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# Peer review of the pesticide risk assessment for the active substance buprofezin in light of confirmatory data submitted

European Food Safety Authority (EFSA)

## Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessment carried out by the competent authority of the rapporteur Member State the United Kingdom, for the pesticide active substance buprofezin are reported. The context of the peer review was that requested by the European Commission following the submission and evaluation of confirmatory residue data. The conclusions were reached on the basis of the evaluation of the representative uses of buprofezin as an insecticide on tomato, lettuce and citrus. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Concerns are identified.

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**Key words:** buprofezin, peer review, confirmatory data, risk assessment, pesticide, insecticide

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## Summary

Buprofezin was included in Annex I to Directive 91/414/EEC on 20 January 2011 by Commission Directive 2011/6/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies regards the processing and conversion factors for consumer risk assessment by 31 January 2013.

In accordance with the specific provision, the applicant, Nichino Europe Co, Ltd, submitted an updated dossier in January 2013, which was evaluated by the designated rapporteur Member State (RMS), the United Kingdom, in the form of an addendum to the assessment report. In compliance with Guidance Document SANCO 5634/2009 rev.4.5, the RMS distributed the Addendum to Member States, the applicant and EFSA for comments on 9 September 2014. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 8 January 2015. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table and finalised the Technical Report in February 2015.

Following consideration of the Technical Report, the European Commission requested EFSA to provide scientific and technical assistance on the unresolved issues of the Technical Report (taking into account the amended good agricultural practice (GAP) where data is not available to support the original GAPs) and to deliver its conclusions.

On the basis of the available data, it can be concluded that sufficient information was not provided to address the issues identified during the peer review of the active substance under Directive 91/414/EEC and related to the original GAPs supported in the draft assessment report (DAR).

Based on the amended GAPs proposed in the framework of the confirmatory data, a risk for the consumers resulting from the presence of residues of buprofezin on lettuce and tomatoes has not been identified. Considering the presence of aniline in processed commodities of tomato, based on a benchmark dose lower limit for a benchmark response of 10% (BMDL10), the estimated margin of exposure (MoE) is greater than the recommended 10,000 threshold value, indicating that the MoE may be of low concern for consumer safety. However, the MoE should not be interpreted without considering the additional authorised uses of buprofezin and the possible presence of aniline in their processed commodities, as well as further possible routes and sources of exposure to aniline (non-pesticide uses). Moreover, the potential exposure to aniline as a residue should be considered *a priori* as a concern since a threshold for a genotoxic carcinogen cannot be assumed.

On citrus fruits, insufficient data are available to complete the consumer risk assessment and a data gap has been identified.

It is stressed that the Scientific Committee (EFSA Scientific Committee, 2005) is of the opinion that 'substances which are both genotoxic and carcinogenic should not be approved for deliberate addition to foods or for use earlier in the food chain, if they leave residues which are both genotoxic and carcinogenic in food'.

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## Background

Buprofezin was included in Annex I to Directive 91/414/EEC on 20 January 2011 by Commission Directive 2011/6/EU<sup>1</sup>, and has been deemed to be approved under Regulation (EC) No 1107/2009<sup>2</sup>, in accordance with Commission Implementing Regulation (EU) No 540/2011<sup>3</sup>, as amended by Commission Implementing Regulation (EU) No 541/2011<sup>4</sup>. EFSA previously finalised a Conclusion on this active substance on 21 May 2010 (EFSA, 2010).

It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies regards the processing and conversion factors for consumer risk assessment by 31 January 2013.

In accordance with the specific provision, the applicant, Nichino Europe Co, Ltd, submitted an updated dossier in January 2013, which was evaluated by the designated rapporteur Member State (RMS), the United Kingdom, in the form of an addendum to the assessment report (United Kingdom, 2014). In compliance with Guidance Document SANCO 5634/2009 rev.4.5 (European Commission, 2011b), the RMS distributed the addendum to Member States, the applicant and EFSA for comments on 9 September 2014. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 8 January 2015. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table and finalised the Technical Report in February 2015 (EFSA, 2015a).

Following consideration of the Technical Report, the European Commission requested EFSA to provide scientific and technical assistance on the unresolved issues of the Technical Report (taking into account the amended GAP where data are not available to support the original GAP) and in particular to conclude on:

- Suitable conversion and processing factors for use in risk assessment, including those for aniline
- The risk to consumers from all the representative uses, based on the amended GAP where data is only available for these modified uses
- The use of the Margin of Exposure (MoE) approach to address the risk of exposure from exposure to aniline as a metabolite arising from processing of crops. While risk managers will discuss whether the use of this approach is appropriate for metabolites of active substances in plant protection products, EFSA is requested to examine if the approach was correctly implemented by the RMS in its assessment of the data submitted (given that the MoE approach was not peer reviewed by Member States as it was added to the addendum post-commenting)

A final consultation on the conclusion took place with Member States via a written procedure in July 2015.

The conclusions laid down in this report were reached on the basis of the RMS's evaluation of the confirmatory data submitted in relation to the processing and conversion factors for the consumer risk assessment. A key supporting document to this conclusion is the peer review report which (EFSA, 2015b) comprises the following document:

- the comments received on the draft EFSA conclusion.

Given the importance of the addendum to the assessment report (United Kingdom, 2014) and the peer review report, these documents are considered as background documents to this conclusion.

<sup>1</sup> Commission Directive 2011/6/EU of 20 January 2011 amending Council Directive 91/414/EEC to include buprofezin as active substance. OJ L 18, 21.1.2011, p. 38–40.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> 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.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

## The active substance and the formulated product

Buprofezin is the ISO common name for (*Z*)-2-*tert*-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one (IUPAC).

Buprofezin belongs to the class of chitin synthesis inhibitors.

The representative formulated product for the evaluation was 'Applaud 25 WP', a wettable powder formulation (WP), containing 250 g/kg buprofezin.

The evaluated representative uses are as an insecticide and acaricide on tomatoes, lettuce and citrus, as proposed by the applicant. Following the confirmatory data submission, the GAP has been modified for the uses on tomato and lettuce. The pre-harvest interval has been changed from 3 to 7 days for tomato grown under indoor conditions and the number of applications has been limited to one application on lettuce. These amendments have been evaluated by the RMS and are transparently presented in the addendum to the draft assessment report (United Kingdom, 2014). Although this is not in accordance with the Guidance Document SANCO 5634/2009 rev.4.5 (European Commission, 2011b), the European Commission requested EFSA to take into account the amended GAP where data are not available to support the original GAP. Full details of the representative uses considered under this assessment can be found in Appendix A to this report.

## Conclusions of the evaluation

Metabolism of buprofezin in primary crops was investigated in the fruit (lemon), leafy (lettuce) and oilseeds/pulses (cotton) crop groups. Based on the available data, the plant residue definitions were proposed as 'buprofezin' for monitoring and as 'sum of buprofezin and BF4 conjugates analysed as BF9 + BF12 under acidic conditions and expressed as buprofezin' for risk assessment (EFSA, 2010).

In the framework of the peer review under Directive 91/414/EEC, a sufficient number of residue trials were submitted to derive MRLs on citrus and tomatoes. However, samples were analysed using an analytical method not including a hydrolysis step in order to convert the metabolite BF4 to metabolites BF9 and BF12 and therefore, these studies were concluded to be inappropriate to derive conversion factors (CF) for risk assessment. Based on the metabolism study data, a default CF value of 1.5 derived from the metabolism studies was provisionally proposed, pending the submission of additional residue trials where samples are analysed according to a method suitable to quantify BF4 as BF9 and BF12 (EFSA, 2010).

Although analysed according to an appropriate analytical method, an MRL was not proposed for lettuce since the submitted trials were not conducted according to the supported GAPs. The submission of GAP compliant trials was therefore identified as a data gap.

Buprofezin was shown to significantly degrade to metabolites BF25 (up to 43 % applied radioactivity (AR)), BF12 (up to 31% AR) and to aniline (up to 19% AR) under standard hydrolysis conditions. Information was not provided on the possible residue levels of aniline in processed commodities. Since aniline is a potential human carcinogen (classified R40), the applicant was requested to provide studies addressing the transfer of aniline in processed commodities.

## Confirmatory residue trials, conversion factor for risk assessment

Samples from the additional trials on citrus and tomato submitted in the framework of the confirmatory data were all analysed for buprofezin, BF9 and BF12 using an analytical method including an acidic step (16 hours at 50 °C in dioxane:hydrochloric acid, 5:2 v/v) and concluded to be sufficiently validated for the determination of residues of buprofezin, BF9 and BF12 (United Kingdom, 2014).

- **Citrus:** Eight trials on oranges and eight trials on clementines conducted in Spain and Greece during the growing season 2009 and 2010 were submitted. The 2009 trials were disregarded since not covered by the storage stability studies in acidic matrices (storage data limited to a period of 12 months for buprofezin and of 6 months only for metabolites BF9 and BF12). The remaining 2010 trials were disregarded also by the RMS, since the ratio pulp/peel was not provided for the calculation of the total residues in the whole fruits, while analyses were conducted on the pulp and peel separately. However, EFSA is of the opinion that these trials can be considered for the purpose

of MRL setting, taking into account a default ratio peel/pulp of 30/70 for orange and of 27/73 for clementine, derived from the trials where this information was available.

As a result, only four trials on oranges and four trials on clementines are available to support the critical GAP on citrus fruits in SEU. Therefore, MRLs are not proposed for oranges, clementines or for the citrus group since in accordance with the requirements specified within SANCO 7525/VI/95 (European Commission, 2011a), a total of eight trials on oranges and eight trials on clementines are required to derive an MRL for the whole citrus fruit group.

Furthermore, the 2000 and 2001 trials on citrus submitted in the framework of the peer review and leading to a MRL proposal of 1 mg/kg (EFSA, 2010) cannot complete the residue dataset. These trials were based on a constant application rate of 25 g/hl with volumes of *ca.* 2000 to 2500 L water/ha, resulting in dose rates of *ca.* 500 to 650 g/ha. In contrast, the 2010 trials were all based on a constant dose rate of *ca.* 1000 g/ha and dose rates per volume in the range of 25 to 67 g/hl, leading to higher residues in fruits at harvest. These two different practices result in two significantly different datasets (U-Test, 5%) that cannot be merged together in order to derive a MRL proposal. In conclusion a data gap has been identified for additional trials on citrus or storage stability studies for buprofezin, BF9 and BF12 covering a storage period in high acid matrices of at least 16 months.

- **Tomatoes:** Sufficient information was not provided to cover the original indoor and northern Europe (NEU) GAPs reported in the DAR in the framework of the peer review under Directive 91/414/EEC. GAPs have been amended under the confirmatory data procedure as follows: the outdoor use in NEU is no longer supported and for the indoor use, the pre-harvest interval (PHI) has been increased from 3 to 7 days. New trials conducted in 2010 and 2011 according to the amended GAPs in southern Europe (SEU) (Spain, Italy) under outdoor conditions and in 2008 and 2009 under indoor conditions (Spain, Greece, France) were submitted. These trials were considered together with the 2001 and 2002 trials reported in the DAR and assessed in the framework of the peer review, since concluded to be valid with regard to the residue levels of buprofezin (EFSA, 2010). Based on the trials conducted under indoor conditions, an MRL of 0.6 mg/kg is proposed for tomato, covering the outdoor use of buprofezin in southern EU.

- **Lettuce:** The applicant has amended the original GAP proposed on lettuce in the framework of the peer review, the number of applications being decreased to a single application only. A sufficient number of residue trials conducted under indoor conditions in The Netherlands, Germany and Italy during the 2008 growing season were provided to propose an MRL value of 0.5 mg/kg.

Based on the residue trials submitted in the framework of the confirmatory data, conversion factors (CF) for risk assessment were calculated by EFSA at the different time points (see Table 1). For citrus, residues in whole fruits were calculated assuming a default ratio peel/pulp of 30/70 and 27/73 for orange and clementines respectively. Metabolites BF9 and BF12 were mainly detected in citrus peel only, at levels close to the LOQ (0.01 mg/kg) with maximum values of 0.05 and 0.04 mg/kg respectively. All values in citrus pulp were below the LOQ. In tomato and lettuce, these metabolites were detected in some rare situations.

**Table 1:** Conversion factor estimated at the different pre-harvest interval (PHI)

Crop	PHI (days) <sup>(b)</sup>							Total samples	BF9 ≥0.01	BF12 ≥0.01
	0 <sup>(a)</sup>	3	5	7	14	21	28			
Citrus (whole fruit)	1.05	1.03	1.06	1.05				28	9	11
Citrus (Peel)	1.02	1.01	1.02	1.02				28	9	11
Tomato (outdoor)	1.15	1.30	1.16	1.25				26	0	2 <sup>(d)</sup>
Tomato (Indoor, 1N)	1.13	1.16	1.11	1.27				32	0	0
Tomato (Indoor, 3N) <sup>(c)</sup>				1.05				8	0	0
Lettuce (Indoor)	1.00				1.01	1.03	1.14	32	2	2

(a): 0, sampling just after the last application

(b): PHI (days) supported in the amended GAPs are greyed

(c): Indoor overdosed trials (3x 750 g/ha, *ca.* 3N)

(d): BF12 detected above the limit of detection (LOD) in eight additional samples (0.005 to 0.009 mg/kg)

These calculated conversion factors should be considered as overestimations, since mostly derived from the default LOQ level of 0.01 mg/kg for metabolites BF9 and BF12 and increases of the CF values are related to a decrease of the buprofezin residue levels. Overall, and considering that the calculated PF that are close to a value of 1.1, are overestimations based on default LOQ level of 0.01 mg/kg, EFSA would not recommend the setting of conversion factors for risk assessment for citrus, tomato and lettuce.

### Processing studies

Under standard hydrolysis conditions simulating pasteurisation, boiling and sterilisation, buprofezin was significantly degraded to metabolites BF25 (up to 43% AR), BF12 (up to 31% AR), aniline (up to 19% AR) and to a lesser extent to metabolite BF11 (up to 4% TRR), this degradation being favoured by acidic conditions. For monitoring, buprofezin was concluded to be the relevant marker of the residues in processed commodities.

Processing studies on citrus and tomato were reported in the addendum to the DAR (United Kingdom, 2009) and processing factors (PF) were derived for buprofezin in various processed commodities. However, PF values were recalculated by EFSA considering the median value as recommended by the current guidance documents (OECD, 2008). A conversion factor (CF) for risk assessment in processed commodities was only proposed for tomato ketchup and tomato puree, where metabolite BF12 was observed in significant levels. CF values were not proposed for the other processed commodities since metabolites BF11, BF12 and BF25 were almost not observed in these fractions. In addition, for citrus and considering the default ratio peel/pulp of 30/70 and 27/73 for orange and clementine respectively, transfer factors of 0.07 to pulp and of 3.2 to peel were calculated.

Since aniline is expected to be formed in significant level under pasteurisation conditions (19% AR), processing studies investigating aniline residues were requested. Two processing studies on tomato were reported in the framework of these confirmatory data. Aniline was below the LOQ of 0.01 mg/kg in all tomato processed fractions (juice, puree, ketchup, paste and canned tomato). However, levels below the LOQ and above the limit of detection (LOD) were reported in the range of 0.0029 mg/kg to 0.0036 mg/kg for tomato puree, ketchup and paste. Considering the initial residue levels of 0.087 and 0.064 mg/kg in the raw tomato fruits (raw agricultural commodity (RAC)) before processing and the LOQ of 0.01 mg/kg, a transfer factor of 0.14 is proposed by EFSA to estimate the transfer of aniline from RAC to tomato processed commodities.

No information was provided on aniline for the processing of citrus. Since processed products from citrus might be subject to pasteurisation or sterilisation (juice, marmalade...) processing studies on citrus considering aniline residues are identified as a data gap. To derive reliable transfer factors, analyses for aniline should be conducted using an analytical method achieving a validated limit of quantification (LOQ) level significantly lower than 0.01 mg/kg.

### Consumer risk assessment

- **For buprofezin**, the consumer risk assessment was conducted using the EFSA PRIMo model, the median (supervised trials median residue (STMR)) and highest residue levels (HR) observed in the residue trials conducted on tomato and lettuce and the acceptable daily intake (ADI) of 0.01 mg/kg per day and the ARfD of 0.5 mg/kg derived in the conclusion of the peer review (EFSA, 2010). Since MRLs were not proposed for citrus, this crop group was not taken into account in the assessment. Risks were not identified for the consumers, the maximum chronic intake was calculated to be 5% of the ADI (WHO, cluster B) and the maximum acute intake 6% of the ARfD for tomato (BE, Child).

- **A specific consumer risk assessment was conducted for the metabolite aniline** suspected to be present in levels close to the LOQ in some processed commodities. Aniline is classified as Muta. 2, H341 'suspected of causing genetic defects' and Carc. 2, H351 'suspected of causing cancer' according to Annex VI of Regulation (EC) No. 1272/2008. A risk assessment of aniline was performed by the EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (CEF Panel) in 2007 when re-evaluating the food colour Red 2G (EFSA, 2007). This approach is in line with the EFSA Statement on the applicability of the Margin of Exposure approach for the safety assessment of impurities which are both genotoxic and carcinogenic in substances added to food/feed (EFSA, 2012). The CEF Panel calculated BMDL10 (benchmark dose causing a 10% increase in tumour incidence) values ranging from 29 to 35 mg/kg (body weight) bw per day. The

lower value was used by the RMS to calculate the margin of exposure (MoE) for aniline resulting from buprofezin applications, considering that a MoE exceeding 10 000 would be considered of low concern.

Aniline is generated during specific processing methods and occurs only in processed commodities following treatment of the crop with buprofezin. Since lettuce is usually not undergoing processing, a dietary risk assessment for aniline is not required. In contrast, citrus can undergo processing, but insufficient acceptable residue trials and processing studies to determine reliable levels of aniline in processed commodities are available to conduct a consumer risk assessment for citrus.

Finally, available data show that aniline can be detected in processed tomato commodities following treatment with buprofezin. Based on the highest buprofezin residue level of 0.41 mg/kg observed in the indoor residue trials and considering a preliminary transfer factor for aniline of 0.14, the residue level for aniline expected in tomato processed commodities is calculated to be 0.056 mg/kg. Consumption data for processed tomato commodities were taken from the EFSA PRIMo model. In addition, high percentile consumptions values (97.5th) for raw tomato fruits were considered for adults and children, to represent the consumption of processed tomato commodities. Consumption data covering different consumer populations and intake calculations are summarised in Table 2.

**Table 2:** Dietary risk assessment for aniline

Commodities	Person	Body weight (kg)	Tomato consumption		Aniline ( $\mu\text{g}/\text{kg}$ )	Estimated intake ( $\mu\text{g}/\text{kg}$ bw per day)	MoE (BMDL10 /Intake)
			(kg/person per day)	(kg/kg bw per day)			
Tomato Juice	DE Child	16.15	0.282	0.017	56	0.976	29 700
Tomato preserve	ES Adult	68.48	0.131	0.002	56	0.107	271 129
Raw tomato	BE Child	17.8	0.180	0.010	56	0.566	51 222
Raw tomato	LT Adult	70	0.450	0.006	56	0.360	80 538

ES: Spain; BE: Belgium; DE: Germany; LT: Latvia

From these calculations, and based on the use of buprofezin on tomato only, it appears that the identified carcinogenic risks for aniline may be of low concern as the estimated MoE exceed the threshold value of 10 000.

However, it should be highlighted that this assessment is incomplete since restricted to the uses of buprofezin on tomato and lettuce only. A sound risk assessment on aniline would require considering the additional authorised uses of buprofezin (e.g. citrus, pome fruits, stone fruits, grapes, strawberries...) and the possible presence of aniline in their processed commodities.

It is also noted that in line with the established standard approach for acute intake assessments of pesticides, which was primarily not designed for the assessment of genotoxic carcinogen compounds, the 97.5th percentile of food consumption is used, and that higher food intakes (e.g. 99th percentile) are realistically possible and would result in a lower MoE as currently calculated. Further, it has to be stressed again that the uncertainty surrounding the applied concentration levels of aniline - owed to the limited availability of processing studies with precise determination of aniline levels - needs to be taken into account when interpreting the results. Moreover, general variability in dietary exposure estimates is noted and has to be born in mind.

In addition, the impact of further routes and sources of exposure to aniline (non-pesticide uses) has not been considered.

Overall, on the basis of the data currently available, it can be concluded that sufficient information has not been provided in the framework of these confirmatory data to address the issues identified during the peer review of the active substance under Directive 91/414/EEC and related to the original GAPs proposed in the DAR (EFSA, 2010).

Based on the amended GAPs proposed in the framework of the confirmatory data, a risk for the consumers resulting from the presence of residues of buprofezin on lettuce and tomatoes has not been identified, considering the residue levels of buprofezin and its metabolites in the raw and

processed commodities. Based on the available information, the identified carcinogenic risks for aniline may be of low concern when considering the expected residue levels of aniline in processed commodities of tomato. In contrast, insufficient data are available to complete the consumer risk assessment for citrus. A data gap has been identified for additional residue trials or storage stability studies in high acid matrices and processing studies on citrus considering aniline residues.

In addition it should be highlighted that the impact of the changes in the GAPs to the assessments conducted in the other sections has not been investigated by EFSA. However, since these amendments consist in less critical GAPs (decrease from 2 to 1 application on lettuce, increase of the PHI on tomato and northern use on tomato no longer supported), the impact on the assessment conducted in the other sections might be considered negligible.

## Data gaps

This is a list of the data gaps identified during the focussed peer review process of confirmatory data. Data gaps identified in the previously finalised EFSA Conclusion on this active substance (EFSA, 2010) that were not part of the focussed peer review process of confirmatory data remain as unchanged.

- Additional residue trials on oranges and clementines or storage stability studies addressing the stability of buprofezin, metabolites BF9 and BF12 in high acid matrices for at least 16 months.
- Processing studies on citrus considering the metabolite aniline and using an analytical method achieving a validated LOQ significantly lower than 0.01 mg/kg.

## Concerns

### 1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011<sup>5</sup>, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

- The consumer risk assessment for the original GAPs supported in the course of the peer review of the active substance under Directive 91/414/EEC could not be finalised, including the representative use of buprofezin on citrus fruits.

### 2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

<sup>5</sup> 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 critical area of concern for the risk to consumers has not been identified for the amended GAPs on tomato and lettuce proposed in the framework of the confirmatory data.

### 3. Overview of the concerns identified for each representative use considered

**Table 3:** Overview of concerns: Potential exposure to aniline as a residue should be considered *a priori* as a concern since a threshold for a genotoxic carcinogen cannot be assumed.

Representative use		Tomato F (SEU)	Tomato G	Lettuce G	Citrus F (SEU)
Consumer risk	Risk identified				
	Assessment not finalised				X <sup>1</sup>

F: Outdoor or field use, G: greenhouse application; SEU: Southern Europe

(1) See items not finalised

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## Abbreviations

ADI	acceptable daily intake
AR	Applied Radioactivity
ARfD	acute reference dose
BMDL	benchmark dose level
bw	body weight
CF	Conversion Factor
DAT	days after treatment
DM	dry matter
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
IUPAC	International Union of Pure and Applied Chemistry
LOD	limit of detection
LOQ	limit of quantification (determination)
Mo	monitoring
MoE	margin of exposure
MRL	maximum residue level
NESTI	national estimated short-term intake
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PHI	pre-harvest interval
RA	Risk Assessment
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WP	wettable powder
WHO	World Health Organization

## Appendix A – List of end points for the active substance and the representative formulation

### Summary of representative uses evaluated

Crop (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks (amendment to GAPs supported under peer review procedure under 91/414/EEC)
					Type (d-f)	Conc. a.s. (i)	Method kind (f-h)	Growth stages & season (j)	Number max (k)	Inter-val (day)	g/hL min-max (l)	Water L/ha min-max	g/ha min-max (l)		
Tomato	SEU	Applaud 25 WP	F	Whitefly	WP	250 g/kg	High volume spraying	BBCH 89	2	3	20	1000	200	7	- NEU outdoor uses no longer supported - PHI for indoor use has been increased from 3 to 7 days
	NEU SEU	Applaud 25 WP	G	Whitefly	WP	250 g/kg	High volume spraying	BBCH 11-87	3	7	25	1250	250	7	
Lettuce	NEU SEU	Applaud 25 WP	G	Whitefly	WP	250 g/kg	High volume spraying	BBCH 49	1	7	25	1250	250	28	Number of applications reduced from 2 to 1
Citrus	SEU	Applaud 25 WP	F	Scale Whitefly	WP	250 g/kg	High volume spraying	BBCH 89	1		25	4000	1000	7	

BBCH: ; NEU ; SEU;

- (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. bentiavalicarb-isopropyl).
- (j) 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
- (k) Indicate the minimum and maximum number of applications possible under practical conditions of use
- (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)
- (m) PHI - minimum pre-harvest interval

## Residues in or on treated products food and feed

**Metabolism in plants** (Regulation (EU) N° 544/2011, Annex Part A, point 6.1 and 6.7, Regulation (EU) N° 545/2011, Annex Part A, point 8.1 and 8.6)

Primary crops (Plant groups covered)	Crop groups	Crop(s)	Application(s)	DAT (days)		
	Fruit crops	Lemon Tomato	Foliar; 1 & 2x 1000 g/ha study informative only	7, 14, 35, 70		
	Root crops	-				
	Leafy crops	Lettuce	Foliar; 2x 850 g/ha	70		
	Cereals/grass crops	-				
	Pulses/Oilseeds	Cotton	Foliar; 2x 850 g/ha	27		
	Miscellaneous					
Rotational crops (metabolic pattern)	Crop groups	Crop(s)	PBI (days)	Comments		
	Root/tuber crops	Radish				
	Leafy crops	Lettuce				
	Cereal (small grain)	Wheat				
Rotational and primary crop metabolism similar?	Yes: buprofezin, BF9 and BF12 identified in rotational crops in similar amounts					
Processed commodities (standard hydrolysis study, % of Applied radioactivity)	Conditions	Buprofezin	BF25	BF11	BF12	Aniline
	20 min, 90°C, pH 4	28.2	42.9	1.4	17.1	8.7
	60 min, 100°C, pH 5	30.5	17.8	0.3	31.1	18.9
	20 min, 120°C, pH 6	76.0	6.6	3.5	5.3	7.2
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No: Buprofezin degraded under standard hydrolysis conditions. Study revealed potentially harmful products (aniline), which are not present or at very low amounts in raw commodities (BF11 and BF25 less than 0.3% TRR in citrus).					
Plant residue definition for monitoring (RD-Mo)	Buprofezin					
Plant residue definition for risk assessment (RD-RA)	Sum buprofezin and BF4 conjugates analysed as BF9 + BF12 under acidic conditions and expressed as buprofezin					
Conversion factor (monitoring to risk assessment)	Default CF of 1.1 proposed for citrus, tomato and lettuce					

DAT: days after treatment; PBI: plant back interval; TRR: total radioactive residue; RD-Mo: Residue Definition for Monitoring; RD-RA: Residue Definition for Risk Assessment

**Metabolism in livestock** (Regulation (EU) N° 544/2011, Annex Part A, point 6.2 and 6.7, Regulation (EU) N° 545/2011, Annex Part A, point 8.1 and 8.6)

	Animal	Dose (mg/kg bw per day)	Duration (days)	N rate/comment
<b>Animals covered</b>	Laying hen	0.8	14	
	Dairy cow	0.38	7	
Time needed to reach a plateau concentration in milk and eggs (days)	Milk: 6 days Eggs: 14 days			
Animal residue definition for monitoring (RD-Mo)	Not proposed, since not considered necessary for the representatives uses			
Animal residue definition for risk assessment (RD-RA)	Not relevant			
Conversion factor (monitoring to risk assessment)	Not relevant			
Metabolism in rat and ruminant similar (Yes/No)	Yes			
Fat soluble residues (Yes/No)	No; Buprofezin log P <sub>ow</sub> = 4.8 but feeding studies reveal that residues are not fat seeking			

**Residues in succeeding crops** (Regulation (EU) N° 544/2011, Annex Part A, point 6.6, Regulation (EU) N°545/2011, Annex Part A, point 8.5)

<b>Confined rotational crop study</b> (Quantitative aspect)	A waiting period of 1 year is needed in glasshouse before sowing or planting of a rotational crop other than lettuce or tomatoes
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**Stability of residues** (Regulation (EU) N° 544/2011, Annex Part A, point 6(v) Regulation (EU) N° 545/2011, Annex Part A, point 8 Introduction)

Plant category	Commodity	T (°C)	Stability (Months)						
			Buprofezin	BF9	BF12	BF11	BF25	BF26	aniline
High water	Lettuce	-20	32	32	32	6	≤1	6	
	Tomato	-20	30	30	30	6		6	
	Apple, peach, courgette	-20	12	-	-				
High acid	Citrus	-20	12	6	6				
	kiwi	-20	12	-	-				
Other	Processed tomato	-20	6	6	6		≤1		
	<b>Apple puree, jelly</b>	-18							7
	Raisin, grape juice, wine	-18							7
	Olive oil, pomace, canned	118							9

**High water matrices:** Buprofezin, BF9 and BF12 stable at least 30 months

**High acid matrices:** Buprofezin stable at least 12 months and BF9, BF12 at least 6 months

Animal	Commodity	T (°C)	Stability (Months)			
			Buprofezin			
Beef	Fat	-10/-20	≤10			
Beef	Liver	-10/-20	12			
Beef	Milk	-10/-20	≤10			

Buprofezin stable no more than 10 months in beef fat and milk, stable at least 12 months in liver

**Residues from livestock feeding studies** (Regulation (EU) N° 544/2011, Annex Part A, point 6.4, Regulation (EU) N° 545/2011, Annex Part A, point 8.3)

	<b>Ruminant:</b>	<b>Poultry:</b>	<b>Pig:</b>
	Conditions of requirement of feeding studies		
Expected intakes by livestock $\geq 0.1$ mg/kg diet (dry weight basis) (yes/no)	not estimated <sup>(a)</sup>		
Potential for accumulation (yes/no):			
Metabolism studies indicate potential level of residues $\geq 0.01$ mg/kg in edible tissues (yes/no)			
	<b>Feeding studies (Dairy cow, ca. 5 mg/kg DM)</b> Maximum residue levels in matrices (mg/kg)		
Muscle	<0.05		
Fat	<0.05		
Liver	<0.05		
Kidney	<0.05		
Milk	<0.01		
Eggs			

DM: dry matter.

(a): Since MRL was not proposed for citrus, buprofezin residue intakes by livestock and resulting from the consumption of citrus pomace cannot be finalised. Since tomato and lettuce and their by-products are usually not fed to livestock, the setting of MRLs in products of animal origin is not necessary, considering these two uses.

**Summary of residues data from the supervised residue trials (Regulation (EU) N° 544/2011, Annex Part A, point 6.3, Regulation (EU) N° 545/2011, Annex Part A, point 8.2)**

Crop (Trial GAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials(b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
<b>Orange and clementine</b> (1x 1000 g/ha, PHI 7 days)	SEU	<b>Whole fruit</b> (Mo: buprofezin): Orange: 0.61, 0.62, 0.82, 1.12 clementine: 0.01, 0.04, 0.46, 0.80  <b>Pulp</b> (RA: buprofezin + BF9 + BF12): Orange: 2x 0.06, 0.15, 0.18 clementine: 2x 0.03, 2x 0.04	Residue level in whole fruit estimated assuming a default ratio peel/pulp of 30/70 and 27/73 in orange and mandarin respectively. All values for metabolites BF9 and BF12 in pulp <0.01 mg/kg <b>Additional trials required to derive MRLs for the citrus group</b>	no proposal		
<b>Tomato</b> (2x 200/271 g/ha, PHI 7 days)	SEU	<b>Mo</b> (2001/02): 0.01, 0.03, 0.05, 2x 0.08, 3x 0.09 <b>Mo</b> (2010/11): <u>2x 0.05</u> , <u>0.07</u> , 2x 0.08, 0.17, <u>0.32</u> , 0.35  RA (2010/11): 2x 0.07, 0.09, 2x 0.10, 0.19, 0.34, 0.37	2001/02 and 2010/11 considered together to derive an MRL proposal. Trials with dose rate slightly above +25% (257 to 271 g/ha) are underlined. MRL <sub>OECD</sub> : 0.49/0.5 BF9: 8x <0.01 and BF12: 5x <0.01, 3x 0.01	0.5	(0.35)	(0.08)
<b>Tomato</b> (3x 250 g/ha, PHI 7 days)	Indoor	<b>Mo</b> (2001/02): 0.04, 0.08, 0.12, 0.17, 0.23, 0.29, 0.35, 0.41 <b>Mo</b> (2010/11): 2x 0.04, 0.05, 2x 0.07, 2x 0.08, 0.15, 0.17, 0.18  RA (2010/11): 2x 0.06, 0.07, 2x 0.09, 2x 0.10, 0.17, 0.19, 0.20	2001/02 and 2010/11 considered together to derive an MRL proposal MRL <sub>OECD</sub> : 0.59/0.6 All values for BF9 and BF12 <0.01 mg/kg	0.6	(0.41)	(0.10)
<b>Lettuce</b> (1x 250 g/ha, PHI 28 days)	Indoor	<b>Mo</b> : <0.01, 0.03, 0.10, 0.13, 0.17, 0.21, 0.22, 0.26  RA: <0.03, 0.05, 0.12, 0.15, 0.19, 0.23, 0.24, 0.28	MRL <sub>OECD</sub> : 0.50/0.50 All values for BF9 and BF12 <0.01 mg/kg	0.5		

(a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.

(b): Residue levels in trials conducted according to GAP reported in ascending order (e.g. 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17).

When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Monitoring** and **Risk Assessment**.

(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR<sub>Mo</sub>).

(d): **STMR**: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMR<sub>Mo</sub>).

(e): HR = HR<sub>Mo</sub> x CF at 7 day PHI (0.41 x 1.27); STMR = STMR<sub>Mo</sub> x CF at 7 day PHI (0.10 x 1.27)

## Conversion Factors (CF) for monitoring to risk assessment

### Plant products

**Median Conversion Factors (CF) calculated at the different PHIs in the supervised residues trials<sup>(a)</sup>**

PHI <sup>(b)</sup> (days)	0+	3	5	7	14	21	28	Comments
Citrus (whole fruit)	1.05	1.03	1.06	1.05				
Citrus (Peel)	1.02	1.01	1.02	1.02				
Tomato (outdoor)	1.15	1.30	1.16	1.25				
Tomato (Indoor, 1N)	1.13	1.16	1.11	1.27				
Tomato (Indoor, 3N) <sup>(c)</sup>				1.05				
Lettuce (Indoor)	1.00				1.01	1.03	1.14	

Since BF9 and BF12 metabolites were almost not detected and considering that the calculated PFs close to a value of 1.1 are overestimations based on default LOQ level of 0.01 mg/kg, the setting of a CF value is not proposed for citrus, tomato and lettuce (CF = 1).

(a): CF calculated at the supported PHI are greyed

(b): 0, sampling just after the last application

**Processing factors** (Regulation (EU) N° 544/2011, Annex Part A, point 6.5, Regulation (EU) N° 545/2011, Annex Part A, point 8.4)

Crop (RAC)/Processed product	Number of studies	Processing Factor (PF)		Conversion Factor (CF <sub>p</sub> ) for RA <sup>(b)</sup>
		Individual values	Median PF	
Citrus/Citrus pulp	8 <sup>(a)</sup>	0.01 to 0.33	0.07	n.n.
Citrus/Citrus peel	8 <sup>(a)</sup>	1.1 to 3.7	3.2	n.n.
Orange/Juice (Pasteurised)	4 <sup>(b)</sup>	0.13, <u>0.24</u> , 0.31, <u>0.56</u> , <u>0.60</u> , 0.63, <u>0.92</u> , 1.30	0.58	n.n.
Orange/Marmalade (Sterilised)	4 <sup>(b)</sup>	0.44, 0.77, <u>0.88</u> , <u>0.99</u> , 1.10, 1.38, <u>2.08</u> , <u>2.59</u>	1.04	n.n.
Orange/Wet pomace	4 <sup>(b)</sup>	<u>1.01</u> , 1.06, 1.23, <u>1.54</u> , <u>1.81</u> , 1.90, 2.13, <u>3.17</u>	1.68	n.n.
Orange/Dry pomace	1	2.69, <u>5.13</u>	-	n.n.
Tomato/Juice (pasteurised)	4 <sup>(c)</sup>	0.18, 0.21, <u>0.22</u> , <u>0.22</u> , 0.31, 0.38, <u>0.42</u> , 0.75	0.27	n.n.
Tomato/Ketchup (sterilised)	4 <sup>(c)</sup>	0.45, 0.47, <u>0.52</u> , <u>0.67</u> , <u>0.67</u> ; <u>0.69</u> , 0.88, 1.25	0.67	2.1
Tomato/Puree (sterilised)	4 <sup>(c)</sup>	<u>0.50</u> , 0.71, 0.81, <u>0.89</u> , <u>0.91</u> , 0.95, 0.96, <u>1.00</u>	0.90	2.8
Tomato/Canned (sterilised)	4 <sup>(c)</sup>	0.03, <u>0.09</u> , <u>0.11</u> , 0.17, 0.19, <u>0.19</u> , <u>0.25</u> , 0.26	0.18	n.n.

n.n.: not necessary;

(a): Citrus; 8 residue trials, 28 samples. Sample analysed for buprofezin, BF-9 and BF-12

(b): Orange; 4 studies with samples collected in a 1N and 3N treated plots (CF from 3N plots are underlined). Samples analysed for buprofezin, BF-9, BF-12 and BF-25.

(c): Tomato; 4 studies with samples collected in a 1N and 3N treated plots (CF from 3N plots are underlined). Samples analysed for buprofezin, BF-11, BF-12 and BF-25.

(d): Metabolites BF-9, BF-11, BF-12 and BF-25 <LOQ or negligible contribution.

**Consumer risk assessment** (Regulation (EU) N° 544/2011, Annex Part A, point 6.9, Regulation (EU) N° 545/2011, Annex Part A, point 8.8).

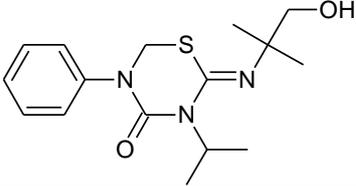
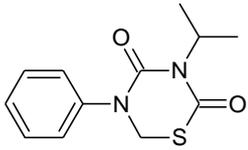
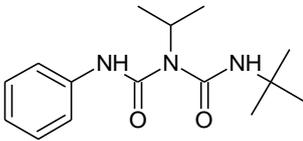
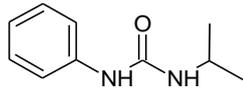
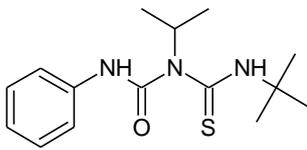
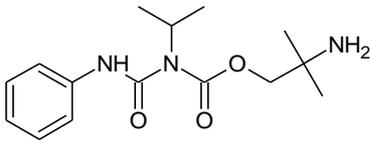
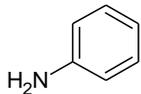
<b>ADI</b>	0.01 mg/kg bw per day
TMDI according to EFSA PRIMo model	Highest TMDI: 20 % ADI (WHO, Cluster B)
NTMDI, according to (to be specified)	
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI: 5 % ADI (WHO, Cluster B)
NEDI (% ADI), according to (to be specified)	
Factors included in the calculations	
<b>ARfD</b>	0.5 mg/kg bw
IESTI (% ARfD), according to EFSA PRIMo	Highest IESTI: 5 % ARfD for tomato (BE, Child)
NESTI (% ARfD), according to (to be specified)	
Factors included in IESTI and NESTI	

**Proposed MRLs** (Regulation (EU) N° 544/2011, Annex Part A, point 6.7, Regulation (EU) N° 545/2011, Annex Part A, point 8.6)

Code <sup>(a)</sup>	Commodity	MRL (mg/kg)	Comments
0110000	Citrus fruits	no proposal	additional trials requested
0231010	Tomatoes	0.6	Indoor and SEU uses
0251020	Lettuces	0.5	Indoor uses

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

## Appendix B – Used compound codes

Code/Trivial name	Chemical name/SMILES notation*	Structural formula
BF4	(2 <i>Z</i> )-2-[(1-hydroxy-2-methylpropan-2-yl)imino]-5-phenyl-3-(propan-2-yl)-1,3,5-thiadiazinan-4-one  <chem>CC(C)(CO)/N=C2\SCN(c1ccccc1)C(=O)N2C(C)C</chem>	
BF9	5-phenyl-3-(propan-2-yl)-1,3,5-thiadiazinane-2,4-dione  <chem>CC(C)N2C(=O)SCN(c1ccccc1)C2=O</chem>	
BF11	<i>N</i> - <i>tert</i> -butyl- <i>N</i> '-phenyl- <i>N</i> -propan-2-yl-dicarbonimidic diamide  <chem>CC(C)(C)N(C(C)C)C(=N)OC(=O)Nc1ccccc1</chem>	
BF12	1-phenyl-3-propan-2-ylurea  <chem>O=C(Nc1ccccc1)NC(C)C</chem>	
BF25	<i>N</i> - <i>tert</i> -butyl- <i>N</i> '-phenyl- <i>N</i> -propan-2-yl-dicarbonimidothioic diamide  <chem>S=C(Nc1ccccc1)OC(=N)N(C(C)C)C(C)(C)C</chem>	
BF26	2-amino-2-methylpropyl (phenylcarbamoyl)propan-2-ylcarbamate  <chem>O=C(Nc1ccccc1)N(C(=O)OCC(C)(C)N)C(C)C</chem>	
Aniline	Aniline  <chem>Nc1ccccc1</chem>	

\*ACD/ChemSketch, Advanced Chemistry Development, Inc. ACD/Labs Release: 12.00. Product version: 12.00 (Build 29305, 25 Nov 2008)