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

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Abstract

The applicant Dow AgroSciences submitted a request to the competent national authority in France to evaluate the confirmatory data that were identified for oryzalin in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the data gaps identified, residue trials on apples were submitted which are appropriate to conclude on the residue situation in kiwi fruits; furthermore, new residue trials on asparagus and on bananas were also provided. The information submitted to address the primary crop metabolism on asparagus was considered not sufficient to elucidate the nature of residues expected in asparagus. Thus, since the data gap for asparagus was not fully addressed, risk managers may consider the deletion of the existing MRL. For kiwi fruits and bananas, the previously derived MRLs do not have to be modified.

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

Requestor: European Commission

Question numbers: EFSA-Q-2018-00896

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Summary

In 2014, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for oryzalin according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) A representative study investigating primary crop metabolism to support the use on asparagus;
2) Four residue trials (e.g. on apples) to confirm a no-residue situation for the southern outdoor Good Agricultural Practice (GAP) on kiwi fruits (in view of MRL setting). (In addition, residue trials on apples and pears were identified as missing for supporting national authorisations. These data gaps are not subject of the current assessment);
3) Four residue trials on bananas supporting the southern outdoor GAP for bananas;
4) Further data on stability of residues to confirm the validity of the residue trials reported for asparagus.

The tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 2015/2075, including footnotes related to data gaps number 1, 2 (relevant only for kiwi fruits) and 4 indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 19 November 2017. Data gap number 3 was not implemented in the MRL regulation, because risk managers decided to set the MRL for bananas at the level of 0.01 mg/kg, corresponding to the specific limit of determination that can be achieved by routine analytical methods.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, Dow AgroSciences submitted an application to the competent national authority in France (evaluating Member State (EMS)) to evaluate the confirmatory data identified during the MRL review. The EMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 7 November 2018.

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

| Code(a) | Commodity | Existing MRL(b) mg/kg | Proposed MRL mg/kg | Conclusion/recommendation |
|---------|-----------|-----------------------|--------------------|--------------------------|
| 0162010 | Kiwi fruits | 0.01* (ft 1) | 0.01* | The data gap identified by EFSA concerning the confirmation of a no-residue situation for the SEU GAP has been addressed. The MRL is confirmed. The previous consumer risk assessment remains valid |
| 0270010 | Asparagus | 0.05* (ft 2) | 0.01* Further risk management consideration required. | The requested information on storage stability has been provided. However, information on primary metabolism in leafy crops is unavailable. Since the data gap is not fully addressed, risk managers may consider the deletion of the existing MRL, replacing it with the LOQ of 0.01* mg/kg; analytical methods are available to enforce the proposed MRL |
| 0163020 | Bananas | 0.01* | 0.01* | Although no confirmatory data were requested for bananas, the applicant provided residue trials representative for the SEU GAP reported in the framework of the MRL review. The trials confirm the previously derived MRL for bananas |

SEU: southern Europe; GAP: Good Agricultural Practice; MRL: maximum residue level; LOQ: limit of quantification.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
*: Indicate lower limit of determination.
(F): Fat-soluble.
ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 19 November 2017, or, if that information is not submitted by that date, the lack of it (footnote related to data gap No 2).
ft 2: The European Food Safety Authority identified some information on storage stability and crop metabolism as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 19 November 2017, or, if that information is not submitted by that date, the lack of it (footnote related to data gap Nos 1 and 4).
Table of contents

Abstract................................................................................................................................................... 1
Summary.................................................................................................................................................. 3
Assessment............................................................................................................................................... 5
  1. Residues in plants ........................................................................................................................ 5
    1.1. Nature of residues and methods of analysis in plants .............................................................. 5
    1.1.1. Nature of residues in primary crops ......................................................................................... 5
    1.1.2. Nature of residues in rotational crops ..................................................................................... 6
    1.1.3. Nature of residues in processed commodities ......................................................................... 6
    1.1.4. Methods of analysis in plants .................................................................................................. 6
    1.1.5. Stability of residues in plants .................................................................................................. 6
    1.1.6. Proposed residue definitions .................................................................................................. 7
    1.2. Magnitude of residues in plants .................................................................................................. 7
    1.2.1. Kiwi fruits .............................................................................................................................. 7
    1.2.2. Asparagus .............................................................................................................................. 7
    1.2.3. Bananas ............................................................................................................................ 7
  2. Residues in livestock ....................................................................................................................... 8
    2.1. Nature of residues ...................................................................................................................... 8
    2.2. Methods of analysis in livestock ................................................................................................ 8
    2.3. Magnitude of residues in livestock ............................................................................................ 8
  3. Consumer risk assessment ................................................................................................................ 8
  4. Conclusion and Recommendations .................................................................................................. 8
References.............................................................................................................................................. 9
Abbreviations .......................................................................................................................................... 9
Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data .................................. 10
Appendix B – List of end points ............................................................................................................ 12
Appendix C – Pesticide Residue Intake Model (PRIMo) ........................................................................ 17
Appendix D – Input values for the exposure calculations ..................................................................... 19
Appendix E – Used compound codes .................................................................................................. 20
Assessment

The review of existing maximum residue levels (MRLs) for the active substance oryzalin according to Article 12 of Regulation (EC) No 396/20051 (MRL review) has been performed in 2014 (EFSA, 2014). The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified. The list of Good Agricultural Practices (GAPs) assessed in the framework of the MRL review that were not fully supported by data and for which confirmatory data were requested are listed in Appendix A.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 2015/20752, including footnotes for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 19 November 2017.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2016) the applicant, Dow AgroSciences, submitted an application to the competent national authority in France (designated evaluating Member State (EMS)) to evaluate the confirmatory data identified during the MRL review. To address the data gaps identified by EFSA, the applicant provided adjusted GAPs for kiwi fruits and asparagus in accordance with the agreed procedure set out in the working document SANTE/10235/2016; in addition, four new residue trials on apples were provided to confirm the no-residue situation for kiwi fruits and four new residue trials on asparagus which are supported by storage stability data. No new studies on primary crop metabolism representative for asparagus were submitted; instead, the applicant referred to metabolism studies in primary and rotational crops which were already assessed previously.

The EMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 7 November 2018 (France, 2018). EFSA assessed the application as requested by the European Commission in accordance with Article 9 of Regulation (EC) No 396/2005.

Although in Regulation (EU) No 2015/2075 no confirmatory data were requested for bananas, the applicant provided residue trials on bananas representative for the GAP reported in Appendix A. Since these studies were assessed by the EMS and the information may be of interest for national competent authorities, EFSA included the assessment of the residue trials in this reasoned opinion.

EFSA based its assessment on the evaluation report submitted by the EMS (France, 2018) and the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005.

For this application, the data requirements established in Regulation (EU) No 544/20113 and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 2015/2075 are applicable. The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/20114.

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

The evaluation report submitted by the EMS (France, 2018) is considered a supporting document to this reasoned opinion and, thus, is made publicly available as a background document to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

To address data gap number 1,5 the applicant did not provide new metabolism studies representative for leafy crop but provided the following argumentation (France, 2018):

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1 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.
2 Commission Regulation (EU) 2015/2075 of 18 November 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, desmedipham, dichlorprop-P, haloxypil-P, oryzalin and phenmedipham in or on certain products. OJ L 302, 19.11.2015, p. 15–50.
3 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
4 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
5 A representative study investigating primary crop metabolism to support the use on asparagus.
The overall primary crop metabolism studies (pre-emergence application on sunflower and soybean) and rotational crop metabolism studies (wheat, cabbage, maize, soybean, sugar beet, tomato) indicate that radioactive residues can be translocated from the soil to the primary crops or to the succeeding crops at various levels (from 0.004 up to 0.58 mg TRR/kg in primary crops and from < 0.005 mg TRR/kg up to 0.272 mg TRR/kg in succeeding crops). The radioactivity found in the different crops was characterised as consisting of polar compounds; parent oryzalin was not detected in rotational crops planted 17 to 57 weeks after treatment (soybean, wheat, cabbage sugar beet, tomatoes) or in primary crops (soybean, sunflower) following a pre-emergence application or soil application before planting.

A more detailed description of the metabolism studies that combined investigation of residues in primary and rotational crops is reported in Section 1.1.2. Overall, EFSA is of the opinion that the metabolism studies in plants give an indication that in primary and rotational crops the uptake of parent oryzalin is low. No further attempts to identify the degradation products or metabolites derived from oryzalin were reported. The available metabolism studies on soybean and sunflower assessed during the peer review were found to have some deficiencies as the characterisation and identification of residues was not carried out (it was not possible in sunflower due to low residues) (EFSA, 2010, 2014).

Thus, the available studies were not appropriate to identify the nature of residues expected in asparagus. Therefore, EFSA concludes that the data gap requesting metabolism studies that would allow to elucidate the nature of residues in asparagus is not sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Crops under consideration are not expected to be grown in rotation. Further investigation of residues in rotational is therefore not required.

In the context of the peer review of the active substance, two rotational crop studies were reported (France, 2009). The applicant suggested to use these studies to address the data gap identified for asparagus.

In the first study, soybeans were planted into soil treated with 14C-oryzalin at a rate of 1.68 kg/ha. Immature soybean plants were harvested after 17 weeks. The immature soybean plants were subjected to a solvent extraction procedure, and the post-extraction solids extracted further by acid and base digestion. The level of uptake of residues from the soil into immature soybeans was low, with a TRR of 0.049 mg/kg in immature plants 6 weeks after application, and 0.038 mg/kg in plants 10 weeks after application. At maturity, the TRRs were 0.016 mg/kg in seed, 0.022 mg/kg in pods and 0.066 mg/kg in stems. Characterisation of the residue in the primary soybean crop showed that about 66% of the TRR was organosoluble in immature soybean plants, 23% TRR was organosoluble in mature seed and 29% was organosoluble from mature stems. No residues of oryzalin or its major degradation products were detected in the soybean samples.

In the second study, soybeans were planted into soil treated with phenyl-UL-14C oryzalin at a rate of 1.7 or 3.4 kg/ha. Soybeans were harvested 17 weeks after treatment. Wheat was seeded as a first rotation crop after harvest of the soybeans and was collected at maturity the following year. The level of radioactivity in soil decreased during the 5 weeks following the treatment (from 99% to 59% of the theoretical radioactivity applied). Parent oryzalin and its major degradation products were not found in rotational crops (wheat, cabbage, soya bean, maize, sugar beet and tomato). It was assumed that residues were likely to consist of several metabolites which were not further characterised or identified (France, 2009; EFSA, 2014).

1.1.3. Nature of residues in processed commodities

Not relevant for the current assessment.

1.1.4. Methods of analysis in plants

Not relevant for the current assessment.

1.1.5. Stability of residues in plants

The potential degradation of residues during storage of the samples was assessed during the peer review (France, 2007; EFSA, 2010). Storage stability of oryzalin was demonstrated at −20°C for a
period of 11 months in matrices with high acid content (grapes) and for 10 months in high water content matrices (apples).

Overall, the available storage stability data are sufficient to confirm that the new submitted trials on apples and asparagus are valid with regard to storage stability.

EFSA concluded that the data gap identified in the framework of the MRL review on storage stability in asparagus was sufficiently addressed.

1.1.6. Proposed residue definitions

In the framework of the MRL review, the residue definition for enforcement and risk assessment for the fruiting crop group was derived as parent oryzalin only. This residue definition is still applicable and limited to fruits and fruiting vegetable, lacking the metabolism studies representative for other crop groups. The data gap on the nature of residues in asparagus was not sufficiently addressed.

1.2. Magnitude of residues in plants

1.2.1. Kiwi fruits

In order to address data gap number 2, the applicant provided four residue trials on apples. The trials were performed in Spain, Italy, Greece and southern France (S-France) (southern Europe (SEU)) with one application of 2,406–2,554 g/ha (within 25% tolerance with both GAP reported in this submission of 2,145 g/ha and previous GAP reported under MRL review of 2 × 1,920 g/ha). In the apples harvested 128–155 days after the treatment, residue levels were below the limit of quantification (LOQ). The apple samples were stored under frozen conditions before analysis for a period for which stability of residues has been demonstrated (147 days). The analytical methods used to analyse the samples were sufficiently validated and fit for purpose.

The data confirms the existing MRL for kiwi fruits, which is set at the LOQ of 0.01*mg/kg. EFSA concluded that the data gap (number 2) identified in the framework of the MRL review was addressed.

1.2.2. Asparagus

In order to address data gap number 4, the applicant provided four new residue trials performed in Germany and N-France (northern Europe (NEU)) and Spain and Italy (SEU). The trials were conducted with one application of 1,022–1,144 g/ha, which is within the acceptable deviation of 25% of the application rate compared with the GAP (adjusted GAP: 1 × 1073 g/ha). Prior to analysis, the asparagus samples were stored under frozen conditions for 155 days. Thus, the trials are valid with respect to storage stability of the residues. The analytical methods used for analysis were sufficiently validated and fit for purpose; the LOQ of the analytical method was 0.01 mg/kg.

Considering that asparagus is a minor crop in NEU and SEU, four residue trials compliant with the NEU and SEU GAP are normally required. Considering that the trials give an indication of a no-residue situation, two NEU and two SEU trials might be sufficient. However, EFSA did not derive an MRL proposal, since the nature of residues in asparagus has not been addressed.

EFSA concluded that the data gap number 4 identified in the framework of the MRL review was addressed.

1.2.3. Bananas

Although the data gap number 3 has not been taken over in the MRL legislation (Regulation (EU) No 2015/2075) and therefore formally no confirmatory data were requested, the applicant submitted five residue trials on bananas supporting a SEU use reported in Appendix A (1 × 1,931 g/ha, BBCH 00–15, preharvest interval (PHI) is defined by the application stage at last treatment).

Since the EMS assessed the data, EFSA decided to report the study assessment in this reasoned opinion, considering that the data may be of relevance for Member States intending to grant uses of oryzalin in bananas.

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6 Four residue trials on apples to confirm a no-residue situation for the southern outdoor GAP on kiwi fruits (in view of MRL setting), and on apples and pears (mainly in view of national authorisations).

7 Further data on stability of residues to confirm the validity of the residue trials reported for asparagus.

8 Four residue trials on banana supporting the SEU GAP for banana.
One residue trial was conducted in Martinique (S-France) with one application of 2,145 g/ha with PHI 206 days (thus, within the acceptable deviation of ±25% of the application rate defined in the current GAP). Four SEU trials (Martinique, S-France) were conducted at a more critical GAP (3 × 1,920 g/ha, PHI 92 days). As the residue were below the LOQ, the more critical GAP tested in the residue trials is acceptable.

It is noted that in the new residue trials submitted for bananas, samples were stored for up to 11 months prior to oryzalin analysis. Thus, the banana samples were stored for a slightly longer period than the period tested for storage stability demonstrated in apples (approximately 10 months). However, this deviation is considered as minor deficiency.

The trials are considered as acceptable and provide sufficient evidence that the residues in the treated crop are not expected at concentrations greater than the limit of quantification (< 0.01 mg/kg).

2. Residues in livestock

   Not relevant for the current assessment.

   2.1. Nature of residues

      Not relevant for the current assessment.

   2.2. Methods of analysis in livestock

      Not relevant for the current assessment.

   2.3. Magnitude of residues in livestock

      Not relevant for the current assessment.

3. Consumer risk assessment

   EFSA updated the previous risk assessment conducted under MRL review, taking into account that the use in asparagus is not sufficiently supported by data.

   The calculated exposures were compared with the toxicological reference value derived for oryzalin. The highest chronic exposure was calculated for German children, representing 0.3% of the acceptable daily intake (ADI).

   Based on the above calculations, EFSA concludes that for the use of oryzalin on crops fully supported by data, the risk is acceptable with regard to consumer exposure.

4. Conclusion and Recommendations

   The following data gaps identified in the framework of the MRL review (EFSA, 2014) have been sufficiently addressed:
   - Residue trials representative for the use of oryzalin in kiwi fruits;
   - Residue trials on asparagus which were stored for a period for which integrity of the samples was demonstrated.

   A representative study investigating primary crop metabolism to support the use on asparagus has not been provided (data gap number 1).

   Overall, EFSA concluded that the data requirements 2 and 4 were addressed, while the information provided was not sufficient to address data gap number 1. Therefore, EFSA proposes to risk managers the deletion of the existing MRL for asparagus, replacing it with the LOQ of 0.01 mg/kg; analytical methods are available to enforce the proposed lower MRL.

   Additional residue trials on bananas were also submitted and assessed by EMS which confirm the existing MRL.

   The overview of the assessment of confirmatory data and the recommended MRL modifications 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
CF conversion factor for enforcement to risk assessment residue definition
DAR draft assessment report
DAT days after treatment
EMS evaluating Member State
GAP Good Agricultural Practice
GC-ECD gas chromatography with electron capture detector
HPLC-MS/MS high performance liquid chromatography with tandem mass spectrometry
HPLC-UV high performance liquid chromatography with ultraviolet detection
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
InChIKey International Chemical Identifier Key
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LC liquid chromatography
LOQ limit of quantification
MRL maximum residue level
MS Member States
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PHI preharvest interval
RA risk assessment
RD residue definition
SC suspension concentrate
SEU southern Europe
SMILES simplified molecular-input line-entry system
STMR supervised trials median residue
TRR total radioactive residue
WHO World Health Organization
### Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data (original GAPs and adjusted GAPs reported by EMS)

| Crop and/or situation | NEU, SEU, MS or country | F, G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|-------------|-----------------------------------|-------------|-----------|-----------------------------|--------------|---------|
|                       |                         |             |                                   | Type(b)     | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min–max | Interval (min) | g a.s./hL min–max | Water L/ha min–max | Rate Unit |               |                     |               |
| **Kiwi fruits**       | SEU                     | F           | Weeds                             | SC          | 480 g/L   | Soil treatment | BBCH 0–75                       | 1–2          | n.a.              | 1,920–3,840 | g/ha      | n.a     | GAP assessed under MRL review (EFSA, 2014) |
|                       | SEU                     | F           | Grasses and broadleaf weeds       | SC          | 429 g/L   | Soil treatment | BBCH 00–14                      | 1           | –                 | 100–200    | 2,145 g/ha | n.a     | adjusted GAP Banded application. Application rate refers to the rate of use in the treated band (30% of the total crop area) |
| **Asparagus**         | NEU, SEU                | F           | Weeds                             | SC          | 480 g/L   | Soil treatment | BBCH 00–30                      | 1–2         | n.a.              | 1,920–3,840 | g/ha      | n.a     | GAP assessed under MRL review (EFSA, 2014) |
|                       | NEU                     | SEU         | Gr axes and broadleaf weeds       | SC          | 429 g/L   | Soil treatment | BBCH 00 pre-emergence or post-harvest Spring/Summer | 1           | –                 | 100–400    | 1,073 g/ha | n.a     | adjusted GAP Banded application for pre-emergence use. Application rate refers to the rate of use in the treated band (75% of the total crop area). Not supported by the data. PHI is defined by the application stage at last treatment |
| Crop and/or situation | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------------------|------------------------------------|-------------|-------------|-------------------------------|------------|---------|
|                       | F, G or I<sup>(a)</sup> |                                    | Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min–max | Interval (min) | g a.s./ hL min–max | Water L/ha min–max | Rate | Unit | |
| Bananas               | SEU F                    | Weeds                              | Soil treatment | 480 g/L   | 1               | 1                       | 960           | 90 | GAP assessed under MRL review (not supported by residue data) (EFSA, 2014) |
|                       | SEU F                    | Annual grasses and broadleaf weeds | Soil treatment | 429 g/L   | BBCH 00–15      | 1                       | 100–400       | 1931 | g/ha | n.a. | Modified GAP |

GAP: Good Agricultural Practice; EMS: evaluating Member State; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; MRL: maximum residue level; SC: suspension concentrate.

<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 formulation types and international coding system.
<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 |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       | Grapes      | Soil, 10.1 kg a.s./ha | 120 485 | Radiolabelled active substance: phenyl-UL-14C-a.s. (EFSA, 2010) |
| Pulses and oilseeds               | Soybeans    | Soil, 1.68 kg a.s./ha | 42 70 119 | Soybeans planted after soil treatment in rotational crop study. Radiolabelled active substance: phenyl-UL-14C-a.s. (France, 2009; EFSA, 2010) |
| Pulses and oilseeds               | Soybeans    | Soil, 1.7 or 3.4 kg a.s./ha | 84 112 | Soybeans planted as a primary crop immediately following soil treatment in rotational crop study. Radiolabelled active substance: phenyl-UL-14C-a.s. (France 2009; EFSA, 2010) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Fruit crops                         | Tomatoes    | Soil, 1.68 kg a.s./ha | 55 weeks 63 weeks | Radiolabelled active substance: phenyl-UL-14C-a.s. (France, 2009; EFSA, 2010) |
| Pulses and oilseeds                 | Soybeans    | Soil, 1.68 kg a.s./ha | 55 weeks 71 weeks | Radiolabelled active substance: phenyl-UL-14C-a.s. (France, 2009; EFSA, 2010) |
| Cereals/grass                       | Wheat       | Soil, 1.68 kg a.s./ha | 49 weeks 55 weeks | Radiolabelled active substance: phenyl-UL-14C-a.s. (France, 2009; EFSA, 2010) |
| Cereals/grass                       | Maize       | Soil, 1.68 kg a.s./ha | 54 weeks 68 weeks | Radiolabelled active substance: phenyl-UL-14C-a.s. (France, 2009; EFSA, 2010) |
| Root and tuber crops                | Sugar beets | Soil, 1.68 kg a.s./ha | 60 weeks 73 weeks | Radiolabelled active substance: phenyl-UL-14C-a.s. (France, 2009; EFSA, 2010) |
| Leafy crops                        | Cabbage     | Soil, 1.68 kg a.s./ha | 59 weeks 67 weeks | Radiolabelled active substance: phenyl-UL-14C-a.s. (France, 2009; EFSA, 2010) |
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period Value | Stability period Unit | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|------------------------|-----------------------|-------------------|----------------|
|                                    | High water content | Apples    | -20    | 315                    | Days                  | Parent            | EFSA (2010)    |
|                                    |          | Pears     | -20    | 64                     | Days                  | Parent            | France (2007)  |
|                                    | High acid content  | Grapes    | -20    | 330                    | Days                  | Parent            | EFSA (2010)    |
|                                    |          | Blueberries | -20  | 95                     | Days                  | Parent            | France (2007)  |
|                                    |          | Raspberries | -20  | 60                     | Days                  | Parent            | France (2007)  |
### 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\(^{(d)}\) |
|------------|-------------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|------------------------|--------------|
| Kiwi fruits | SEU                     | Apples: 4 × < 0.01; Peaches: 3 × < 0.01; Plums: 2 × < 0.01     | Residue trials on apples, peaches and plums compliant (25% tolerance) with the adjusted GAP. Extrapolation from stone fruits to kiwi fruits is possible since residues are below LOQ                                              | 0.01*                  | 0.01                 | 0.01                   | –            |
| Asparagus  | NEU                     | 2 × < 0.01                                                   | Residue trials compliant with the adjusted GAP (Appendix A); due to data gap regarding a representative metabolism study, no MRL proposal was derived                                                 |                        | 0.01                 | 0.01                   | –            |
|            | SEU                     | 2 × < 0.01                                                   |                                                                                                                                  |                        |                      |                        |              |
| Bananas    | SEU                     | 5 × < 0.01                                                   | Four residue trials conducted at a more critical GAP (3 × 1,920 g/ha, PHI 92 days) than the modified GAP reported by the EMS (1 × 1931 g/ha; see Appendix A). Data are acceptable as they demonstrate a no residue situation | 0.01*                  | 0.01                 | 0.01                   | –            |

MRL: maximum residue level; GAP: Good Agricultural Practice; LOQ: limit of quantification; PHI: preharvest interval; EMS: evaluating Member State.

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

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

\(^{(b)}\): Highest residue. 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.
### B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Not triggered | EFSA (2014) |
|---|---|---|
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered | EFSA (2014) |

### B.1.2.3. Processing factors

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

### B.2. Residues in livestock

Not relevant.

### B.3. Not relevant. Consumer risk assessment

| ARfD | Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance (EFSA, 2010) |
|---|---|
| Highest IESTI, according to EFSA PRIMo | - |
| Assumptions made for the calculations | - |

| ADI | 0.05 mg/kg bw per day (EFSA, 2010) |
|---|---|
| Highest IEDI, according to EFSA PRIMo | 0.3% ADI (DE child) |
| Contribution of crops assessed: | Kiwi fruits: < 0.01% of ADI |
| Banana: 0.04% of ADI |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for raw agricultural commodities for which uses were reported. |
| | The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation. |
| | Asparagus was not included in the calculation, since the data were not sufficient to derive a definitive MRL proposal. |

ARfD: acute reference dose; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; GAP: Good Agricultural Practice; MRL: maximum residue level.
## B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity | Existing MRL<sup>(b)</sup> mg/kg | Proposed MRL mg/kg | Conclusion/recommendation |
|-------------------|-----------|---------------------------------|-------------------|--------------------------|
| 0162010           | Kiwi fruits | 0.01* (0)                       | 0.01*             | The data gap identified by EFSA concerning the confirmation of a no-residue situation for the SEU GAP has been addressed. The MRL is confirmed. The previous consumer risk assessment remains valid. |
| 0270010           | Asparagus  | 0.05* (ft 2)                    | 0.01*             | The requested information on storage stability has been provided. However, information on primary metabolism in leafy crops is unavailable. Since the data gap is not fully addressed, risk managers may consider the deletion of the existing MRL, replacing it with the LOQ of 0.01* mg/kg; analytical methods are available to enforce the proposed MRL. |
| 0163020           | Bananas   | 0.01*                           | 0.01*             | Although no confirmatory data were requested for bananas, the applicant provided residue trials representative for the SEU GAP reported in the framework of the MRL review. The trials confirm the previously derived MRL for bananas. |

**Enforcement residue definition**: oryzalin (F)

---

SEU: southern Europe; GAP: Good Agricultural Practice; MRL: maximum residue level; LOQ: limit of quantification.

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

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

*: Indicate lower limit of determination.

(F): Fat-soluble.

ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 19 November 2017, or, if that information is not submitted by that date, the lack of it (footnote related to data gap No 2).

ft 2: The European Food Safety Authority identified some information on storage stability and crop metabolism as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 19 November 2017, or, if that information is not submitted by that date, the lack of it (footnote related to data gap Nos 1 and 4).
### Oryzalin

**Status of the active substance:** Approved  
**CODE no.:** Proposed LOQ  
**LOQ (mg/kg bw):** n.n.

#### Toxicological end points

| ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Source of ADI | Source of ARfD | Year of evaluation |
|------------------------|----------------|---------------|----------------|-------------------|
| 0.05                   | n.n.           | EFSA          | EFSA           | 2010              |

**No of diets exceeding ADI:** ---

#### Chronic risk assessment – refined calculations

| MS Diet | Commodity/group of commodities | TMDI (range) in % of ADI | 2nd contributor | Commodity/group of commodities | 3rd contributor | Commodity/group of commodities | pTMRLs at LOQ (in % of ADI) |
|---------|--------------------------------|-------------------------|----------------|--------------------------------|----------------|--------------------------------|----------------------------|
| DE child| 0.2 Apples                      | 0.0 Table grapes        | 0.0 Bananas    | 0.0 Pears               | 0.0 Pears    | 0.0 Table grapes        | 0.0 Table grapes        |
| NL child| 0.1 Apples                      | 0.0 Table grapes        | 0.0 Bananas    | 0.0 Pears               | 0.0 Pears    | 0.0 Table grapes        | 0.0 Table grapes        |
| FR all population | 0.0 Wine grapes | 0.0 Apples | 0.0 Apples | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas |
| IE adult | 0.1 Wine grapes     | 0.0 Apples | 0.0 Apples | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas |
| PT General population | 0.0 Wine grapes | 0.0 Apples | 0.0 Apples | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas |
| WHO Cluster diet B | 0.0 Wine grapes | 0.0 Apples | 0.0 Apples | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas |
| DK child | 0.0 Apples                      | 0.0 Table grapes        | 0.0 Bananas    | 0.0 Pears               | 0.0 Pears    | 0.0 Table grapes        | 0.0 Table grapes        |
| FR toddler | 0.1 Apples                  | 0.0 Bananas | 0.0 Bananas  | 0.0 Pears               | 0.0 Pears    | 0.0 Bananas | 0.0 Bananas |
| FR infant | 0.1 Apples                     | 0.0 Bananas | 0.0 Bananas  | 0.0 Pears               | 0.0 Pears    | 0.0 Bananas | 0.0 Bananas |
| WHO cluster diet E | 0.0 Wine grapes | 0.0 Apples | 0.0 Apples | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas |
| UK infant | 0.0 Apples                      | 0.0 Bananas | 0.0 Bananas  | 0.0 Pears               | 0.0 Pears    | 0.0 Bananas | 0.0 Bananas |
| UK general population 90th percentile | 0.0 Apples | 0.0 Table grapes | 0.0 Bananas | 0.0 Pears | 0.0 Pears | 0.0 Table grapes | 0.0 Table grapes |
| UK Toddler | 0.0 Apples                      | 0.0 Bananas | 0.0 Bananas  | 0.0 Pears               | 0.0 Pears    | 0.0 Bananas | 0.0 Bananas |
| NL general | 0.0 Wine grapes      | 0.0 Apples | 0.0 Apples | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas |
| IT child/toddler | 0.0 Apples                  | 0.0 Bananas | 0.0 Bananas  | 0.0 Pears               | 0.0 Pears    | 0.0 Bananas | 0.0 Bananas |
| ES adult | 0.0 Wine grapes                | 0.0 Apples | 0.0 Apples | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas |
| IT adult | 0.0 Apples                      | 0.0 Bananas | 0.0 Bananas  | 0.0 Pears               | 0.0 Pears    | 0.0 Bananas | 0.0 Bananas |
| UK vegetarian | 0.0 Wine grapes | 0.0 Apples | 0.0 Apples | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas |
| UK adult | 0.0 Wine grapes                | 0.0 Apples | 0.0 Apples | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas |
| WHO regional European diet | 0.0 Wine grapes | 0.0 Apples | 0.0 Apples | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas | 0.0 Bananas |
| WHO cluster diet D | 0.0 Apples                      | 0.0 Bananas | 0.0 Bananas  | 0.0 Pears               | 0.0 Pears    | 0.0 Bananas | 0.0 Bananas |
| FI adult | 0.0 Apples                      | 0.0 Bananas | 0.0 Bananas  | 0.0 Pears               | 0.0 Pears    | 0.0 Bananas | 0.0 Bananas |

**Conclusion:**  
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Oryzalin is unlikely to present a public health concern.
Acute risk assessment is not necessary. For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation. In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002) for lettuce, a variability factor of 3 was used. In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3. Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

### Acute risk assessment/children – refined calculations

| Highest % of ARfD/ADI | Commodity | pTMRL/threshold MRL (mg/kg) |
|-----------------------|-----------|-----------------------------|
| IESTI 1 | *) | ***) |
| IESTI 2 | **) |

### Acute risk assessment/adults/general population – refined calculations

| Highest % of ARfD/ADI | Commodity | pTMRL/threshold MRL (mg/kg) |
|-----------------------|-----------|-----------------------------|
| IESTI 1 | *) | ***) |
| IESTI 2 | **) |

### No of critical MRLs (IESTI 1)

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

### No of critical MRLs (IESTI 2)

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

### Processed commodities

| No of commodities for which ARfD/ADI is exceeded: | --- |
|------------------------------------------------|------|

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

### Conclusion:

As no ARfD was considered necessary, it is concluded that the short-term intake of Oryzalin residues is unlikely to present a public health concern.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations
Not relevant for the current assessment.

D.2. Consumer risk assessment

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment              |
| Kiwi fruits                | 0.01                    | STMR                  |                      |                      |
| Bananas                    | 0.01                    | STMR                  |                      |                      |
| Apples and pears           | 0.01                    | STMR (EFSA 2014)      |                      |                      |
| Stone fruits               | 0.01                    | STMR (EFSA 2014)      |                      |                      |
| Table and wine grapes      | 0.01                    | STMR (EFSA 2014)      |                      | Not relevant         |

STMR: supervised trials median residue.
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|--------------------------------|-------------------------------------------------|---------------------------------|
| Oryzalin                       | 3,5-dinitro-4,4-dipropylsulfanilamide            | ![Structural formula image](image) |

O-S(N(=O)c1 cc(c(c(c1)[N+][O-]) = O)N(CCC)CCC)[N+] ([O-]) = O

UNAHYJYOSSJHH-UHFFFAOYSA-N

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

<sup>(a)</sup> ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

<sup>(b)</sup> ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).