REASONED OPINION

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Setting of import tolerances for teflubenzuron in grapefruits, mandarins and broccoli

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant BASF Agro BV submitted a request to the competent national authority in the United Kingdom to set import tolerances for the active substance teflubenzuron in grapefruits and mandarins imported from Brazil and for broccoli imported from Paraguay. The data submitted were found to be sufficient to derive maximum residue level (MRL) proposals for grapefruits and broccoli. The MRL derived for mandarins is not fully compliant with the EU guidance on extrapolation and the proposal requires further risk management consideration. Adequate analytical methods for enforcement are available to control the residues of teflubenzuron on the commodities under consideration. Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the use of teflubenzuron according to the reported agricultural practices is unlikely to present a risk to consumer health.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF Agro BV submitted an application to the competent national authority in the United Kingdom (evaluating Member State (EMS)) to set import tolerances for the active substance teflubenzuron in grapefruits, mandarins and broccoli. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 8 March 2018. The EMS proposed to establish maximum residue levels (MRLs) for grapefruits and mandarins imported from Brazil at the level of 0.5 mg/kg and for broccoli imported from Paraguay at the level of 0.2 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification which were requested from the EMS. On 9 August 2018, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions were derived.

The metabolism of teflubenzuron following foliar applications was investigated in fruit crops, root crops, leafy crops and pulses/oilseeds. Studies investigating the effect of processing on the nature of teflubenzuron (hydrolysis studies) demonstrated that the active substance is stable. As the proposed uses of teflubenzuron are on permanent and imported crops, investigations of residues in rotational crops are not required. Based on the metabolic pattern identified in metabolism studies and hydrolysis studies, the residue definitions for plant products were proposed as 'teflubenzuron' for enforcement and risk assessment. These residue definitions are applicable to primary crops and processed products, including the crops under assessment in this MRL application.

Sufficiently validated analytical methods are available to quantify residues in grapefruits, mandarins and broccoli according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (limit of quantification (LOQ)).

The available residue trials were sufficient to derive MRL proposals for grapefruits and broccoli. The MRL proposed for mandarins is not fully compliant with the EU guidance on extrapolation for pesticides and requires further risk management consideration.

Specific studies investigating the magnitude of teflubenzuron residues in processed broccoli were not required as significant residues are not expected in raw agricultural commodity. From two processing studies with oranges, tentative processing factors for juice and oil were derived. Due to the limited data set, they are not recommended to be included in Annex VI of Regulation (EC) No 396/2005.

Grapefruits and mandarins imported from Brazil may be industrially processed and their by-products potentially are used as feed items. Since the calculated livestock dietary burden did not exceeded the trigger value of 0.1 mg/kg dry matter (DM) for the relevant animal species, there was no need to reconsider the MRLs for commodities of animal origin.

The toxicological profile of teflubenzuron was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.1 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary. The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). EFSA concluded that the reported use of teflubenzuron on grapefruits, mandarins and broccoli will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers' health.

EFSA proposed to amend the existing MRLs as reported in the summary table below.

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Teflubenzuron[(F)]				
0110010	Grapefruits	0.01*	0.5	The submitted data were sufficient to derive an import tolerance (Brazil GAP) by extrapolation from proportionally scaled residue data on oranges. The MRL proposal corresponds to the MRL applicable in Brazil. Risk for consumers unlikely
0110050	Mandarins	0.01*	Further risk management consideration required	The EMS proposed a MRL of 0.5 mg/kg based on 11 residue trials on oranges and only 5 residue trials on lemons (merged data set) of proportionally scaled values to reflect the BR GAP. The extrapolation is not fully compliant with the EU extrapolation guideline. The MRL proposal corresponds to the MRL applicable in Brazil. Risk for consumers unlikely
0241010	Broccoli	0.01*	0.2 Further risk management consideration required	The submitted data are sufficient to derive an import tolerance (Paraguay GAP). Since no information on the authorisation of the use of teflubenzuron in broccoli in Paraguay and the legal limit applicable in the country of origin was provided, risk management considerations are required regarding the acceptability of the derived MRL proposal. Risk for consumers unlikely

MRL: maximum residue level; GAP: Good Agricultural Practice; EMS: evaluating Member State.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

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Assessment

The applicant requested a modification of the existing maximum residue level (MRL) for teflubenzuron in grapefruits, mandarins and broccoli. The detailed description of the uses of teflubenzuron in Brazil and Paraguay, which were the basis for the current MRL application, is reported in Appendix A. In Brazil, teflubenzuron is authorised for use on citrus fruits and a MRL of 0.5 mg/kg is established based on a preharvest interval (PHI) of 28 days. Evidence of the approval of the use of teflubenzuron in broccoli in Paraguay could not be provided as the crop is not clearly reported in the commercial label. Furthermore, due to the lack of a national authorisation system for pesticides comparable with the European Union (EU), no information on the MRL set for broccoli in Paraguay was reported (United Kingdom, 2018).

Teflubenzuron was evaluated in the framework of Directive 91/414/EEC[1] with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on apples and tomatoes. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by the European Food Safety Authority (EFSA, 2018). Teflubenzuron was approved[2] for the use as an insecticide on 1 December 2009.

The EU MRLs for teflubenzuron are established in Annexes II of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014) and the proposed modifications have been implemented in the MRL legislation.[4] Certain Codex maximum residue limits (CXLs) for teflubenzuron derived in 2017 following a periodic review of the active substance by JMPR have been recently taken over in the EU MRL legislation (Regulation (EU) 2018/687). It should be also highlighted that some of the previous CXLs taken over in the EU MRL legislation, have been revoked by Codex Alimentarius in 2017.

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF Agro BV submitted an application to the competent national authority in the United Kingdom (EMS) to set import tolerances for the active substance teflubenzuron in various crops. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 8 March 2018. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps for which further clarification were requested from the EMS. On 9 August 2018, the EMS submitted a revised evaluation report (United Kingdom, 2018), which replaced the previously submitted evaluation report.

It is noted that the original application received covered not only the setting of import tolerances for teflubenzuron in various crops, but also the assessment of confirmatory data (EFSA-Q-2018-00241). Since EFSA identified data gaps for the application on import tolerances, the assessment of confirmatory data has been performed in a separate reasoned opinion (EFSA, 2018).

EFSA based its assessment on the evaluation report submitted by the EMS (United Kingdom, 2018), the DAR and its addendum (United Kingdom, 2007, 2008) prepared under Directive 91/414/EEC, the Commission review report on teflubenzuron (European Commission, 2010b), the JMPR Evaluation report (FAO, 2016b), the conclusion on the peer review of the pesticide risk assessment of the active substance teflubenzuron (EFSA, 2018) as well as the conclusions from previous EFSA opinions (EFSA, 2012, 2014, 2018) and the scientific report (EFSA, 2017) on teflubenzuron.

For this application, the data requirements established in Regulation (EU) No 544/2011[5] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,c, 2015; OECD, 2011, 2013). The assessment was performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[6].

[1] 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.

[2] Commission Directive 2009/37/EC of 23 April 2009 amending Council Directive 91/414/EEC to include chlormequat, copper compounds, propaquizafop, quizalofop-P, teflubenzuron and zeta-cypermethrin as active substances. OJ L 104, 24.4.2009, p. 23–32.

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

[4] For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN

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

[6] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application, including the end points of relevant studies assessed previously, are presented in Appendix B.

The evaluation report submitted by the EMS (United Kingdom, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of teflubenzuron in primary crops was investigated on fruit, root and leafy crops after foliar application and also on root crops after soil application in the framework of the EU pesticides peer review (EFSA, 2018). The metabolism on pulses/oilseeds was assessed in the MRL review (EFSA, 2014). A new metabolism study on leafy crops with the active substance radiolabelled on both the aniline and the benzoyl ring was recently assessed as confirmatory data to the MRL review (EFSA, 2018). Unchanged parent compound was found to be the predominant compound of the total residues and a cleavage of the molecule was not observed. Details of the studies assessed are presented in Appendix A.

1.1.2. Nature of residues in rotational crops

Not relevant for permanent and/or imported crops.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of teflubenzuron residues was assessed in the framework of the EU pesticides peer review and previous EFSA opinions (EFSA, 2014, 2018). Taking into account that teflubenzuron was shown to be stable under realistic heating processing conditions and the results of the hydrolysis study even if carried out with non-radiolabelled material, EFSA confirmed the conclusion of the EU pesticides peer review that parent compound is expected to be stable following processing. Details of the study are presented in Appendix A.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of teflubenzuron residues in high water content commodities were assessed in the framework of the EU pesticides peer review and the MRL review (EFSA, 2014, 2018). The high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) (QuEChERS) multi-residue method described in the European Standard EN 15662:2008 is also applicable for the determination of teflubenzuron residues in high acid content matrices at the validated limit of quantification (LOQ) of 0.01 mg/kg (CEN, 2008).

EFSA concluded that sufficiently validated analytical methods are available to monitor teflubenzuron residues in the crops under consideration.

1.1.5. Stability of residues in plants

The storage stability of teflubenzuron in high water content commodities was assessed during the EU pesticides peer review (EFSA, 2018). New freezer storage stability data in oranges were provided in the framework of the current MRL application (United Kingdom, 2018). Low recovery rates were observed at 6 months, giving an indication that teflubenzuron may degrade in matrices with high acid content when stored in the freezer. However, in samples analysed after longer storage period (12, 18 and 24 months) the recovery was sufficiently high. Thus, overall it is concluded that teflubenzuron is expected to be stable in high acid content commodities for the 24-month period investigated in the study.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism and hydrolysis studies, EFSA concluded that the previously derived residue definition for enforcement and risk assessment (i.e. the parent 'teflubenzuron') is also appropriate for the crops under assessment.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, residue trials with lemons and oranges conducted in Brazil and with broccoli from Guatemala, Honduras and Costa Rica were submitted. According to the EMS, the samples obtained from the residue trials were analysed with a method that was sufficiently validated and were valid as per storage stability (United Kingdom, 2018).

Grapefruits

A total of 11 residue trials with oranges were submitted. According to the EU guidance, results from trials with oranges can be extrapolated to grapefruits (European Commission, 2015). All trials were compliant with the critical Brazilian use for grapefruits in terms of number of applications and preharvest interval (PHI), but were conducted at a higher application rate. Residue levels were proportionally scaled in order to estimate the MRL and the input values for the risk assessment reflecting the use under assessment.

Mandarins

A total of 11 residue trials on oranges and only 5 residue trials on lemons were submitted. All trials were compliant with the critical use on mandarins in Brazil, but conducted at a higher application rate and therefore the results were scaled in accordance with the OECD guidance document (OECD, 2016). Since mandarins are a major crop worldwide, at least eight Good Agricultural Practice (GAP)-compliant residue trials would be required. Instead of trials in mandarins, residue trials in lemons would be acceptable to derive a MRL proposal by extrapolation. Alternatively, a mixed data set of eight residue trials in oranges and/or grapefruits and eight residue trials on lemons and/or mandarins would be also acceptable (European Commission, 2015). Thus, to comply with the guidance document, three additional trials in lemons or mandarins are missing.

Overall, the number of residue trials (16) is in line with the guidance; the EMS proposed to derive a MRL for mandarins by extrapolation from the merged data set of proportionally scaled values (United Kingdom, 2018), considering that the orange and lemon data sets showed to belong to a similar population (U-test, 5%).

Broccoli

Four independent residue trials conducted according to the Paraguayan GAP allowed deriving a MRL proposal and the input values for the risk assessment.

1.2.2. Magnitude of residues in rotational crops

Not relevant for permanent and/or imported crops.

1.2.3. Magnitude of residues in processed commodities

Specific studies investigating the magnitude of teflubenzuron residues in processed broccoli were not provided and are not required as significant residues are not expected in raw agricultural commodity.

The results of two processing studies on oranges allowed deriving processing factors. In these studies, the teflubenzuron was applied with a higher application rate than defined in the GAP (2N dose) and the treated fruit were harvested at a PHI of 15 days, while in the critical GAP the PHI is defined as 28 days. The processing factors are tentative due to the limited data set. A reduction of teflubenzuron residues was observed in the juice and concentration in orange oil (see Appendix B.1.2.3).

Investigation on the distribution of teflubenzuron residues in peel and pulp from six residue trials (three on lemons and three on oranges), showed that residues were mainly located on the peel of the fruits.

1.2.4. Proposed MRLs

The data were sufficient to derive MRL proposals for grapefruits and for broccoli.

For mandarins, the extrapolation proposed by the United Kingdom is not fully compliant with the EU guidance for pesticides (European Commission, 2015). Using residues data generated mainly from

larger fruits, such as oranges, would very likely lead to an underestimation of the residues on mandarins. Nevertheless, the two data sets for orange and lemon residue levels showed to belong to a similar population (see Section 1.2.1). Therefore, EFSA derived a MRL proposal for further risk management consideration. The MRL proposed for grapefruits and mandarins are equal to the MRL set in the country of origin.

2. Residues in livestock

As dried citrus pulp can be used for feed purposes, the possible transfer of residues from feed to animal products had to be assessed. For that purpose, EFSA calculated the theoretical maximum dietary burden of livestock, taking into account residues expected in feed items that can contain teflubenzuron residues.

The intake of teflubenzuron residues via feed was calculated according to the OECD methodology (OECD, 2013) and the input value used is reported in Appendix D. These calculations demonstrated that dietary intake of livestock is not expected to exceed the trigger value of 0.1 mg/kg dry matter (DM) for dairy cattle and swine (see Appendix C). Hence, further investigations and the setting of MRLs in products of animal origin are not required.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016a).

The estimated exposure was then compared with the acceptable daily intake (ADI) of 0.01 mg/kg body weight (bw) per day derived for teflubenzuron. An acute reference dose (ARfD) was deemed unnecessary (European Commission, 2010b).

The most recent long-term exposure assessments performed by EFSA (2014, 2017) were updated with the median residue value (STMR) derived for grapefruits, mandarins and broccoli from the residue trials submitted. The input values used for the dietary exposure calculation are summarised in Appendix D.

No long-term intake concern was identified for any of the European diets incorporated in the EFSA PRIMo. The total chronic calculated intake accounted for less than 83% of the ADI, with maximum individual contribution of the residues on the crops under consideration accounting for less than 1 % of the ADI.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted were found to be sufficient to derive MRL proposals for grapefruits and broccoli. The MRL derived for mandarins is not fully compliant with the EU guidance on extrapolation for pesticides and the proposal requires further risk management consideration. EFSA concluded that the long-term intake of residues resulting from the use of teflubenzuron according to the reported agricultural practices is unlikely to present a risk to consumer health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight

CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
EMS	evaluating Member State
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
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
STMR	supervised trials median residue
WHO	World Health Organization

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages and season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min-max	Rate			
Grapefruits Mandarins	Brazil	F	*Diaphorina citri*	SC	75 g/L	Spray		2	Not specified	1.5–1.875	2,000	37.5	g/ha	15	Not assessed in the current application, since the GAP below was identified as the critical GAP
Grapefruits Mandarins	Brazil	F	*Ecdytolopha aurantiana*	SC	150 g/L	Spray		2	Not specified	3.75–4.5	2,000	75–90	g/ha	28	Critical GAP
Broccoli	Paraguay	F	*Plutella xylostella, Pieris brassicae*	SC	150 g/L	Spray		2	Not specified	3.75	400–1,000	37.5	g/ha	14	

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and 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**	**Comment/source**
	Fruit crops	Apple	Foliar, 3 × 20 g/hL	5, 6, 15, 21, 30 DALA	Radiolabelled a.s.: U-^{14}C-aniline ring. Total rate: 0.9 mL/fruit (EFSA, 2018)
	Root crops	Potato	Foliar, 4 × 90 g/ha	63 DALA	Radiolabelled a.s.: U-^{14}C-aniline ring (EFSA, 2018)
			Soil, 4 × 90 g/ha	63 DALA	
	Leafy crops	Spinach	Foliar, 1 × 60 g/ha	0, 8, 15 DAT	Radiolabelled a.s.: U-^{14}C-aniline ring (EFSA, 2018)
			Foliar, 1 × 100 g/ha	< 1, 15 (immature), 30 (mature DAT	Radiolabelled a.s.: U-^{14}C-aniline and benzoyl ring (EFSA, 2018)
	Pulses/oilseeds	Cotton	Foliar, 2 × 156 g/ha	Not reported	Before the applications, unlabelled a.s applied at 81 g/ha (EFSA, 2014)

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application (s)**	**PBI (DAT)**	**Comment/source**
	Root/tuber crops	Carrot	Indoor, 500 g/ha	30, 121/120, 360/365	Radiolabelled a.s.: ^{14}C-aniline and benzoyl ring. Low application rate and insufficient identification of residues (EFSA, 2018)
	Leafy crops	Lettuce	Indoor, 500 g/ha	30, 121/120, 360/365	
	Cereal (small grain)	Wheat	Indoor, 500 g/ha	30, 121/120, 360/365	

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes	Test substance not radiolabelled (EFSA, 2018)
	Baking, brewing, boiling (60 min, 100°C, pH 5)	Not tested	
	Sterilisation (20 min, 120°C, pH 6)	Yes	

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2018)
Rotational crop and primary crop metabolism similar?	Inconclusive	EFSA (2008)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2018)
Plant residue definition for monitoring (RD-Mo)	Teflubenzuron	
Plant residue definition for risk assessment (RD-RA)	Teflubenzuron	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content: HPLC–MS/MS (QuEChERS), LOQ 0.01 mg/kg (EFSA, 2014) Matrices with high h acid content: HPLC–MS/MS (QuEChERS), LOQ 0.01 mg/kg (CEN, 2008).	

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ source**
				Value	**Unit**		
	High water content	Apple, pear, potato, cabbage	−20	36	Months	Parent	EFSA (2018)
		Tomato	−18	18	Months	Parent	EFSA (2018)
	High acid content	Orange	−20	24	Months	Parent	United Kingdom (2018)

B.1.2. Magnitude of residues in plants

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

Commodity	Region/ indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Grapefruits	BR	2 × 0.02; 0.03; 0.04; 0.12; 0.14; 0.22; 0.23; 0.24; 0.25; 0.26 2 × 0.015; 0.023; 0.030; 0.090; 0.105; 0.165; 0.173; 0.180; 0.188; 0.195 (orange scaled)	Residue trials on oranges scaled down by a factor of 0.75 to match the reported BR GAP. Higher residue at a longer PHI of 35 days is underlined. MRL of 0.5 mg/kg (PHI 28 days) set in the exporting country. MRL_{OECD}: 0.41 (unrounded)	0.5	0.20	0.11	NA
Mandarins	BR	Lemons: 0.06; 0.09; 0.12; 2 × 0.36 0.045; 0.068; 0.090; 2 × 0.270 (scaled) Oranges: 2 × 0.02; 0.03; 0.04; 0.12; 0.14; 0.22; 0.23; 0.24; 0.25; 0.26 2 × 0.015; 0.023; 0.030; 0.090; 0.105; 0.165; 0.173; 0.180; 0.188; 0.195 (scaled)	Combined data set of residue trials on lemons (5) and oranges (11) scaled down by a factor of 0.75 to match the reported BR GAP. Higher residue at a longer PHI of 35 days is underlined. Extrapolation not fully compliant with EU guidanceMRL of 0.5 mg/kg (PHI 28 days) set in the exporting country. MRL_{OECD}:0.47 (unrounded)	(0.5) (tentative, risk management decision)	0.27	0.10	NA
Broccoli	PY	< 0.01; 0.04; 0.08; 0.08	Residue trials on broccoli compliant with the reported GAP. Higher residue at a longer PHI of 17 days is underlined. Evidence of registration in broccoli and related MRL in exporting country not available. MRL_{OECD}: 0.19 (unrounded)	0.2	0.08	0.06	NA

MRL: maximum residue level; GAP: Good Agricultural Practice; PHI: preharvest interval; OECD: Organisation for Economic Co-operation and Development.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. NA, not applicable.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	Application for permanent, imported crops
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	Application for permanent, imported crops

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/source
		Individual values	Median PF		
Orange, pulp	3	2 × < 0.04; < 0.08	< 0.04	NA	Tentative[c] (United Kingdom, 2018)
Lemon, pulp	3	< 0.03; < 0.08; 0.20	< 0.08	NA	Tentative[c] (United Kingdom, 2018)
Orange, peel	3	3.8; 4.0; 5.2	4.0	NA	Tentative[c] (United Kingdom, 2018)
Lemon, peel	3	4.1; 4.3; 8.0	4.3	NA	Tentative[c] (United Kingdom, 2018)
Orange, juice	2	< 0.03; < 0.05	< 0.04	NA	Tentative[c] (United Kingdom, 2018)
Orange, oil	2	91; 413	252	NA	Tentative[c] (United Kingdom, 2018
Orange, dried pulp	2	0.7; 1.4	1.1	NA	Tentative[c] (United Kingdom, 2018

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial. NA, not applicable.
(c): A tentative PF is derived based on a limited data set.

B.2. Residues in livestock

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[a]	Most critical commodity[b]	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Cattle (all)	0.001	0.001	0.027	0.027	Dairy cattle	Citrus, dried pulp	N
Cattle (dairy only)	0.001	0.001	0.027	0.027	Dairy cattle	Citrus, dried pulp	N
Sheep (all)	N/A						
Sheep (ewe only)	N/A						
Swine (all)	0.0005	0.0005	0.020	0.020	Swine, breeding	Citrus, dried pulp	N
Poultry (all)	N/A						
Poultry (layer only)	N/A						
Fish	N/A						

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.3. Consumer risk assessment

ARfD	Unnecessary (European Commission, 2010b)
ADI	0.01 mg/kg bw per day (European Commission, 2010b)
Highest IEDI, according to EFSA PRIMo revision 2	82.5% ADI (German child diet) Contribution of crops assessed: Grapefruits: 0.77% of ADI Mandarins: 0.74% of ADI Broccoli: 0.24% of ADI
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural grapefruits, mandarins and broccoli and used in the most recent EFSA consumers risk assessments (EFSA, 2014, 2017). For citrus and melons, residues refer to the whole fruit The contributions of commodities where no GAP and safe Codex MRL was reported in the framework of the MRL review were not included in the calculation

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; GAP: Good Agricultural Practice; MRL: maximum residue level.

B.4. Recommended MRLs

Code[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Teflubenzuron[F]				
0110010	Grapefruits	0.01*	0.5	The submitted data were sufficient to derive an import tolerance (Brazil GAP) by extrapolation form proportionally scaled residue data on oranges. The MRL proposal corresponds to the MRL applicable in Brazil. Risk for consumers unlikely
0110050	Mandarins	0.01*	Further risk management consideration required	The EMS proposed a MRL of 0.5 mg/kg based on 11 residue trials on oranges and only 5 residue trials on lemons (merged data set) of proportionally scaled values to reflect the BR GAP. The extrapolation is not fully compliant with the EU extrapolation guideline. The MRL proposal corresponds to the MRL applicable in Brazil. Risk for consumers unlikely
0241010	Broccoli	0.01*	0.2 Further risk management consideration required	The submitted data are sufficient to derive an import tolerance (Paraguay GAP). Since no information on the authorisation of the use of teflubenzuron in broccoli in Paraguay and the legal limit applicable in the country of origin was provided, risk management considerations are required regarding the acceptability of the derived MRL proposal. Risk for consumers unlikely

MRL: maximum residue level; GAP: Good Agricultural Practice; EMS: evaluating Member State.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

Appendix C – Pesticide Residue Intake Model (PRIMo)

Teflubenzuron			
Status of the active substance:	Approved	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.01	ARfD (mg/kg bw):	n.n.
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2010	Year of evaluation:	2010

MRLs according to Reg. (EU) 2018/687. Considering the outcome of confirmatory data,except the LOQ lowering of the MRL in animal products (EFSA,2018). New proposed MRLs on grapefruits,mandarins and broccoli

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum	maximum
8	82
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
82.5	DE child	57.9	Apples	7.1	Milk and cream	4.2	Oranges	
61.1	NL child	30.4	Apples	14.7	Milk and cream	3.4	Oranges	
44.2	FR toddler	19.8	Milk and cream	12.6	Apples	2.5	Potatoes	
33.9	UK Infant	19.4	Milk and cream	7.5	Apples	1.6	Potatoes	
32.0	FR infant	12.9	Milk and cream	12.0	Apples	2.1	Potatoes	
30.8	WHO Cluster diet B	10.0	Tomatoes	4.8	Apples	2.3	Peppers	
27.6	DK child	11.1	Apples	6.3	Milk and cream	3.3	Pears	
26.9	UK Toddler	10.3	Milk and cream	8.2	Apples	2.2	Oranges	
24.2	ES child	6.3	Milk and cream	5.5	Apples	3.2	Tomatoes	
23.0	SE general population 90th percentile	6.2	Milk and cream	5.0	Apples	2.5	Tomatoes	
20.2	IE adult	3.9	Apples	3.2	Pears	1.4	Milk and cream	
17.8	WHO regional European diet	3.6	Tomatoes	3.2	Apples	2.4	Milk and cream	
17.8	LT adult	9.0	Apples	2.0	Tomatoes	2.0	Milk and cream	
17.8	NL general	5.7	Apples	3.3	Milk and cream	1.6	Oranges	
17.5	PL general population	9.8	Apples	2.9	Tomatoes	1.7	Potatoes	
16.9	PT General population	5.0	Apples	2.9	Tomatoes	2.7	Potatoes	
16.3	WHO cluster diet E	4.1	Apples	1.9	Potatoes	1.7	Tomatoes	
15.8	WHO cluster diet D	3.3	Tomatoes	3.2	Apples	2.5	Milk and cream	
15.4	ES adult	3.7	Apples	2.5	Tomatoes	2.5	Milk and cream	
14.8	WHO Cluster diet F	3.2	Apples	2.2	Tomatoes	2.0	Milk and cream	
12.8	IT kids/toddler	4.6	Tomatoes	4.3	Apples	1.7	Pears	
12.7	DK adult	3.8	Apples	2.7	Milk and cream	1.3	Tomatoes	
12.4	FR all population	3.8	Wine grapes	2.3	Apples	1.4	Tomatoes	
10.8	IT adult	3.8	Apples	3.8	Tomatoes	1.1	Pears	
10.7	UK vegetarian	2.8	Apples	2.0	Tomatoes	1.6	Milk and cream	
9.3	FI adult	2.8	Milk and cream	1.9	Apples	1.4	Tomatoes	
8.4	UK Adult	2.0	Apples	1.5	Milk and cream	1.4	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI),based on pTMRLs were below the ADI.
A long-term intake of residues of Teflubenzuron is unlikely to present a public health concern.

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment[(a)]	Input value (mg/kg)	Comment
Citrus, dried pulp	0.12	STMR × PF (1.1)[(a)]	0.12	STMR × PF (1.1)[(a)]

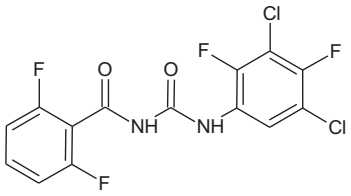
STMR: supervised trials median residue; PF: processing factor.
(a): For dried pulp the processing factor used was derived from a limited data set of two trials.

D.2. Consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Grapefruits	0.11	STMR (orange) whole fruit
Oranges, Lemons, Limes	0.11	STMR (FAO, 2016b) whole fruit
Mandarins	0.10	STMR (lemon + orange) whole fruit
Pome fruits	0.48	STMR (EFSA, 2014)
Table, Wine grapes	0.10	STMR (FAO, 2016b)
Papayas	0.16	STMR (FAO, 2016b)
Plums	0.04	STMR (EFSA, 2014)
Potatoes	0.05	STMR (EFSA, 2014)
Tomatoes	0.33	STMR (EFSA, 2014)
Peppers	0.46	STMR (EFSA, 2012)
Aubergines	0.33	STMR (EFSA, 2014)
Cucumbers	0.10	STMR (FAO, 2016b)
Gherkins	0.33	STMR (EFSA, 2014)
Courgettes	0.10	STMR (EFSA, 2014)
Melons	0.02	STMR (FAO, 2016b) whole fruit
Broccoli	0.06	STMR
Brussels sprouts	0.21	STMR (EFSA, 2014)
Head cabbages	0.20	MRL (CXL)
Sunflower seeds	0.01	STMR (FAO, 2016b)
Soya beans	0.01	STMR (FAO, 2016b)
Maize	0.01	STMR (FAO, 2016b)
Coffee beans	0.01	STMR (FAO, 2016b)
Sugar cane	0.01	STMR (FAO, 2016b)
Farm animal, muscle	0.05	MRL (EFSA, 2014)[(a)]
Farm animal, fat	0.05	MRL (EFSA, 2014)[(a)]
Farm animal, liver	0.05	MRL (EFSA, 2014)[(a)]
Farm animal, kidney	0.05	MRL (EFSA, 2014)[(a)]
Farm animal, edible offal	0.05	MRL (EFSA, 2014)[(a)]
Farm animal, other products	0.05	MRL (EFSA, 2014)[(a)]
Milks	0.05	MRL (EFSA, 2014)[(a)]
Bird's eggs	0.05	MRL (EFSA, 2014)[(a)]

STMR: supervised trials median residue; MRL: maximum residue level; CXL: Codex maximum residue limit.
(a): Farm animals: swine, bovine, sheep, goat, equine, poultry, other farm terrestrial animals. It is noted that in the framework of the assessment of the confirmatory data, EFSA has proposed to lower the existing MRLs in products of animal origin from the LOQ of 0.05 mg/kg to the LOQ of 0.01 mg/kg (EFSA, 2018).

Appendix E – Used compound codes

Code/trivial name	IUPAC name/SMILES notation/InChiKey[a]	Structural formula[b]
teflubenzuron	1-(3,5-dichloro-2,4-difluorophenyl)-3-(2,6-difluorobenzoyl)urea Clc2cc(NC(=O)NC(=O)c1c(F)cccc1F)c(F)c(Cl)c2F CJDWRQLODFKPEL-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(b): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).