.5 g/kg| Foliar treatment – broadcast spraying | 13–32           | 1            | 7.5 g a.s./ha | n.a.     |
| Wheat                 | NL            | F          | Annual weeds                       | WG 37.5 g/kg| Foliar treatment – broadcast spraying | 13–32           | 1            | 7.5 g a.s./ha | n.a.     |

Authorised also for triticale, spelt and durum wheat
| Crop and/or situation | MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|----------------------|--------------|-------------|-----------------------------------|-------------|-------------|-------------------------------|--------------|---------|
| Sugar beets          | BE           | F           | Monocots and dicots               | OD 30 g/L   | Foliar treatment – broadcast spraying | 10–18 1 | – – | 30 g a.s./ha (10 days interval): 1st appl. at BBCH 10–14, 2nd appl. at BBCH 12–18 |
| Maize (for forage)   | HU           | F           | Annual monocotyledinous and dicotyledinous weed plants | SC 90 g/L   | Foliar treatment – broadcast spraying | 13 1   | – – | 40 g a.s./ha |
| Fodder beets         | BE           | F           | Monocots and dicots               | OD 30 g/L   | Foliar treatment – broadcast spraying | 10–18 1 | – – | 30 g a.s./ha |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; MS: Member State; a.s.: active substance; n.a.: not applicable; SC: suspension concentrate; WG: water-dispersible granule; OD: oil dispersion.
(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.
## A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | F G or I<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Conc. a.s. | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min-max | Interval between application (min) | PHI (days)<sup>(d)</sup> | Application rate per treatment | Remarks |
|-----------------------|---------------|-------------------------|-----------------------------------|-------------|-----------|------------|---------------------------------|----------------|-----------------------------|-----------------|----------------------------|---------|
| Maize                 | ES            | F                       | Weeds                             | SC          | 90 g/L   | Foliar treatment – broadcast spraying | 0–13             | 1                           | --              | 40 g a.s./ha               | n.a.    |
| Rye                   | ES            | F                       | Weeds                             | SC          | 68 g/L   | Foliar treatment – broadcast spraying | 20–32            | 1                           | --              | 7.5 g a.s./ha              | n.a.    |
| Sorghum               | FR            | F                       | Broad leaved weeds and grasses    | SC          | 90 g/L   | Foliar treatment – broadcast spraying | 0–13             | 1                           | --              | 40 g a.s./ha              | n.a.    |
| Wheat                 | IT            | F                       | Weeds                             | WG          | 22.5 g/kg| Foliar treatment – broadcast spraying | 12–32            | 1                           | --              | 7.5 g a.s./ha              | n.a.    |
| Sugar beets           | IT            | F                       | Weeds                             | OD          | 30 g/L   | Foliar treatment – broadcast spraying | 10–18            | 1                           | --              | 30 g a.s./ha              | n.a.    |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; MS: Member State; a.s.: active substance; n.a.: not applicable; SC: suspension concentrate; WG: water-dispersible granule; n.a.: not applicable.

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

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

<sup>(c)</sup>: 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.

<sup>(d)</sup>: PHI: minimum preharvest interval.
## Appendix B – List of end points

### B.1. Residues in plants

#### B.1.1. Nature of residues and methods of analysis in plants

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Root crops                        | Sugar beet  | Foliar, 2 × 16 g a.s./ha, BBCH 12–14 and 14–18 or Foliar, 2 × 32 g a.s./ha, BBCH 12–14 and 14–18 | Leaves and roots: 97–98 | Dihydrotriazole 14C-thiencarbazone-methyl (France, 2019) |
|                                  | Sugar beet  | Foliar, 2 × 16 g a.s./ha, BBCH 12–14 and 14–18 or Foliar, 2 × 31 g a.s./ha, BBCH 12–14 and 14–18 | Leaves, roots: 96–97 | Thiophene 14C-thiencarbazone-methyl (France, 2019) |
| Cereals/grass                     | Maize       | Soil (pre-emergence), 1 × 48 g a.s./ha | Forage: 104 Stover, grain: 153 | Dihydrotriazole or thiophene 14C-thiencarbazone-methyl (United Kingdom, 2012) |
|                                  | Maize       | Foliar (early post-emergence), 1 × 12 g a.s./ha, BBCH 13–16 | Forage: 70, 71 Stover, grain: 109, 110 | Dihydrotriazole or thiophene 14C-thiencarbazone-methyl (United Kingdom, 2012) |
|                                  | Maize       | Split-application: foliar, 1 × 32 g a.s./ha, BBCH 16 and soil, 1 × 16 g a.s./ha, BBCH 19 | Forage: 46 Stover, grain: 95 | Dihydrotriazole or thiophene 14C-thiencarbazone-methyl (United Kingdom, 2012) |
|                                  | Wheat       | Foliar (early post-emergence), 1 × 16 g a.s./ha, BBCH 14–15 | Forage: 16 Hay: 54 Straw and grain: 89 | Dihydrotriazole 14C-thiencarbazone-methyl (United Kingdom, 2012) |
|                                  | Wheat       | Foliar (early post-emergence), 1 × 17 g a.s./ha, BBCH 13–14 | Forage: 16 Hay: 54 Straw and grain: 89 | Thiophene 14C-thiencarbazone-methyl (United Kingdom, 2012) |
### Rotational crops (available studies)

| Crop groups              | Crop(s)          | Application(s)                              | PBI (DAT)       | Comment/source                                                                 |
|--------------------------|------------------|---------------------------------------------|-----------------|-------------------------------------------------------------------------------|
| Root/tuber crops         | Turnip           | Bare soil, 45 g a.s./ha                     | 180, 270        | Dihydrotriazole or thiophene 14C-thiencarbazone-methyl (United Kingdom, 2012) |
|                          |                  | Bare soil, 30 g a.s./ha                     | 180, 269        |                                                                                |
|                          |                  | Bare soil, 15 g a.s./ha                     | 29, 118, 247    |                                                                                |
| Leafy crops              | Swiss chard      | Bare soil, 15 g a.s./ha                     | 29, 118, 247    | Dihydrotriazole or thiophene 14C-thiencarbazone-methyl (United Kingdom, 2012) |
| Cereal (small grain)     | Wheat            | Bare soil, 45 g a.s./ha                     | 90, 270         | Dihydrotriazole or thiophene 14C-thiencarbazone-methyl (United Kingdom, 2012) |
|                          |                  | Bare soil, 30 g a.s./ha                     | 90, 269         |                                                                                |
|                          |                  | Bare soil, 15 g a.s./ha                     | 29, 118, 247    |                                                                                |
| Pulses and oilseeds      | Soybean          | Bare soil, 45 g a.s./ha                     | 90, 270         | Dihydrotriazole or thiophene 14C-thiencarbazone-methyl (United Kingdom, 2012) |
|                          |                  | Bare soil, 30 g a.s./ha                     | 90, 269         |                                                                                |

### Processed commodities (hydrolysis study)

| Conditions                      | Stable? | Comment/Source                                                                 |
|---------------------------------|---------|-------------------------------------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4) | Not triggered | Studies with dihydrotriazole or thiophene 14C-thiencarbazone-methyl were provided and reported the parent to be instable (France, 2019) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Not triggered | Studies with dihydrotriazole or thiophene 14C-thiencarbazone-methyl were provided and reported the parent to be instable (France, 2019) |
| Sterilisation (20 min, 120°C, pH 6) | Not triggered | Studies with dihydrotriazole or thiophene 14C-thiencarbazone-methyl were provided and reported the parent to be instable (France, 2019) |
| Sugar refining (120 min, 95°C, pH 9) | Not triggered | Studies with dihydrotriazole or thiophene 14C-thiencarbazone-methyl were provided and reported the parent to be instable (France, 2019) |

a.s.: active substance; PBI: plant-back interval; DAT: days after treatment; HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; QuOil: variation of QuEChERS method for fat and oil content commodities; LOQ: limit of quantification; ILV: independent laboratory validation.
| Question                                                                 | Answer                                                                                           |
|------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| Can a general residue definition be proposed for primary crops?         | no Metabolism investigated in two crop groups only (cereals and root and tuber vegetables)       |
| Rotational crop and primary crop metabolism similar?                    | yes Standard hydrolysis studies were not triggered.                                             |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | not applicable Primary and rotational crops: thiencarbazone-methyl (cereals, root and tuber vegetables only) |
| Plant residue definition for monitoring (RD-Mo)                        | Primary and rotational crops: sum of thiencarbazone-methyl, BYH 18636-N-desmethyland BYH 18636-MMT-glucoside, expressed as thiencarbazone-methyl (cereals, root and tuber vegetables only) |
| Plant residue definition for risk assessment (RD-RA)                   | High water, high oil, high acid content and dry matrices:                                        |
| Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs) | HPLC–MS/MS; LOQ 0.01 mg/kg                                                                 |
|                                                                       | Confirmatory method available                                                                    |
|                                                                       | ILV available for maize (grain and forage) and wheat straw                                      |
|                                                                       | (United Kingdom, 2012; EFSA, 2013)                                                              |
|                                                                       | HPLC-MS/MS, (QuEChERS method for high water content, high acid content and dry matrices and QuOIL method for high oil content) |
|                                                                       | LOQ 0.01 mg/kg in high water, high oil and high acid content matrices                           |
|                                                                       | LOQ 0.005 mg/kg in dry commodities                                                               |

a.s.: active substance; PBI: plant-back interval; DAT: days after treatment; BBCH: growth stages of mono- and dicotyledonous plants; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; QuOIL: variation of QuEChERS method for fat and oil content commodities; LOQ: limit of quantification; ILV: independent laboratory validation.
## B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category               | Commodity                        | T (°C) | Stability period | Compounds covered                                                                 | Comment/source                      |
|------------------------------------|------------------------|----------------------------------|--------|-----------------|-----------------------------------------------------------------------------------|-------------------------------------|
|                                    | High water content     | Lettuce, tomato, maize forage, potato | –18    | 26 Months       | Thiencarbazone-methyl, BYH18636-N-desmethyl and BYH 18636-MMT-glucoside           | United Kingdom (2013), EFSA (2013)  |
|                                    | High oil content       | Soybean seeds                     | –18    | 26 Months       | Thiencarbazone-methyl, BYH18636-N-desmethyl and BYH 18636-MMT-glucoside           | United Kingdom (2013), EFSA (2013)  |
|                                    | Dry commodities       | Maize grain                       | –18    | 26 Months       | Thiencarbazone-methyl, BYH18636-N-desmethyl and BYH 18636-MMT-glucoside           | United Kingdom (2013), EFSA (2013)  |
|                                    | Others                 | Maize stover                      | –18    | 26 Months       | Thiencarbazone-methyl, BYH18636-N-desmethyl and BYH 18636-MMT-glucoside           | United Kingdom (2013), EFSA (2013)  |
## B.1.2. Magnitude of residues in plants

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

| Commodity                  | Region/indoor<sup>(c)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|----------------------------|----------------------------|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------------|---------------------------|-----------------|
| Maize/corn grains          | NEU                        | Mo: 20 × < 0.01 RA: 20 × < 0.034                                | Residue trials on maize compliant with GAP. Extrapolation to sweet corn (maize harvested before BBCH 85) and common millet is applicable (United Kingdom, 2012; EFSA, 2013; France, 2019) MRL<sub>OECD</sub> = 0.01 | 0.01*                  | 0.01                     | 0.01                       | 1<sup>(e)</sup> |
| Sweet corn                 |                            |                                                                 |                                                                                                                                                                                                            |                        |                          |                           |                 |
| Common millet grains       |                            |                                                                 |                                                                                                                                                                                                            |                        |                          |                           |                 |
| Maize/corn grains          | SEU                        | Mo: 20 × < 0.01 RA: 20 × < 0.034                                | Residue trials on maize compliant with GAP. Extrapolation to sweet corn (maize harvested before BBCH 85) and sorghum is applicable (United Kingdom, 2012; EFSA, 2013; France, 2019) MRL<sub>OECD</sub> = 0.01 | 0.01*                  | 0.01                     | 0.01                       | 1<sup>(e)</sup> |
| Sorghum grains             |                            |                                                                 |                                                                                                                                                                                                            |                        |                          |                           |                 |
| Wheat grains               | NEU                        | Mo: 8 × < 0.01 RA: 8 × < 0.034                                  | Residue trials on wheat compliant with GAP. Extrapolation to rye and barley is applicable (France, 2019) MRL<sub>OECD</sub> = 0.01                                                                                       | 0.01*                  | 0.01                     | 0.01                       | 1<sup>(e)</sup> |
| Rye grains                 |                            |                                                                 |                                                                                                                                                                                                            |                        |                          |                           |                 |
| Barley grains              |                            |                                                                 |                                                                                                                                                                                                            |                        |                          |                           |                 |
| Wheat grains               | SEU                        | Mo: 8 × < 0.01 RA: 8 × < 0.034                                  | Residue trials on wheat compliant with GAP. Extrapolation to rye is applicable (France, 2019) MRL<sub>OECD</sub> = 0.01                                                                                       | 0.01*                  | 0.01                     | 0.01                       | 1<sup>(e)</sup> |
| Rye grains                 |                            |                                                                 |                                                                                                                                                                                                            |                        |                          |                           |                 |
| Sugar beet roots           | NEU                        | Mo: 17 × < 0.01 RA: 17 × < 0.034                                | Residue trials on sugar beet compliant with GAP. Extrapolation to fodder beet is applicable (France, 2019) MRL<sub>OECD</sub> = 0.01                                                                            | 0.01*                  | 0.01                     | 0.01                       | 1<sup>(e)</sup> |
| Fodder beet roots          |                            |                                                                 |                                                                                                                                                                                                            |                        |                          |                           |                 |
| Sugar beet roots           | SEU                        | Mo: 17 × < 0.01 RA: 17 × < 0.034                                | Residue trials on sugar beet compliant with GAP (France, 2019) MRL<sub>OECD</sub> = 0.01                                                                                                                    | 0.01*                  | 0.01                     | 0.01                       | 1<sup>(e)</sup> |
| Maize for forage           | NEU                        | Mo: 20 × < 0.01 RA: 20 × < 0.034                                | Residue trials on maize for forage compliant with GAP (United Kingdom, 2012; EFSA, 2013; France, 2019) MRL<sub>OECD</sub> = 0.01                                                                                | 0.01*                  | 0.01                     | 0.01                       | 1<sup>(e)</sup> |
| Maize/corn stover          | NEU                        | Mo: 20 × < 0.01 RA: 20 × < 0.034                                | Residue trials on maize compliant with GAP. Extrapolation to common millet straw is applicable (United Kingdom, 2012; EFSA, 2013; France, 2019) MRL<sub>OECD</sub> = 0.01 | 0.01*                  | 0.01                     | 0.01                       | 1<sup>(e)</sup> |
| Commodity          | Region/indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-------------------|------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Maize/corn stover | SEU              | **Mo**: 20 × < 0.01; **RA**: 20 × < 0.034                      | Residue trials on maize compliant with GAP. Extrapolation to sorghum stover is applicable (United Kingdom, 2012; EFSA, 2013; France, 2019) MRL_{OECD} = 0.01 | 0.01* 0.01 0.01 1(e)  |
| Sorghum stover    |                  |                                                              |                                                                                  |                        |              |                |       |
| Wheat straw       | NEU              | **Mo**: 8 × < 0.01; **RA**: 8 × < 0.034                        | Residue trials on wheat compliant with GAP. Extrapolation to rye straw and barley straw is applicable (France, 2019) MRL_{OECD} = 0.01 | 0.01* 0.01 0.01 1(e)  |
| Barley straw      |                  |                                                              |                                                                                  |                        |              |                |       |
| Rye straw         | SEU              | **Mo**: 7 × < 0.01; **RA**: 7 × < 0.034; 0.041                 | Residue trials on wheat compliant with GAP. Extrapolation to rye straw is applicable (France, 2019) MRL_{OECD} = 0.02 | 0.02 0.02 0.01 1(f)   |
| Wheat straw       |                  |                                                              |                                                                                  |                        |              |                |       |
| Rye straw         |                  |                                                              |                                                                                  |                        |              |                |       |
| Sugar beet tops   | NEU              | **Mo**: 17 × < 0.01; **RA**: 17 × < 0.034                      | Residue trials on sugar beet compliant with GAP. Extrapolation to fodder beet is applicable (France, 2019) MRL_{OECD} = 0.01 | 0.01* 0.01 0.01 1(e)  |
| Fodder beet tops  |                  |                                                              |                                                                                  |                        |              |                |       |
| Sugar beet tops   | SEU              | **Mo**: 17 × < 0.01; **RA**: 17 × < 0.034                      | Residue trials on sugar beet compliant with GAP (France, 2019) MRL_{OECD} = 0.01 | 0.01* 0.01 0.01 1(e)  |
|                   |                  |                                                              |                                                                                  |                        |              |                |       |

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.

Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): CF of 1 applied considering the no residue situation.
(f): CF of 1 applied considering that residue levels of metabolites are always below LOQ.
B.1.2.2. Residues in rotational crops

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

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

No residue above 0.01 mg/kg in edible parts of rotational crops and no residue above 0.05 mg/kg in feed commodities were found in the available study performed at a dose rate just above 1N compared to the application rate of the most critical GAP under assessment. However, this study does not cover the multiannual applications according to the most critical GAP.

In all rotated crops, parent thiencarbazone-methyl and BYH 18636-N-desmethyl residues were found to be lower than 0.01 mg/kg. BYH 18636-MMT-glucoside was also below LOQ in wheat matrices and soybean seeds, while it occurred up to 0.02 mg/kg in soya forage and up to 0.07 mg/kg in soya hay. Residue levels above LOQ were only found in non-edible parts of soybean (United Kingdom, 2012; EFSA, 2013).

However, a field rotational crop study performed at an exaggerated dose, covering the plateau concentration calculated for the persistent metabolite BYH 18636-carboxylic acid, is still required to confirm that no significant residues of thiencarbazone-methyl are expected following multiannual applications according to the most critical GAP assessed in this review (data gap).

GAP: Good Agricultural Practice; LOQ: Limit of quantification.

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Yes/No) |
|-----------------------------|---------------------------------------------|---------------------------|----------------------------|---------------------------|
|                             | Median | Maximum | Median | Maximum |                          |                          |                            |
| Cattle (all diets)          | 0.0018 | 0.0018  | 0.05   | 0.05    | Cattle (dairy)           | Beet, mangel, roots      | No                         |
| Cattle (dairy only)         | 0.0018 | 0.0018  | 0.05   | 0.05    | Cattle (dairy)           | Beet, mangel, roots      | No                         |
| Sheep (all diets)           | 0.0009 | 0.0009  | 0.02   | 0.02    | Sheep (lamb)             | Beet, sugar, tops        | No                         |
| Sheep (ewe only)            | 0.0007 | 0.0007  | 0.02   | 0.02    | Sheep (ram/ewe)          | Beet, sugar, tops        | No                         |
| Swine (all diets)           | 0.0005 | 0.0005  | 0.02   | 0.02    | Swine (breeding)         | Beet, mangel, roots      | No                         |
| Poultry (all diets)         | 0.0009 | 0.0009  | 0.01   | 0.01    | Poultry (layer)          | Corn, field, forage/silage | No                        |
| Poultry (layer only)        | 0.0009 | 0.0009  | 0.01   | 0.01    | Poultry (layer)          | Corn, field, forage/silage | No                        |
### Relevant groups (subgroups)

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup<sup>(a)</sup> | Most critical commodity<sup>(b)</sup> | Trigger exceeded (Yes/No) |
|-----------------------------|------------------------------------------|---------------------------------|---------------------------------|--------------------------|
|                             | Median | Maximum | Median | Maximum |                         |                                |
| Fish                        | –      | –       | –      | –       | –                       | Not investigated             |

bw: body weight; DM: dry matter.

(a): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

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

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

| Livestock (available studies) | Animal               | Dose (mg/kg bw per day) | Duration (days) | Comment/source                                                                 |
|-------------------------------|----------------------|-------------------------|-----------------|-------------------------------------------------------------------------------|
| Laying hens                   | 2                    | 14                      | Poultry, dihydrotriazole or thiophene $^{14}$C-thiencarbazone-methyl (United Kingdom, 2012) Study provided, although not triggered |
| Lactating ruminants           | 2                    | 5                       | Goat, dihydrotriazole or thiophene $^{14}$C-thiencarbazone-methyl (United Kingdom, 2012) Study provided, although not triggered |
### Time needed to reach a plateau concentration in milk and eggs (days)

- **Milk**: 3 days
- **Dihydrotriazole $^{14}$C-thiencarbazone-methyl**
- **Eggs**: 7 days
- **Thiophene $^{14}$C-thiencarbazone-methyl**
- (9 days in the study with dihydrotriazole $^{14}$C-thiencarbazone-methyl)

| Metabolism in rat and ruminant similar | Yes | No |
|---------------------------------------|-----|----|

### Can a general residue definition be proposed for animals?

- Yes
- No

### Animal residue definition for monitoring (RD-Mo)

- Thiencarbazone-methyl and BYH 18636-MMT, expressed as thiencarbazone-methyl (EFSA, 2013)
- However, not applicable in the framework of the current review

### Animal residue definition for risk assessment (RD-RA)

- Thiencarbazone-methyl and BYH 18636-MMT, expressed as thiencarbazone-methyl (EFSA, 2013)
- However, not applicable in the framework of the current review

### Fat soluble residues

- No
- $\log P_{ow} = -1.98$ at 24 °C, pH 7 (< 3)
- (EFSA, 2013)

### Methods of analysis for monitoring of residues

**(analytical technique, matrix groups, LOQs)**

- **Milk, Eggs, Muscle, Fat, Liver, Kidney:**
  
  - HPLC–MS/MS, enforcement LOQ 0.04 mg/kg (for thiencarbazone-methyl and BYH 18636-MMT individually, LOQ 0.01 mg/kg)
  - ILV for milk, liver and fat
  
  (United Kingdom, 2012; EFSA, 2013; France, 2019)

- **Muscle, Liver, Eggs:**
  
  - HPLC–MS/MS (QuEChERS method)
  - LOQ 0.01 mg/kg for thiencarbazone-methyl in muscle and liver
  - LOQ 0.01 mg/kg for BYH 18636-MMT in muscle, liver and eggs
  
  (EURLs, 2019)

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bw: body weight; $P_{ow}$: partition coefficient between n-octanol and water; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T ($^\circ$C) | Stability period Value | Unit | Compounds covered | Comment/source |
|------------------------------------|--------|-----------|--------------|------------------------|------|-------------------|---------------|
| Animal products (available studies)| Bovine | Fat       | –18          | 2                      | Months | BYH 18636-sulfonamide | Compound not included in the residue definition (United Kingdom, 2012) |
| Animal products (available studies)| Bovine | Milk      | –18          | 2                      | Months | BYH 18636-sulfonamide | Compound not included in the residue definition (United Kingdom, 2012) |
B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies
Not relevant (dietary burden calculations are below the trigger value and no MRLs are needed).

B.3. Consumer risk assessment

No ARfD has been considered necessary and an acute consumer risk assessment was not performed.

| ADI | 0.23 mg/kg bw per day (EFSA, 2013) |
| TMDI according to EFSA PRiMo | Not assessed in this review |
| NTMDI, according to (to be specified) | Not assessed in this review |
| Highest IEDI, according to EFSA PRiMo (rev.3) | 0.1% ADI (NL toddler) |
| NEDI (% ADI) | Not assessed in this review |

Assumptions made for the calculations

The calculation is based on the median residue (STMR) levels derived for raw agricultural commodities, multiplied by the conversion factor for risk assessment (which is 1, considering the no-residue situation or at least that residues of the metabolites are below LOQ)

The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003).

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

B.4. Proposed MRLs

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Outcome of the review | Comment |
|-------------|------------|------------------------|----------------------|-------------|-----------------------|---------|
| 234000      | Sweet corn | 0.01*                  | –                    | 0.01*       | Recommended(a)        |         |
| 500010      | Barley grain | 0.01*                 | –                    | 0.01*       | Recommended(a)        |         |
| 500030      | Maize grain | 0.01*                  | –                    | 0.01*       | Recommended(a)        |         |
| 500040      | Millet grain | 0.01*                  | –                    | 0.01*       | Recommended(a)        |         |
| 500070      | Rye grain | 0.01*                  | –                    | 0.01*       | Recommended(a)        |         |
| 500080      | Sorghum grain | 0.01*                 | –                    | 0.01*       | Recommended(a)        |         |
| 500090      | Wheat grain | 0.01*                  | –                    | 0.01*       | Recommended(a)        |         |
| 900010      | Sugar beet (root) | 0.01*              | –                    | 0.01*       | Recommended(a)        |         |

Enforcement residue definition: thiencarbazone-methyl
### Code number

| Code number | Commodity                              | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review |
|-------------|----------------------------------------|-------------------------|----------------------|-----------------------|
| –           | Other commodities of plant and/or animal origin | See Art.18(1)(b) of Reg 396/2005 | –                    | Further consideration needed(b) |

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

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

(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).

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

**PRIMo(EU)**

### Thiacarbazon

**Toxicological reference values**

| LOQs (mg/kg) | ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Source | Year of evaluation |
|--------------|------------------------|----------------|--------|--------------------|
| 0.01–0.01    | 0.23                   | not necessary  | EFSA   | 2013               |

**Details – chronic risk assessment**

| Commodity/group of commodities | Exposure resulting from | Contributed to MS diet (% of ADI) | Contributed to MS diet (in % of ADI) |
|--------------------------------|-------------------------|-----------------------------------|-------------------------------------|
| Wheat                          | 0.0%                    | 0.0%                              | 0.0%                                |
| Maize/corn                     | 0.0%                    | 0.0%                              | 0.0%                                |
| Sweet corn                     | 0.0%                    | 0.0%                              | 0.0%                                |
| Rye                            | 0.0%                    | 0.0%                              | 0.0%                                |
| Sugar beet roots               | 0.0%                    | 0.0%                              | 0.0%                                |
| Barley                         | 0.0%                    | 0.0%                              | 0.0%                                |
| Grapefruits                    | 0.0%                    | 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 thiacarbazon is unlikely to present a public health concern.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Show results for all crops

#### Unprocessed commodities

| Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-------------|-----------------------------|---------------------|
|                       |             |                             |                     |

**Results for children**

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

**Results for adults**

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

#### Processed commodities

| Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-------------|-----------------------------|---------------------|
|                       |             |                             |                     |

**Results for children**

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

**Results for adults**

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

**Conclusion:**

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation).
**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                |
|                                       |                       |                        |
| **Risk assessment residue definition:** | Sum of thiencarbazone-methyl, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside, expressed as thiencarbazone-methyl |
| Barley, grain                         | 0.01* STMR            | 0.01* STMR             |
| Brewer's grain, dried                 | 0.01* STMR(a)         | 0.01* STMR(a)          |
| Corn, field (Maize), grain            | 0.01* STMR            | 0.01* STMR             |
| Corn, pop, grain                      | 0.01* STMR            | 0.01* STMR             |
| Corn, field, milled by-pdts           | 0.01* STMR(a)         | 0.01* STMR(a)          |
| Corn, field, hominy meal              | 0.01* STMR(a)         | 0.01* STMR(a)          |
| Corn, field, distiller's grain (dry)  | 0.01* STMR(a)         | 0.01* STMR(a)          |
| Corn, field, gluten feed              | 0.01* STMR(a)         | 0.01* STMR(a)          |
| Corn, field, gluten, meal             | 0.01* STMR(a)         | 0.01* STMR(a)          |
| Millet, grain                         | 0.01* STMR            | 0.01* STMR             |
| Rye, grain                            | 0.01* STMR            | 0.01* STMR             |
| Sorghum, grain                        | 0.01* STMR            | 0.01* STMR             |
| Triticale, grain                      | 0.01* STMR            | 0.01* STMR             |
| Wheat, grain                          | 0.01* STMR            | 0.01* STMR             |
| Wheat, distiller's grain (dry)        | 0.01* STMR(a)         | 0.01* STMR(a)          |
| Wheat gluten, meal                    | 0.01* STMR(a)         | 0.01* STMR(a)          |
| Wheat, milled by-pdts                 | 0.01* STMR(a)         | 0.01* STMR(a)          |
| Beet, sugar, dried pulp               | 0.01* STMR(a)         | 0.01* STMR(a)          |
| Beet, sugar, ensiled pulp             | 0.01* STMR(a)         | 0.01* STMR(a)          |
| Beet, sugar, molasses                 | 0.01* STMR(a)         | 0.01* STMR(a)          |
| Corn, field, forage/silage            | 0.01* STMR            | 0.01* STMR             |
| Barley, straw                         | 0.01* STMR            | 0.01* STMR             |
| Millet, straw (fodder, dry)           | 0.01* STMR            | 0.01* STMR             |
| Corn, field, stover (fodder)          | 0.01* STMR            | 0.01* STMR             |
| Corn, pop, stover                     | 0.01* STMR            | 0.01* STMR             |
| Rye, straw                            | 0.01* STMR            | 0.02* HR               |
| Sorghum, grain, stover                | 0.01* STMR            | 0.01* HR               |
| Triticale, straw                      | 0.01* STMR            | 0.02* HR               |
| Wheat, straw                          | 0.01* STMR            | 0.02* HR               |
| Beet, mangel, roots                   | 0.01* STMR            | 0.01* HR               |
| Beet, mangel, tops                    | 0.01* STMR            | 0.01* HR               |
| Beet, sugar, tops                     | 0.01* STMR            | 0.01* HR               |

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

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

(a): For brewer's grain, processed commodities of corn, wheat and sugar beet, no default processing factor was applied because thiencarbazone-methyl 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                | Input value (mg/kg) | Comment               |
|--------------------------|---------------------|-----------------------|
| Risk assessment residue definition: sum of thiencarbazone-methyl, BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside, expressed as thiencarbazone-methyl | | |
| Sweet corn               | 0.01*               | **STMR_{Mo} × CF**    |
| Barley                   | 0.01*               | **STMR_{Mo} × CF**    |
| Maize/corn               | 0.01*               | **STMR_{Mo} × CF**    |
| Common millet/proso millet | 0.01*              | **STMR_{Mo} × CF**    |
| Rye                      | 0.01*               | **STMR_{Mo} × CF**    |
| Sorghum                  | 0.01*               | **STMR_{Mo} × CF**    |
| Wheat                    | 0.01*               | **STMR_{Mo} × CF**    |
| Sugar beet roots         | 0.01*               | **STMR_{Mo} × CF**    |

*STMR_{Mo}: supervised trials median residue for monitoring; CF: conversion factor.

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

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|--------------------------------|---------------------------------|-------------------------------|
| Thiencarbazone-methyl BYH 18636 | methyl 4-[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonylsulfamoyl]-5-methylthiophene-3-carboxylate COC(=O)c1csc(C)c1S(=O)(=O)NC(=O)N1N=C(OC)N(C)C1=O XSKZXF5DCXQX-UHFFFAOYSA-N | ![Structural formula](attachment:image1.png) |
| Thiencarbazone is a published ISO common name BYH 18636-carboxylic acid | 4-[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonylsulfamoyl]-5-methylthiophene-3-carboxylic acid O=S(=O)(NC(=O)N1N=C(OC)N(C)C1=O)c1c(C)sc1C(O)=O GLDAZAQRCSFN-P-UHFFFAOYSA-N | ![Structural formula](attachment:image2.png) |
| BYH 18636-sulfonamide-carboxylic acid | 5-methyl-4-sulfamoylthiophene-3-carboxylic acid O=S(N)(=O)c1c(C)sc1C(O)=O VPXWITYNJWPD-U-UHFFFAOYSA-N | ![Structural formula](attachment:image3.png) |
| BYH 18636-hydroxy-sulfonamide-carboxylic acid | 5-(hydroxymethyl)-4-sulfamoylthiophene-3-carboxylic acid O=S(N)(=O)c1c(CO)sc1C(O)=O JXBTVEPQMVRYAU-UHFFFAOYSA-N | ![Structural formula](attachment:image4.png) |
| BYH 18636-thienosaccharine | 6-methylthieno[3,4-d][1,2]thiazol-3(2H)-one 1,1-dioxide O=C1NS(=O)(=O)c2c(C)sc21 LHUVTABLXDEUNO-UHFFFAOYSA-N | ![Structural formula](attachment:image5.png) |
| BYH 18636-N-desmethyl | methyl 4-[[3-methoxy-5-oxo-2,5-dihydro-1H-1,2,4-triazol-1-yl]carbonylsulfamoyl]-5-methylthiophene-3-carboxylate COC(=O)c1csc(C)c1S(=O)(=O)NC(=O)N1N=C(OC)N(C)C1=O BIQVHHSUYKZPU-UHFFFAOYSA-N | ![Structural formula](attachment:image6.png) |
| BYH 18636-N-desmethyl-hydroxy | methyl 5-(hydroxymethyl)-4-[[3-methoxy-5-oxo-4,5-dihydro-1H-1,2,4-triazol-1-yl]carbonylsulfamoyl]thiophene-3-carboxylate COC(=O)c1csc(CO)c1S(=O)(=O)NC(=O)N1N=C(OC)N(C)C1=O QZFGZOXKFMFHLE-UHFFFAOYSA-N | ![Structural formula](attachment:image7.png) |
| BYH 18636-sulfonamide | methyl 5-methyl-4-sulfamoylthiophene-3-carboxylate COC(=O)c1csc(C)c1S(N)(=O)=O HZYUFKOKLHCVKN-UHFFFAOYSA-N | ![Structural formula](attachment:image8.png) |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-----------------------------|---------------------------------|-----------------------------|
| BYH 18636-hydroxy- sulfonamide-glucoside | methyl 5-[(D-glucopyranosyloxy)methyl]-4-sulfamoylthiophene-3-carboxylate | ![Structure](image1) |
| | COC(=O)c1cc(COC2O[C@H](CO)[C@@H](O)[C@@H](O)[C@@H]2O)c15S(N)(=O)=O | |
| BYH 18636-MMT | 5-methoxy-4-methyl-2,4-dihydro-3H-1,2,4-triazol-3-one | ![Structure](image2) |
| | O=C1NN=C(OC)N1C | |
| BYH 18636-MMT-glucoside | 2-D-glucopyranosyl-5-methoxy-4-methyl-2,4-dihydro-3H-1,2,4-triazol-3-one | ![Structure](image3) |
| | O=C1(N=C(OC)N1C)C1O[C@H](CO)[C@@H](O)[C@@H](O)[C@@H]1O | |
| Methyl carbamate | methyl carbamate | ![Structure](image4) |
| | NC(=O)OC | |
| BYH 18636-hydroxy- sulfonamide-carboxylic acid-glucoside | 5-[(D-glucopyranosyloxy)methyl]-4-sulfamoylthiophene-3-carboxylic acid | ![Structure](image5) |
| | O=SN(=O)c1cc(COC2O[C@H](CO)[C@@H](O)[C@@H](O)[C@@H]2O)scc1C(O)=O | |
| BYH 18636-hydroxy-thienosaccharine | 6-(hydroxymethyl)thieno[3,4-d][1,2]thiazol-3(2H)-one 1,1-dioxide | ![Structure](image6) |
| | O=C1NS(=O)c2c(CO)scc21 | |

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

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