Evaluation of confirmatory data following the Article 12 MRL review for chlorothalonil, including assessments for import tolerances for banana, papaya and peanuts

European Food Safety Authority (EFSA), Maria Anastassiadou, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira, Luna Greco, Samira Jarrah, Alja Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Alejandro Rojas, Angela Sacchi, Miguel Santos, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract

The applicants Syngenta Crop Protection, UPL Europe Ltd. and Oxon Italia S.p.A. submitted requests to the competent national authority in the Netherlands to evaluate the confirmatory data for chlorothalonil that were identified in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 as not available; in addition, Syngenta and UPL submitted requests for modifications of existing MRLs. Considering the recent decision on the non-approval of chlorothalonil, the requests for amending existing MRLs to reflect intended EU uses for chlorothalonil and confirmatory data for EU uses became obsolete. EFSA focused therefore its assessment on the import tolerances and on general information on the analytical method required to enforce legal limits for chlorothalonil and its metabolite SDS-3701 (R182281). Analytical methods for enforcement are available to control the residues of chlorothalonil and SDS-3701 in plant matrices at the validated LOQ of 0.01 mg/kg; data on the extraction efficiency for high oil content matrices as requested in the MRL review were not provided. This data gap is relevant for the import tolerance for peanuts. The data submitted in support of import tolerances were found to be sufficient to derive MRL proposals for chlorothalonil and SDS-3701 for bagged bananas, papayas and peanuts. Studies investigating the effect of high temperature processing on the magnitude of SDS-3701 in processed products are not available. Based on exposure calculations for chlorothalonil, EFSA concluded that the long-term intake of residues resulting from the use of chlorothalonil according to the reported agricultural practices is unlikely to present a risk to consumers. For papaya, an acute intake concern was noted for chlorothalonil, while for banana and peanuts, the expected short-term intake of chlorothalonil residues was below the toxicological reference value. For the metabolite SDS-3701, the toxicological profile is not fully elucidated, and therefore, toxicological reference values could not be derived. Hence, for this metabolite, the consumer risk assessment cannot be finalised.

© 2020 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: chlorothalonil, import tolerance, banana, papaya and peanuts, pesticide, MRL, consumer risk assessment

Requestor: European Commission

Question numbers: EFSA-Q-2018-00332 and EFSA-Q-2018-00333

Correspondence: pesticides.mrl@efsa.europa.eu
Acknowledgements: EFSA wishes to thank the following for the support provided to this scientific output: Chris Anagnostopoulos, Laszlo Bura, Viktoria Krivova, Silvia Ruocco and Viktor Toth.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Theobald A, Vagenende B and Verani A, 2020. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for chlorothalonil, including assessments for import tolerances for banana, papaya and peanuts. EFSA Journal 2020;18(9):6239, 48 pp. https://doi.org/10.2903/j.efsa.2020.6239

ISSN: 1831-4732

© 2020 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Summary

In 2012, when the European Food Safety Authority (EFSA) reviewed the existing Maximum Residue Levels (MRLs) for chlorothalonil 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 which are considered relevant for the current assessment:

a) for the finalisation of the risk assessment of SDS-3701:
   1) A validated method for enforcement of metabolite SDS-3701 in plant commodities, including processed fractions;
   2) A complete set of residue trials compliant with available guidance documents and allowing for the estimation of SDS-3701 levels in all crops supported in the framework of this review;
   3) Storage stability studies demonstrating the stability of SDS-3701 in plant commodities, including processed fractions;
   4) Further information on the magnitude of SDS-3701 in processed commodities that have been subject to high temperatures;
   5) A study investigating metabolism of chlorothalonil and metabolite SDS-3701 in pigs;
   6) Further characterisation of the total radioactive residue (TRR) in poultry commodities (if the dietary burden increases in the future).

b) for the parent chlorothalonil:
   7) An analytical method, its ILV and a confirmatory method fully validated for the determination of parent chlorothalonil in hops;
   8) A storage stability study for parent chlorothalonil in high acid content commodities;
   9) Eight residue trials on apples and pears (with a minimum of four trials on apples) complying with the southern outdoor good agricultural practices (GAPs) for apples, quinces, medlars and loquats;
10) Four residue trials on apricots and four residue trials on peaches complying with the southern outdoor GAP;
11) Four residue trials on turnips complying with the southern outdoor GAP;
12) Eight residue trials on head cabbage complying with the northern outdoor GAP;
13) Eight residue trials on leek complying with the northern outdoor GAP;
14) Four additional trials on fresh peas (without pods) complying with the southern outdoor GAP;
15) Four residue trials on hops complying with the northern outdoor GAP.

Tentative MRL proposals for chlorothalonil have been implemented in the MRL legislation by Commission Regulation (EU) No 1146/2014, including footnotes related to data gaps number 1–15 referred to above, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 29 October 2016. Considering the data gaps identified, MRL proposals for the metabolite SDS-3701 could not be derived, and consequently, no specific MRLs for SDS-3701 have been implemented in Regulation (EC) No 396/2005.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, the applicants Syngenta Crop Protection, UPL Europe Ltd. (formerly Arysta LifeScience SAS) and Oxon Italia S.p.A (members of Chlorothalonil Task Force) submitted applications to the competent national authority in the Netherlands (rapporteur Member State, RMS) providing confirmatory data identified during the MRL review for a wide range of crops. In addition, applications for modifications of some of the existing MRLs were submitted reflecting intended modifications of the EU use patterns by Syngenta Crop Protection and UPL Europe Ltd. (formerly Arysta LifeScience SAS).

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 26 April 2018.

When assessing the evaluation report, EFSA identified points which needed further clarifications. On 16 January 2020, the EMS submitted a revised evaluation report which addressed the points for clarification.

It is noted that on 29 April 2019, a decision on the non-renewal of the approval of chlorothalonil under Regulation (EC) No 1107/2009 was taken, because of concerns – amongst other concerns – regarding the dietary consumer risk assessment. The toxicological profile of certain metabolites/
degradation products (i.e. SDS-3701 (R182281), R613636 and R417888) was not fully elucidated and, consequently, definitive residue definitions for risk assessment in plant and animal commodities could not be derived by EFSA in previous assessments. Hence, a comprehensive risks assessment cannot be performed.

Following the decision on the non-renewal of the approval, the EU uses of plant protection products containing chlorothalonil had to be withdrawn by 20 November 2019 (period of grace according to Article 46 of Regulation (EC) No 1107/2009: 20 May 2020). Considering the new situation for EU authorisations, data gaps identified in the MRL review related to the EU uses became obsolete (i.e. data gaps 7 and 9 to 15 and eventually data gaps 2 and 4 to 6).

The submitted applications of Syngenta Crop Protection and UPL Europe Ltd. (formerly Arysta LifeScience SAS) for new EU uses of chlorothalonil also became obsolete.

In the current assessment, EFSA therefore focused on the import tolerance requests and the generic data gap on analytical method, storage stability and the data gap on the magnitude of SDS-3701 in processed commodities that have been subject to high temperatures, which are also relevant for the import tolerance requests. In addition, EFSA re-evaluated whether metabolism studies in pigs and data to characterise the TRR in poultry commodities are still required, considering the import tolerances for crops that are used as feed items. It should be highlighted that the current assessment was not an assessment of data gaps identified in the renewal process.

Based on the data available, the following conclusions were derived:

Analytical methods for enforcement are available to control the residues of chlorothalonil and SDS-3701 in plant matrices at or above the LOQ of 0.01 mg/kg; however, further data on the extraction efficiency for SDS-3701 are still required for high oil content matrices. Hence, data gap number 1 was partially addressed; for peanuts, the enforcement method for the determination of SDS-3701 is not fully compliant with the data requirements.

Studies investigating the storage stability of chlorothalonil and SDS-3701 in high acid content commodities were assessed in the framework of the renewal of chlorothalonil. The data gaps number 3 and 8 were sufficiently addressed.

The following provisional residue definitions for enforcement and risk assessment were previously derived for plant commodities (MRL review):

Residue definition 1: chlorothalonil;
Residue definition 2: R182281 (SDS-3701);

In Regulation (EC) No 396/2005, currently the residue definition for plant commodities is only parent chlorothalonil. Since no data on the residue levels expected for SDS-3701 were available at the time of the MRL review, residue definition 2 has not been implemented in the EU MRL legislation.

The current EU residue definitions may need to be revised, taking into account the considerations of the renewal process.

To address data gap number 2, residue data were provided for bananas, papayas and peanuts. EFSA concluded that the available residue trials in bagged bananas are sufficient to derive MRL proposals of 0.02* mg/kg for chlorothalonil and 0.01* mg/kg for SDS-3701 for the reported Latin American GAPs. It is noted that EFSA received authorised labels for banana in Latin American countries; however, the conditions of use did not match with the GAP assessed in this reasoned Opinion.

The available trials are sufficient to derive MRL proposals of 15 mg/kg for chlorothalonil and 0.02 mg/kg for SDS-3701 on papaya in support of the authorised Brazilian GAP. The available trials are sufficient to derive MRL proposals of 0.01* mg/kg for chlorothalonil and SDS-3701 on peanuts in support of the authorised US GAP.

Processing studies to investigate the impact of high temperature treatment on the magnitude of residues parent chlorothalonil and the possible formation of the degradation products identified in standard hydrolysis studies (i.e. R182281 and R613636) are not available.

The dietary burden calculation was updated in the current assessment. The only remaining use relevant for feed is the use in peanuts. Overall, the expected intake of chlorothalonil by livestock was below the trigger value for all animal species. Hence, the existing MRLs for animal products are no longer required and risk managers may consider lowering them to the LOQ.

Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the use of chlorothalonil according to the reported agricultural practices is unlikely to present a risk to consumer health for parent chlorothalonil. For papaya, an acute intake concern was
identified (433% of the acute reference dose (ARfD)). For banana and peanuts, no acute consumer risk for chlorothalonil was derived.

Since toxicological reference values for SDS-3701 are not available, the consumer risk assessment for this metabolite could not be finalised.

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<sup>(a)</sup> | Commodity                  | Existing MRL Chlorothalonil<sup>(b)</sup> | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation                                                                                                                                 |
|----------------|---------------------------|------------------------------------------|-----------------------------|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0130000        | Pome fruit                | 2 (ft1)                                  | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised SEU GAP. Uses in third countries have not been reported. Codex MRL (CXL) is not in place for pome fruits. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL for chlorothalonil to the LOQ should be considered. |
| 0140010 0140030| Apricots Peaches          | 1 (ft 1)                                  | 0.01*                       | 0.01*                 | The existing MRL is based on the previously authorised SEU GAP. Uses in third countries have not been reported. CXL: 1.5 mg/kg (set by Codex Alimentarius Commission (CAC) in 2016, EU reservation because a separate residue definition for SDS-3701 is considered necessary<sup>(c)</sup>; Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0151000        | Table and wine grapes     | 3 (ft 2)                                  | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised NEU GAPs. Uses in third countries have not been reported. CXLs for grapes (3 mg/kg chlorothalonil), strawberries (5 mg/kg chlorothalonil) and gooseberries (20 mg/kg chlorothalonil) were already in place when the MRL review was performed. Data on SDS-3701 demonstrated that significant residues of the metabolite cannot be excluded for grapes (HR: 0.15 mg/kg); in strawberries and gooseberries, residues of SDS-3701 were not analysed<sup>(c)</sup>. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0152000        | Strawberries              | 4 (ft 2)                                  | 0.01*                       | 0.01*                 |                                                                                                                                                           |
| 0154040        | Gooseberries              | 15 (ft 2)                                 | 0.01*                       | 0.01*                 |                                                                                                                                                           |
| 0163020        | Bananas                   | 0.15 (ft 3)                               | 0.02* Further risk management considerations required | 0.01*                 | Label information for Latin American countries was provided for Mexico and Brazil, which did not match with the use pattern of the residue trials submitted in support of the application. Based on the submitted trials in bagged bananas, a tentative MRL proposal was derived. For unbagged bananas, the number of trials was insufficient. Further risk management considerations are required whether setting of an MRL at the level of the highest LOQ of the available residue trials in bagged bananas is appropriate. Chlorothalonil MRLs in Latin American countries: 15 mg/kg in Costa Rica, 3 mg/kg in Brazil, 0.2 mg/kg pulp in Argentina and 0.01 mg/kg in Chile. CXL: 15 mg/kg (set by CAC in 2013, EU reservation because of concerns on metabolite SDS-3701)<sup>(c)</sup>. |

**Existing enforcement residue definition for plants and animals:** Chlorothalonil

**Additional residue definitions for enforcement for plants:** R182281 (SDS-3701) (proposed in the MRL review, not yet implemented)
| Code(a) | Commodity | Existing MRL Chlorothalonil(b) | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation |
|--------|-----------|-------------------------------|-----------------------------|----------------------|--------------------------|
| 0163040 | Papaya    | 15 (ft 3)                     | 0.01*                       | 0.01*                | Residue data on chlorothalonil and SDS-3701 were provided reflecting the authorised GAP in Brazil (calculated MRL for chlorothalonil: 15 mg/kg, SDS-3701: 0.02 mg/kg). For chlorothalonil, an acute consumer health risk could not be excluded. The tolerance established in the US and Brazil is 15 mg/kg CXL: 20 mg/kg chlorothalonil (set by CAC in 2011, no EU reservation was noted). The lowering of the existing MRL to the LOQ should be considered. |
| 0211000 | Potatoes  | 0.01 (ft 3)                   | 0.01*                       | 0.01*                | The existing MRL reflects the previously authorised NEU/SEU GAPs. Uses in third countries have not been reported. Codex MRL is not in place for potatoes. Following the non-approval of chlorothalonil in the EU, the MRL at the LOQ of 0.01 mg/kg is appropriate. |
| 0213020 | Carrots   | 0.3 (ft 3)                    | 0.01*                       | 0.01*                | The existing MRL reflects the previously authorised NEU/SEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for carrots. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0213030 | Celeriac  | 1 (ft 3)                      | 0.01*                       | 0.01*                | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRLs are not in place for celeriac. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0213040 | Horseradishes | 0.3 (ft 3)               | 0.01*                       | 0.01*                | The existing MRL reflects the previously authorised NEU/SEU GAP. Uses in third countries have not been reported. CXL: 1 mg/kg for chlorothalonil, set by CAC 2016; EU reservation because of their concern on metabolite SDS-3701. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0213060 | Parsnips  | 0.3 (ft 3)                    | 0.01*                       | 0.01*                | The existing MRLs reflect the previously authorised NEU/SEU GAP. Uses in third countries have not been reported. CXL: 0.3 mg/kg for chlorothalonil (set by CAC 2016. EU reservation because a separate residue definition for SDS-3701 is considered necessary). Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |

(a) Code according to Commission Regulation (EC) No 401/2006, as amended.
(b) Commodity following the Article 12 MRL review for chlorothalonil.
| Code<sup>a</sup> | Commodity | Existing MRL Chlorothalonil<sup>b</sup> | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation |
|-----------------|-----------|--------------------------------------|---------------------------|-----------------------|---------------------------|
| 0213110         | Turnips   | 0.3 (ft 1)                           | 0.01*                     | 0.01*                 | The existing MRL reflects the previously authorised SEU GAP. Uses in third countries have not been reported CXL of 0.3 mg/kg for chlorothalonil (set by CAC 2016. EU reservation because a separate residue definition for SDS-3701 is considered necessary)<sup>c</sup> Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
| 0220001         | Garlic    | 0.01* (ft 3)                         | 0.01*                     | 0.01*                 | The existing MRL reflects the previously authorised NEU/SEU GAPs Uses in third countries have not been reported No Codex MRL for garlic; for onions, bulb and shallots CXL of 1.5 mg/kg (set by CAC 2016. EU reservation because a separate residue definition for SDS-3701 is considered necessary)<sup>c</sup> Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
| 0220020         | Onions    |                                      |                           |                       |                           |
| 0220030         | Shallots  |                                      |                           |                       |                           |
| 0220040         | Spring onions | 10 (ft 3)                            | 0.01*                     | 0.01*                 | The existing MRL reflects the previously authorised NEU/SEU GAP Uses in third countries have not been reported CXL of 10 mg/kg chlorothalonil (set by CAC 2016. EU reservation because a separate residue definition for SDS-3701 is considered necessary)<sup>c</sup> Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
| 0231010         | Tomatoes  | 6 (ft 3)                              | 0.01*                     | 0.01*                 | The existing MRL reflects the previously authorised EU indoor GAP Uses in third countries have not been reported CXL: 5 mg/kg for chlorothalonil (set by CAC 2016. EU reservation not explicitly mentioned in CCPR report.) Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
| 0231030         | Aubergines | 6 (ft 3)                              | 0.01*                     | 0.01*                 | The existing MRL reflects the previously authorised EU indoor GAP Uses in third countries have not been reported Codex MRL is not in place for aubergines Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
| Code(a) | Commodity                  | Existing MRL Chlorothalonil(b) | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation                                                                                                                                                                                                 |
|--------|----------------------------|-------------------------------|-----------------------------|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0232000| Cucurbits-edible peel      | 5 (ft 3)                      | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised EU indoor GAP. Uses in third countries have not been reported. CXL: 3 mg/kg for chlorothalonil in cucumber, gherkins and courgettes (set by CAC 2011. EU reservation for cucumber (insufficient data set), gherkins, and summer squash (extrapolation practice of JMPR was not agreed by EU). Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0233000| Cucurbits (inedible peel)  | 1 (ft 3)                      | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised EU indoor/SEU GAP. Uses in third countries have not been reported. CXL: 2 mg/kg for chlorothalonil for melons (set by CAC 2011; EU reservation because extrapolation practice of JMPR was not agreed by EU). Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0241020| Cauliflower                | 2 (ft 3)                      | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised NEU/SEU GAP. Uses in third countries have not been reported. CXL: 5 mg/kg for chlorothalonil (set by CAC in 2011; no EU reservation was noted). Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0242010| Brussels sprouts           | 3 (ft 3)                      | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. CXL: 6 mg/kg for chlorothalonil (set by CAC in 2011; EU reservation because a lower MRL of 0.5 mg/kg was suggested when using the OECD calculator) Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0242020| Head cabbage               | 0.6 (ft 1)                    | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised SEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for head cabbage. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0256030| Celery leaves Parsley      | 5 (ft 3)                      | 0.01*                       | 0.01*                 | The existing MRLs reflect the previously authorised NEU GAPS. Uses in third countries have not been reported. Codex MRLs are not in place for celery leaves and parsley. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
### Evaluation of confirmatory data following the Article 12 MRL review for chlorothalonil

| Code<sup>(a)</sup> | Commodity               | Existing MRL Chlorothalonil<sup>(b)</sup> | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation |
|---------------------|-------------------------|-------------------------------------------|-----------------------------|-----------------------|---------------------------|
| 0260010             | Beans (with pods)       | 5 (ft 3)                                  | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for beans with pods. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0260020             | Beans (without pods)    | 3 (ft 3)                                  | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for beans without pods. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0260030             | Peas (with pods)        | 5 (ft 3)                                  | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for peas with pods. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0260040             | Peas (without pods)     | 1 (ft 1)                                  | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised SEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for peas without pods. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0260050             | Lentils                 | 0.6 (ft 3)                                | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for lentils. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0270010             | Asparagus               | 0.01* (ft 3)                              | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised NEU/SEU GAPs. Uses in third countries have not been reported. CXL: 0.01* mg/kg for chlorothalonil (set by CAC in 2016); no EU reservation. |
| 0270030             | Celeries                | 10 (ft 3)                                 | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. CXL: 20 mg/kg for chlorothalonil (set by CAC in 2011; no EU reservation). Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| Code(a) | Commodity       | Existing MRL Chlorothalonil(b) | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation                                                                                                                                                                                                 |
|---------|-----------------|--------------------------------|----------------------------|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0270060 | Leeks           | 8 (ft 1)                       | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised SEU GAP. Uses in third countries have not been reported. CXL: 40 mg/kg (EFSA, 2011) (EU reservation in CCPR: The EU requested JMPR to perform a short-term dietary risk assessment for leeks). Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0280010 | Cultivated fungi| 0.5 (ft 3)                     | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised EU indoor GAP. Uses in third countries have not been reported. Codex MRL is not in place for cultivated fungi. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0300010 | Beans           | 3 (ft 3)                       | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for beans. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0300020 | Lentils         | 0.2 (ft 3)                     | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for lentils. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0300030 | Peas            | 1 (ft 3)                       | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised SEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for peas. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0300040 | Lupins          | 0.2 (ft 3)                     | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for lupins. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| Code<sup>(a)</sup> | Commodity    | Existing MRL Chlorothalonil<sup>(b)</sup> | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation |
|------------------|--------------|-----------------------------------------|----------------------------|-----------------------|---------------------------|
| 0401020          | Peanuts      | 0.1 (ft 3)                              | 0.01*                      | 0.01*                 | In response to the confirmatory data request, the applicant submitted 13 trials for chlorothalonil and SDS-3701, representative for the US GAP. Residues were below the LOQ of 0.01 mg/kg for both residue definitions. A US tolerance for peanuts of 0.3 mg/kg is established. Existing CXL: 0.1 mg/kg chlorothalonil (EFSA, 2011). Analytical method for SDS-3701: data gap on extraction efficiency not addressed. |
| 0500010          | Barley       | 0.4 (ft 3)                              | 0.01*                      | 0.01*                 | The existing MRLs reflect the previously authorised SEU GAP. Uses in third countries have not been reported. Codex MRLs are not in place for barley and oats. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0500050          | Oats         | 0.1 (ft 3)                              | 0.01*                      | 0.01*                 | The existing MRLs reflect the previously authorised SEU GAP. Uses in third countries have not been reported. Codex MRLs are not in place for barley and oats. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0500070          | Rye          | 0.1 (ft 3)                              | 0.01*                      | 0.01*                 | The existing MRLs reflect the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRLs are not in place for rye and wheat. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0500090          | Wheat        | 0.1 (ft 3)                              | 0.01*                      | 0.01*                 | The existing MRLs reflect the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRLs are not in place for rye and wheat. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0700000          | Hops (dried) | 60 (ft 4)                               | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for hops. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |

**Residue definitions for enforcement for animal commodities:** SDS-3701 (R182281)

| Code<sup>(a)</sup> | Commodity     | Existing MRL SDS-3701 | Proposed MRL SDS-3701 | Conclusion/recommendation |
|------------------|---------------|-----------------------|-----------------------|---------------------------|
| 1011010          | Swine muscle  | 0.02 (ft 5)           | 0.01*                 | Considering the withdrawal of EU uses in feed, the dietary burden was re-calculated. The requested confirmatory data (a study investigating metabolism of chlorothalonil and metabolite SDS-3701 in pigs) is no longer relevant, since the dietary burden was below the trigger value. The lowering of the existing MRL to the LOQ should be considered. Codex MRLs of 0.02 mg/kg in place for swine meat; lacking data on the toxicological profile of SDS-3701, the consumer risk assessment for this CXL cannot be performed. In addition, the commodity description of the EU and Codex are not compatible (meat vs. muscle). |
### Evaluation of confirmatory data following the Article 12 MRL review for chlorothalonil

| Code(a) | Commodity     | Existing MRL SDS-3701 | Proposed MRL SDS-3701 | Conclusion/recommendation |
|---------|---------------|-----------------------|-----------------------|--------------------------|
| 1011020 | Swine fat     | 0.07 (ft 5)           | 0.01*                 | Considering the withdrawal of EU uses in feed, the dietary burden was re-calculated. The requested confirmatory data (a study investigating metabolism of chlorothalonil and metabolite SDS-3701 in pigs) is no longer relevant, since the dietary burden was below the trigger value. The lowering of the existing MRL to the LOQ should be considered. Codex MRLs of 0.07 mg/kg in place for swine fat; lacking data on the toxicological profile of SDS-3701, the consumer risk assessment for this CXL cannot be performed. |
| 1011030 | Swine liver   | 0.2 (ft 5)            | 0.01*                 | Considering the withdrawal of EU uses in feed, the dietary burden was re-calculated. The requested confirmatory data (a study investigating metabolism of chlorothalonil and metabolite SDS-3701 in pigs) is no longer relevant, since the dietary burden was below the trigger value. The lowering of the existing MRL to the LOQ should be considered. Codex MRLs of 0.2 mg/kg in place for liver and kidney; lacking data on the toxicological profile of SDS-3701, the consumer risk assessment for this CXL cannot be performed. |
| 1011040 | Swine kidney  |                       |                       |                          |
| 1011050 | Swine edible offal |                |                       |                          |
| 1016000 | (f) Poultry   | 0.01* (ft 5)          | 0.01*                 | Considering the withdrawal of EU uses in feed, the dietary burden was re-calculated. The requested confirmatory data (a study investigating metabolism of chlorothalonil and metabolite SDS-3701 in pigs) is no longer relevant, since the dietary burden was below the trigger value. The existing MRL should be maintained at the LOQ. Codex MRLs of 0.01* mg/kg in place for bird eggs. |
| 1030000 | (iii) Bird eggs |                      |                       |                          |

*: Indicates that the MRL is proposed at the 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.
(c): Risk management decision is required as regards the CXL, considering also the lack of information on the genotoxicity of metabolites/degradation products that may be formed during processing.

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 29 October 2016, or, if that information is not submitted by that date, the lack of it. Moreover, the European Food Safety Authority highlights that the metabolite 2,5,6-trichloro-4 hydroxyphtalonitrile (SDS-3701) has not been taken into account, given that a validated method for enforcement, a complete set of residues trials, storage stability studies and data on processing of SDS-3701, are unavailable for all plant commodities. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1, 2, 3, 4, 9, 10, 11, 12, 13, 14).

ft 2: The European Food Safety Authority identified some information on storage stability 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 29 October 2016, or, if that information is not submitted by that date, the lack of it. Moreover, the European Food Safety Authority highlights that the metabolite 2,5,6-trichloro-4 hydroxyphtalonitrile (SDS-3701) has not been taken into account, given that a validated method for enforcement, a complete set of residues trials, storage stability studies and data on processing of SDS-3701, are unavailable for all plant commodities. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1, 2, 3, 4, 8).

ft 3: The European Food Safety Authority highlights that the metabolite 2,5,6-trichloro-4 hydroxyphtalonitrile (SDS-3701) has not been taken into account, given that a validated method for enforcement, a complete set of residues trials, storage stability studies and data on processing of SDS-3701, are unavailable for all plant commodities. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1, 2, 3, 4).

ft 4: The European Food Safety Authority identified some information on analytical methods and 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 29 October 2016, or, if that information is not submitted by that date, the lack of it. Moreover, the European Food Safety Authority highlights that the metabolite 2,5,6-trichloro-4 hydroxyphtalonitrile (SDS-3701) has not been taken into account, given that a validated method for enforcement, a complete set of residues trials, storage stability studies and data on processing of SDS-3701, are unavailable for all plant commodities. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1, 2, 3, 4).
residues trials, storage stability studies and data on processing of SDS-3701, are unavailable for all plant commodities. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 7, 15).

ft 5: The European Food Safety Authority identified some information on pigs metabolism and in TRR in poultry commodities 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 29 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 5, 6).
Table of contents

Abstract................................................................................................................................................... 1
Summary................................................................................................................................................. 3
Assessment.............................................................................................................................................. 16
1. Residues in plants .................................................................................................................................. 18
   1.1. Nature of residues and methods of analysis in plants........................................................................ 18
      1.1.1. Nature of residues in primary crops .............................................................................................. 18
      1.1.2. Nature of residues in rotational crops ........................................................................................... 18
      1.1.3. Nature of residues in processed commodities ................................................................................ 18
      1.1.4. Methods of analysis in plants ........................................................................................................ 18
      1.1.5. Storage stability of residues in plants ............................................................................................ 19
      1.1.6. Proposed residue definitions......................................................................................................... 19
   1.2. Magnitude of residues in plants .................................................................................................... 20
      1.2.1. Magnitude of residues in primary crops ......................................................................................... 20
      1.2.1.1. Banana ....................................................................................................................................... 20
      1.2.1.2. Papaya ....................................................................................................................................... 20
      1.2.1.3. Peanuts ...................................................................................................................................... 21
      1.2.2. Magnitude of residues in rotational crops ...................................................................................... 21
      1.2.3. Magnitude of residues in processed commodities ........................................................................... 21
   2. Residues in livestock ........................................................................................................................ 22
   3. Consumer risk assessment .............................................................................................................. 22
   4. Conclusion and Recommendations .................................................................................................. 23
References............................................................................................................................................... 24
Abbreviations ........................................................................................................................................... 24
Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data and import tolerances .... 26
Appendix B – List of end points ............................................................................................................ 27
Appendix C – Pesticide Residue Intake Model (PRIMo) ........................................................................ 44
Appendix D – Input values for the exposure calculations ......................................................................... 46
Appendix E – Used compound codes.................................................................................................... 47
Assessment

The review of existing MRLs for the active substance chlorothalonil according to Article 12 of Regulation (EC) No 396/2005\(^1\) (MRL review) has been performed in 2012 (EFSA, 2012). 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 following data gaps were identified by EFSA:

Data gaps for the finalisation of the risk assessment of SDS-3701:

1) A validated method for enforcement of metabolite SDS-3701 in plant commodities, including processed fractions;
2) A complete set of residue trials compliant with available guidance documents and allowing for the estimation of SDS-3701 levels in all crops supported in the framework of this review;
3) Storage stability studies demonstrating the stability of SDS-3701 in plant commodities, including processed fractions;
4) Further information on the magnitude of SDS-3701 in processed commodities that have been subject to high temperatures;
5) A study investigating metabolism of chlorothalonil and metabolite SDS-3701 in pigs;
6) Further characterisation of the TRR in poultry commodities (if the dietary burden increases in the future).

Data gaps for the parent chlorothalonil:

7) An analytical method, its ILV and a confirmatory method fully validated for the determination of parent chlorothalonil in hops;
8) A storage stability study for parent chlorothalonil in high acid content commodities;
9) Eight residue trials on apples and pears (with a minimum of 4 trials on apples) complying with the southern outdoor good agricultural practices (GAPs) for apples, quinces, medlars and loquats;
10) Four residue trials on apricots and four residue trials on peaches complying with the southern outdoor GAP;
11) Four residue trials on turnips complying with the southern outdoor GAP;
12) Eight residue trials on head cabbage complying with the northern outdoor GAP;
13) Eight residue trials on leek complying with the northern outdoor GAP;
14) Four additional trials on fresh peas (without pods) complying with the southern outdoor GAP;
15) Four residue trials on hops complying with the northern outdoor GAP.

Following the MRL review, the MRL modifications proposed for chlorothalonil have been implemented in the MRL legislation by Commission Regulation (EU) No 1146/2014\(^2\), including footnotes implementing the data gaps identified by EFSA in points 1–15 (above) as confirmatory data requirements. Lacking data for SDS-3701, MRLs for the second residue definition could not be established.

Any parties having an interest in maintaining the tentative MRLs were requested to address the confirmatory data requirement by 29 October 2016.

In accordance with the specific provisions, the applicants Syngenta Crop Protection, UPL Europe Ltd. (Arysta LifeScience SAS) and Oxon Italia S.p.A (members of Chlorothalonil Task Force) submitted applications to the competent national authority in the Netherlands (designated rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review. In support of the applications, the applicants provided residue trials and referred to data that were assessed in the framework of the renewal of the approval of chlorothalonil (EFSA, 2018a). In addition, applications for modifications of some of the existing MRLs were submitted reflecting intended modifications of the EU use patterns.

\(^1\) 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) No 1146/2014 of 23 October 2014 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for anthraquione, benfluralin, bentazone, bromoxynil, chlorothalonil, fomoxadone, imazamox, methyl bromide, propanil and sulphuric acid in or on certain products. OJ L 308, 29.10.2014, p. 3-60.
The applicant Syngenta Crop Protection provided the following information:

- Information to support import tolerances for chlorothalonil in peanuts, bananas and papaya (for papaya and peanuts, the GAPs assessed in the framework of the MRL review were no longer supported. Instead, alternative GAPs were reported);
- Data to justify the modification of the existing MRLs for chlorothalonil on peaches (incl. nectarines), apricots, grapes, carrot, parsley, salsify, parsnips, horseradish, radish, spring onions/welsh onions, cauliflower, Brussels sprouts, head cabbage, beans without pods, peas without pods and leek;
- Data to support the setting MRLs for SDS-3701 (R182281) in spring onions/welsh onions, cucurbits-edible peel, cauliflower, Brussels sprouts, head cabbage, fresh legumes (beans and peas with pods, beans and peas without pods), asparagus, pulses (beans without pods, chickpeas), barley, oats, wheat, rye, triticale.

OXON Italia S.p.A. submitted information to address the confirmatory data requirements for metabolite SDS-3701: residue trials were submitted for melon, cucumber/courgette, peas and sugar beet for GAPs which were less critical compared to the authorised EU GAPs assessed during the Article 12 review (EFSA, 2012).

UPL Europe Ltd. (formerly Arysta LifeScience SAS) submitted residue data on wheat, barley, tomatoes and dry peas (pulses) to address the confirmatory data requirements for the metabolite SDS-3701; the data on wheat, barley and tomatoes were already assessed during the renewal process (EFSA, 2018a).

The RMS assessed the relevant information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on April 2018 (Netherlands, 2018).

EFSA proceeded with the assessment of the application and confirmatory data as requested by the European Commission in accordance with Article 9 of the Regulation. During the detailed assessment, EFSA identified points which needed further clarifications. In response to the clock-stop letter, on 16 January 2020, the RMS submitted a revised evaluation report which addressed the points for clarification.

In the framework of the process on the renewal of the approval of chlorothalonil, a number of data gaps relevant for the consumer risk assessment were identified (data to elucidate the toxicological profile of the metabolite SDS-3701 (R182281), R613636 and R417888 were missing, and consequently, definitive residue definitions for risk assessment in plant and animal commodities could not be derived) (EFSA, 2018a).

On 29 April 2019, a decision on the non-renewal of the approval of chlorothalonil under Regulation (EC) No 1107/2009 was taken. Following the decision on the non-renewal of the approval, the EU uses of plant protection products containing chlorothalonil had to be withdrawn by 20 November 2019 (period of grace according to Article 46 of Regulation (EC) No 1107/2009: 20 May 2020). Considering the new situation for EU authorisations, the data gaps related to the EU uses (i.e. data gaps 7 and 9 to 15 and partially data gaps 2 and 4 to 6) became obsolete.

EFSA therefore focused in this assessment on the import tolerance for banana, papaya and peanuts and the generic data gap on analytical method, storage stability and the data gap on the magnitude of SDS-3701 in processed commodities that have been subject to high temperatures, which are also relevant for the import tolerance requests. For certain crops for which confirmatory data were requested, Codex MRLs are in place. EFSA also provided information to risk managers on the existing Codex MRLs. It should be highlighted that the purpose of the current assessment was not the assessment of data gaps identified in the renewal process that lead to the non-renewal of the approval. However, to provide a comprehensive view and allow risk managers to take an informed decision, EFSA noted the relevance of the data gaps for the uses assessed, where relevant.

EFSA based its assessment on the evaluation report and additional information provided in response to the clock-stop letter submitted by the RMS (Netherlands, 2018), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 and additional assessments of chlorothalonil performed after the MRL review (EFSA, 2015, 2018a).
The evaluation of confirmatory data was performed in accordance with the procedure set out in the Commission Staff Working Document SANTE/10235/2016 (European Commission, 2020). For this application, the data requirements established in Regulation (EU) No 544/2011 and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 1146/2014 are applicable.

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

The evaluation report submitted by the RMS (Netherlands, 2018) is considered as 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**

Not relevant for the current assessment.

1.1.2. **Nature of residues in rotational crops**

No confirmatory data were requested in the MRL review.

1.1.3. **Nature of residues in processed commodities**

No confirmatory data were requested in the MRL review.

In the framework of the renewal process, potentially genotoxic degradation products were identified (SDS-3701 (R182281) and SDS-47525 (R613636)) which are formed under processing conditions employing temperatures representative for baking/brewing/boiling and sterilisation. The genotoxic potential for both degradation products has not been adequately addressed (EFSA, 2018a).

For import tolerance applications in commodities that are likely to undergo processing (pasteurisation, baking/brewing/boiling and sterilisation at slightly acidic pH), the data gap on the degradation products R613636 and SDS-3701 should be addressed by providing the relevant toxicological studies or by providing evidence that these degradation products are not formed.

Lacking this information, a final conclusion on the residue definition for processed products cannot be derived.

1.1.4. **Methods of analysis in plants**

- **Chlorothalonil**: no data gap/no confirmatory data requirement.
- **Metabolite SDS-3701**: Studies for addressing the data gap number (1) were assessed in the framework of the renewal of the approval of chlorothalonil (EFSA, 2018a). It was concluded that the analytical enforcement method (LC-MS/MS) was sufficiently validated for the determination of SDS-3701 residues in all crop groups at an LOQ of 0.01 mg/kg, except in dry and high oil content commodities where a data gap regarding extraction efficiency was noted. Details on the analytical method are presented in Appendix B.1.1.1. In the framework of the current assessment, information on the extraction efficiency for dry and high oil content commodities has not been submitted.

For the import tolerance requests for banana and papaya sufficiently validated analytical methods are available for both residue definitions (chlorothalonil and SDS-3701). For peanuts, belonging to the matrix class of high oil content, validated analytical methods are available to determine residues of chlorothalonil; as regards the method for the determination of SDS-3701, further data on the extraction efficiency are still required.

---

4 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.

5 The data gap number (1): ‘a validated method for enforcement of metabolite SDS-3701 in plant commodities, including processed fractions’. 
1.1.5. Storage stability of residues in plants

Chlorothalonil: the studies addressing data gap number (8)\(^6\) were assessed in the framework of the renewal of the approval of chlorothalonil (EFSA, 2018a). Chlorothalonil was demonstrated to be stable in high acid content matrices for at least 24 months when stored at \(\leq -18^\circ\text{C}\). EFSA concludes that the data gap is sufficiently addressed.

Metabolite SDS-3701: studies addressing data gap number (3)\(^7\) were assessed in the framework of the renewal of the approval of chlorothalonil (EFSA, 2018a). Metabolite SDS-3701 was considered stable for 24 months in commodities with high oil, high starch and high acid content when stored \(\leq -18^\circ\text{C}\). The stability of SDS-3701 in high water content commodities varies depending on the crop and ranged from less than 3 months in onions to 24 months in tomatoes. The results of these studies are considered sufficiently representative also for processed commodities with similar matrix characteristics.

EFSA concluded that the data gap identified in the framework of the MRL review has been addressed.

1.1.6. Proposed residue definitions

In the framework of MRL review (EFSA, 2012), the following residue definitions were derived for unprocessed plant commodities:

Residue definitions 1 and 2 for enforcement and risk assessment:
- Residue definition 1: chlorothalonil;
- Residue definition 2: R182281 (SDS-3701).

In Regulation (EC) No 396/2005 currently the residue definition for plant commodities is only parent chlorothalonil. Since no data on the residue levels expected for SDS-3701 were available at the time of the MRL review, residue definition 2 has not been implemented in the EU MRL legislation.

It is noted that in the framework of the renewal of chlorothalonil (EFSA, 2018a), additional considerations on the setting of residue definitions were made, leading to proposals of the following provisional residue definitions:

| Residue definition for monitoring/enforcement | Residue definition for risk assessment |
|----------------------------------------------|--------------------------------------|
| **Primary crop**                              |                                      |
| Chlorothalonil and its conjugates;            | Chlorothalonil and its conjugates;   |
| R182281 (SDS-3701) and its conjugates         | R182281 (SDS-3701) and its conjugates |
|                                             |                                      |
| **Processed products**                        |                                      |
| Chlorothalonil and its conjugates;            | Chlorothalonil and its conjugates;   |
| R182281 (SDS-3701) and its conjugates         | R182281 (SDS-3701) and its conjugates;|
|                                             | R613636 (SDS-19221)                  |
| **Rotational crops**                          |                                      |
| Chlorothalonil and its conjugates;            | R611965 (SDS-46851)/R417888, and conjugates of |
| R182281 (SDS-3701) and its conjugates         | metabolites R613636, R613800 (C15) and R611968 |
|                                             |                                      |

The residue definitions derived in the renewal process are provisional pending further metabolism studies, storage stability studies and studies on the toxicity of metabolites/degradation products observed in rotational crops studies/processing studies. Additionally, for processed commodities, information needs to be provided to demonstrate that 4-amino-2,5,6-trichloroisophthalonitrile is an artefact and not a degradation product not relevant for processed products (EFSA, 2018a).

For the current assessment, the residue definitions derived in the framework of the MRL review are considered relevant, since the residue definitions derived in the framework of the renewal process are not formally approved.

---

\(^6\) The data gap number (8): ‘a storage stability study for parent chlorothalonil in high acid content commodities’.

\(^7\) The data gap number (3): ‘Storage stability studies demonstrating the stability of SDS-3701 in plant commodities, including processed fractions’.
1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In the framework of the current application, a wide range of residue data was provided, which were assessed by the RMS in the evaluation report (Netherlands, 2018).

Since EFSA focused in this assessment on the data gaps identified for the import tolerances on banana, papaya and peanuts, the residue studies on other commodities are not reported by EFSA.

1.2.1.1. Banana

GAP Latin America: 10 × 1,500 g/ha, 10–14 days interval, PHI 0 days (bagged bananas)

The applicant submitted a wide range of residue trials in bananas performed in Panama, Guatemala, Honduras, Costa Rica, Philippines and Mexico in 1977–1993 with treatment regimens comparable to or more critical than the reported Latin American GAP (9–27 times application of 1.3–2 kg/ha). In some of the residue studies, bananas were covered by plastic bags over the developing stems to protect the fruit until harvest. Results were reported for whole fruit and for peeled bananas separately for bagged and unbagged bananas.

According to the EMS, the analytical methods were sufficiently validated and fit for purpose. Samples were stored for approximately 7 months before analysis which is within the demonstrated storage period for which integrity of the samples was demonstrated.

Chlorothalonil: The residue trials submitted for bagged bananas allowed to derive an MRL proposal of 0.02* mg/kg. This MRL proposal is lower than the existing MRL for bananas (15 mg/kg) which was derived in the framework of the MRL review from residue trials performed for the same GAP in unbagged bananas.

For unbagged bananas, only three residue trials are available. The data set would therefore not be sufficient to derive an MRL proposal for banana which is considered as a major crop.

SDS-3701: The residue trials in bagged bananas were sufficient to derive an MRL proposal of 0.01 mg/kg (equal to the limit of quantification) for SDS-3701 and to address the data gap number (2).

Overall, the available trials are sufficient to address the data gaps identified in the MRL review and to derive an MRL proposal of 0.02* mg/kg for chlorothalonil and 0.01* mg/kg for SDS-3701 in support of the authorised GAP in bagged bananas.

A valid label for the registration of chlorothalonil in Latin American countries was not provided to verify whether the residue trials assessed are representative for the approved uses. MRLs established in several Latin American countries could be retrieved from publicly available sources (Costa Rica 15 mg/kg, Brazil 3 mg/kg, Argentina 0.2 (pulp) mg/kg and Chile of 0.01 mg/kg).

It is noted that the current Codex MRL is set at the level of 15 mg/kg for chlorothalonil. A corresponding Codex MRL for SDS-3701 is not established, no data are reported as regards the residue levels of SDS-3701 in treated bananas.

1.2.1.2. Papaya

GAP Brazil: 6 × 1.65 kg/ha, 14 d interval, PHI 7 days (EFSA, 2012)

Chlorothalonil: The data submitted in the framework of the MRL review were found sufficient to derive an MRL proposal for chlorothalonil for the Brazilian GAP, i.e. 15 mg/kg. No confirmatory data were requested.

---

8 This LOQ refers to LOQ of the method used for the residue trials. It is noted that a more sensitive analytical method for enforcement purposes is available (see Appendix B.1.1.1).

9 A complete set of residue trials compliant with available guidance documents and allowing for the estimation of SDS-3701 levels.

10 Labels for the banana GAPs in Brazil and Mexico were provided; however, the conditions of use did not match with reported GAP assessed in this reasoned Opinion. For other Latin American countries, no information is available. According to the EMS, the GAP for banana which is the basis for the import tolerances should have been rather verified at the beginning of the MRL review process where this GAP was already assessed.

11 http://app.sfe.go.cr/SFEInsumos/aspx/Pantallas/PantallaSeleccion.aspx

12 http://portal.anvisa.gov.br/registros/e-autorizacoes/agrotoxicos/produtos/monografia-de-agrotoxicos/autorizadas

13 https://www.argentina.gob.ar/sites/default/files/lmr_de_activos_por_cultivo_octubre_2019.xls

14 http://extwprlegs1.fao.org/docs/pdf/ch140105.pdf

15 In support of the alternative GAP: 5 × 1.73 kg/ha, PHI 7 day, the applicant submitted six trials on papaya as performed in 2001 and 2002 in Brazil. Two trials were considered not independent, and thus, the mean value was selected of these trials. However, since data on residues of SDS-3701 were not provided for these trials, no MRL proposal is derived.
SDS-3701: In order to address the data gap number (2) for the authorised GAP in Brazil, the applicant submitted information on the residues of SDS-3701 in all trials used to derive the MRL proposal for chlorothalonil. The data gap is thus considered addressed. Residues of SDS-3701 were at or below the LOQ in all samples.

EFSA concluded that the existing MRL of 15 mg/kg for chlorothalonil is confirmed; an MRL proposal of 0.02 mg/kg is derived for SDS-3701 residues (See also the risk assessment results for this crop reported in Section 3).

The applicant provided information on the registered label in Brazil supporting the current MRL application. The tolerance established in Brazil12 is 15 mg/kg.

1.2.1.3. Peanuts

GAP USA: 8 × 1,200 g/ha, 14 d interval, PHI 14 days (EFSA, 2012).16

Chlorothalonil: The data submitted in the framework of the MRL review were found sufficient to derive an MRL proposal for chlorothalonil for the US GAP, i.e. 0.1 mg/kg. No confirmatory data were requested. In order to address the data gap number (2) (information on residue levels of SDS-3701), the applicant re-submitted 13 residue trials where samples were analysed for chlorothalonil and SDS-3701. In none of these studies, quantifiable residues of chlorothalonil were found.17

SDS-3701: In the residue trials submitted to address data gap number (2), residues of SDS-3701 were at or below the LOQ in all samples.

The available trials are sufficient to address the data gaps identified in the MRL review and to derive MRL proposals of 0.01* mg/kg for chlorothalonil and SDS-3701 on peanuts in support of the authorised GAP.

The tolerance established in the USA18 for chlorothalonil in peanuts is 0.3 mg/kg.

A Codex MRL of 0.1 mg/kg19 for chlorothalonil on peanuts is in place. A corresponding Codex MRL for SDS-3701 is not established, but data for SDS-3701 are available with demonstrated that no quantifiable residues are occurring in peanuts (nutmeat).

1.2.2. Magnitude of residues in rotational crops

Information on the magnitude of residues in rotational crops is not relevant for the current assessment for banana and papaya which are considered as permanent/semi-permanent crops.

It is noted that the peer review identified the following compounds that may be relevant for rotational crops and that should be further investigated as regards the residue levels and the toxicity: R611965/R417888 (not separated but likely of different toxicity), the conjugates of R613636, R611968 and R613800 (C15). Information whether these compounds occur in peanuts grown as succeeding/rotational crop on soils previously treated with chlorothalonil has not been provided.

Noting that residues for chlorothalonil and metabolite SDS-3701 in peanuts are below the LOQ of 0.01 mg/kg, it is rather unlikely that the data gap identified in the peer review in 2018 (EFSA, 2018a) is relevant for peanuts. However, it would be desirable to get more information on the possible occurrence of the soil metabolites in peanuts and data to conclude on the genotoxicity of R613636 conjugate and R417888.

1.2.3. Magnitude of residues in processed commodities

Specific peeling data are available for two trials in papaya which give an indication that lower residues of parent chlorothalonil are expected in the pulp compared to the whole fruit. However, due to the limited number of trials, a reliable peeling factor cannot be derived. For metabolite SDS-3701, the residues in pulp and whole fruit were below the LOQ (2 trials only).

In nine of the residue trials submitted (bagged bananas), results were provided for the whole fruit and peeled banana all of which were below the LOQ which gave an indication that chlorothalonil and SDS-3701 are not accumulating in the pulp. Based on three available trials for unbagged banana for whole fruit and pulp, two values for whole fruit are above the LOQ and equally indicate no accumulation of parent and metabolite in the pulp (see Table B.1.2.3).

16 No residue trials were provided for the alternative GAP (4 × 2.52 kg/ha, PHI 14 days).
17 The EMS verified the correctness of the results of the re-submitted residue trials which differed from the results in the MRL review (EFSA, 2012).
18 https://www.ecfr.gov/cgi-bin/text-idx?SID=a3b649316cccb17c31211db2edd8f1f789&mce=true&node=pt40.24.180&rgn=div5
19 The CXL was derived in the JMPR assessment 2010 for a US GAP (1.3,g ai/ha, max. 10 kg ai/ha and year, PHI 14 d).
Processing data to address data gap number (4)\textsuperscript{20} have been requested as confirmatory data in MRL review also for the crops under assessment.

Peanuts: A processing study with peanuts treated at the recommended and at an exaggerated application rate (13 ×) of 1.24 kg a.s./ha was carried out. Peanut nutmeat and hulls were directly collected from the field and were analysed for chlorothalonil, SDS-3701 and SDS 46851. Processing data indicated a concentration of chlorothalonil from peanut nutmeat to peanut crude oil (solvent extract) by a factor of 1.5; in refined oil, chlorothalonil residues were below the LOQ of 0.01 mg/kg. Individual values for metabolites SDS-3701 and SDS-46851 were not presented. It was described that SDS-46851 levels amounted up to 0.3 mg/kg in peanut nutmeats and hulls following both treatments and showed no concentration upon processing (Netherlands, 2020).

Since SDS-3701 was reported to show no accumulation in peanut oil processing, for this commodity, the data requirement is considered addressed noting that the individual data were not shown.

Processing studies on high temperature treatment of banana and papaya that investigate the magnitude of residues of the degradation products identified in standard hydrolysis studies (i.e. R182281 and R613636) are not available.

For the import tolerance application for banana and papaya, it would be desirable to get further evidence that the degradation products identified in standard hydrolysis studies are not formed when the products undergo pasteurisation, baking/brewing/boiling and sterilisation, considering that data on the toxicological properties of these degradation products were found insufficient to conclude on the toxicological profiles.

2. Residues in livestock

In the framework of the MRL review, the dietary burden was calculated for dairy ruminants, meat ruminants, poultry and pigs taking into account the notified EU uses and uses in third countries for which import tolerances were requested. The dietary burden calculation was the basis for deriving MRL proposals for food of animal origin in the MRL review (EFSA, 2012).

Considering that the EU authorisations for most of the crops used in the dietary burden calculation have been withdrawn due to the decision of non-approval of chlorothalonil, the dietary burden calculation was updated in the current assessment. The only remaining use relevant for the dietary burden calculation is the use in peanuts.

The animal exposure calculation for peanut meal was performed according to the new methodology currently in use (OECD, 2013). Since residues of chlorothalonil and SDS-3701 were both below the LOQ, respectively, the default processing factor for peanut meal of 2 was not used in the calculation of the animal dietary burden. The results of the dietary burden calculation for chlorothalonil and SDS-3701 are presented in Appendix B.2. The calculated dietary burden was below the trigger value for all animal species. Hence, EFSA concluded that the existing MRLs for animal products could be lowered to the LOQ. Data gap number (5)\textsuperscript{21} and (6)\textsuperscript{22} of the MRL review are not relevant, as long as no other feed items treated with chlorothalonil enter the EU feed chain.

3. Consumer risk assessment

Chlorothalonil

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed for chlorothalonil, taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2012). In 2015, the risk assessment was updated including the expected residue levels for the import tolerance in cranberries (EFSA, 2015). EFSA now updated the previous risk assessment with the residue levels (STMR and HR) derived from the residue trials conducted on banana, papaya and peanuts (see Appendix D.2). The food commodities, for which the previously reported uses were withdrawn due to the non-approval decision, were excluded from the exposure calculation, assuming that these crops are no longer a source of dietary exposure for chlorothalonil.

\textsuperscript{20} Further information on the magnitude of SDS-3701 in processed commodities that have been subject to high temperature treatment.

\textsuperscript{21} A study investigating metabolism of chlorothalonil and metabolite SDS-3701 in pigs.

\textsuperscript{22} Further characterisation of the TRR in poultry commodities (if the dietary burden increases in the future).
For the risk assessment of chlorothalonil EFSA used the toxicological reference values (ADI and ARfD) for chlorothalonil derived in the framework of the renewal process (EFSA, 2018a). The calculations were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018b, 2019).

For banana and peanuts, the short-term exposure did not exceed the ARfD of chlorothalonil (4% of ARfD and 0.06% of ARfD, respectively). For papaya, short-term exposure accounted for 433% of the ARfD and by applying the tentative peeling factor of 0.3, the exposure was still exceeding the ARfD (130% of ARfD).

The long-term exposure related to the crops under assessment and the previously assessed import tolerance for cranberries accounted for maximum 0.8% of the ADI.

**Metabolite SDS-3701**

For unprocessed commodities under assessment the residue trials demonstrated that residues of SDS-3701 are not expected to occur in significant concentrations (all results below the LOQ). However, it cannot be excluded that SDS-3701 and other degradation products are formed during processing involving higher temperatures in particular in commodities that contain residues of chlorothalonil above the LOQ. In animal products, residues of SDS-3701 are not expected, considering the results of the updated dietary burden calculation.

Lacking detailed information on the magnitude of SDS-3701 in processed products (particularly for papayas, where significant residues of chlorothalonil are expected in unprocessed products) and lacking data to conclude on the toxicological reference values for SDS-3701, the risk assessment for SDS-3701 cannot be completed.

4. **Conclusion and Recommendations**

The applicants Syngenta Crop Protection, Oxon Italia S.p.A. and UPL Europe Ltd. (formerly Arysta LifeScience SAS) submitted data to address the data gaps identified in the framework of the MRL review (EFSA, 2012). Considering the decision on the non-approval of chlorothalonil, confirmatory data for EU uses became obsolete. EFSA therefore focused in this assessment on the import tolerance for banana, papaya and peanuts and the generic data gap on analytical method, storage stability and the data gap on the magnitude of SDS-3701 in processed commodities that have been subject to high temperatures, which are also relevant for the import tolerance requests.

The submitted residue trials were sufficient to derive MRL proposals for banana, papaya and peanuts for chlorothalonil and SDS-3701. For banana, a valid label for the registration of chlorothalonil in Latin American countries, which describes the use conditions for chlorothalonil in detail, was not provided.

Storage stability data were provided and were considered sufficient to address the data gap identified in the MRL review.

Adequate analytical methods for enforcement are available to control the residues of chlorothalonil and SDS-3701 in plant matrices at the validated LOQ of 0.01 mg/kg. However, data to demonstrate that the method is capable to quantify reliably residues of SDS-3701 in high oil commodities (data on the extraction efficiency of the method) are not available and the previously identified data gap is not addressed.

For papaya, the lack of high temperature processing studies was noted; hence, the formation of relevant concentrations of the degradation products SDS-3701 and R613636 for which the toxicological profile is not fully elucidated cannot be excluded.

The long-term exposure to chlorothalonil residues in the crops for which uses in third countries were reported/assessed did not exceed the ADI. For banana and peanuts, the expected short-term exposure did not exceed the ARfD; for papaya, a short-term consumer health risk could not be excluded for chlorothalonil residues. As regards SDS-3701, the consumer risk assessment could not be finalised, lacking data on the toxicological profile of this metabolite/degradation product.

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

**References**

EFSA (European Food Safety Authority), 2011. Scientific support for preparing an EU position in the 43rd Session of CCPR. EFSA Journal 2011;9(9):2360, 123 pp. https://doi.org/10.2903/j.efsa.2011.2360
EFSA (European Food Safety Authority), 2012. Review of the existing maximum residue levels for chlorothalonil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(10):2940, 87 pp. https://doi.org/10.2903/j.efsa.2012.2940

EFSA (European Food Safety Authority), 2015. Reasoned opinion on setting of an import tolerance for chlorothalonil in cranberries. EFSA Journal 2015;13(7):4193, 21 pp. https://doi.org/10.2903/j.efsa.2015.4193

EFSA (European Food Safety Authority), Arena M, Auteri D, Barmaz S, Bellisai G, Brancato A, Brocca D, Bura L, Byers H, Chiusolo A, Court Marques D, Crivellente F, De Lentdecker C, Egsmose M, Erdos Z, Fait G, Ferreira L, Goumenou M, Greco L, Ippolito A, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Medina P, Miron I, Molnar T, Nougadere A, Padovani L, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Serafimova R, Sharp R, Stanek A, Streissl F, Sturma J, Tarazona J, Terron A, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2018a. Conclusion on the peer review of the peer review of the pesticide risk assessment of the active substance chlorothalonil. EFSA Journal 2018;16(1):5126, 40 pp. https://doi.org/10.2903/j.efsa.2018.5126

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018b. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019. Pesticide Residue Intake Model- EFSA PRIMo revision 3.1. EFSA supporting publication 2019;16(3):EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.en-1605

European Commission, 2020. Commission staff working document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 18 February 2020. SANTE/E4/VW 10235/2016 – Rev. 4, 6 pp., Brussels, 18 February 2020.

FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Edition. FAO Plant Production and Protection Paper 225, 298 pp.

Netherlands, 2017. Revised Renewal Assessment Report (RAR) on chlorothalonil prepared by the rapporteur Member State the Netherlands in the framework of Commission Implementing Regulation (EU) No 844/2012, October 2017. Available online: www.efsa.europa.eu

Netherlands, 2018. Evaluation report on the confirmatory data for the evaluation of MRLs for Chlorothalonil according to Article 12 of Regulation (EC) No 396/2005 and MRL applications and Import tolerance requests in various crops. March 2018, revised in January 2020, 652 pp.

Netherlands, 2020. Renewal Assessment Report and Proposed decision of the Netherlands prepared in the context of the possible approval of chlorothalonil under Regulation (EC) 1107/2009. June 2020.

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013.

**Abbreviations**

- a.s. active substance
- ADI acceptable daily intake
- AR applied radioactivity
- ARfD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- Bw body weight
- CAC Codex Alimentarius Commission
- CAS Chemical Abstract Service
- CCPR Codex Committee on Pesticide Residues
- CEN European Committee for Standardisation (Comité Européen de Normalisation)
- CF conversion factor for enforcement to risk assessment residue definition
- CIRCA (EU) Communication & Information Resource Centre Administrator
- CS capsule suspension
- CV coefficient of variation (relative standard deviation)
- CXL Codex maximum residue limit
- DAR draft assessment report
- DAT days after treatment
- DM dry matter
- DP dustable powder
| Abbreviation | Description |
|--------------|-------------|
| DS           | powder for dry seed treatment |
| DT<sub>90</sub> | period required for 90% dissipation (define method of estimation) |
| EC           | emulsifiable concentrate |
| EDI          | estimated daily intake |
| EMS          | evaluating Member State |
| FID          | flame ionisation detector |
| FLD          | fluorescence detector |
| FPD          | flame photometric detector |
| GAP          | Good Agricultural Practice |
| GC-MS        | gas chromatography with mass spectrometry |
| GS           | growth stage |
| HR           | highest residue |
| IEDI         | international estimated daily intake |
| IESTI        | international estimated short-term intake |
| ILV          | independent laboratory validation |
| IPCS         | International Programme of Chemical Safety |
| ISO          | International Organisation for Standardisation |
| IUPAC        | International Union of Pure and Applied Chemistry |
| JMPR         | Joint FAO/WHO Meeting on Pesticide Residues |
| LC           | liquid chromatography |
| LOQ          | limit of quantification |
| MRL          | maximum residue level |
| MS           | Member States |
| MS/MS        | tandem mass spectrometry detector |
| MW           | molecular weight |
| NEU          | northern Europe |
| OECD         | Organisation for Economic Co-operation and Development |
| PF           | processing factor |
| PHI          | preharvest interval |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| RA           | risk assessment |
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| RPF          | relative potency factor |
| SANCO        | Directorate-General for Health and Consumers |
| SC           | suspension concentrate |
| SL           | soluble concentrate |
| SP           | water-soluble powder |
| STMR         | supervised trials median residue |
| TAR          | total applied radioactivity |
| TMDI         | theoretical maximum daily intake |
| TRR          | total radioactive residue |
| UV           | ultraviolet (detector) |
| WG           | water-dispersible granule |
| WHO          | World Health Organization |
| WP           | wettable powder |
Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data and import tolerances

| Crop and/or situation | NEU, SEU, MS or country | F, G or I(a) | Pests or group of pests controlled | Preparation Type(b) | Conc. a.s. (g/L) | Method kind | Application Range of growth stages & season(c) | Number min–max | Interval between application (min) | Application rate per treatment g a.s./hl min–max | Water L/ha min–max | Rate | Unit | PHI (days)(d) | Remarks |
|----------------------|-------------------------|-------------|-----------------------------------|---------------------|----------------|------------|-----------------------------------------------|---------------|----------------------------------|-----------------------------------------------|------------------|-------|------|----------------|---------|
| For GAPs assessed in the framework of the Article 12 MRL review for which confirmatory data were requested, see EFSA (2012) |
| Import tolerances assessed in the current evaluation |

**Banana**
- Latin America
- F
- PHI: 10
- 10–14
- 1.5 kg/ha
- 0
- Art 12 GAP (EFSA, 2012)
- Application by Syngenta Crop Protection

**Papaya**
- Brazil
- F
- PHI: 6–89
- 14
- 1.65 kg/ha
- 7
- Assessed in Art. 12 MRL review (EFSA, 2012)

**Papaya**
- Brazil
- F
- PHI: 61–89
- 14
- 1.728 kg/ha
- 7
- Alternative GAP Application by Syngenta Crop Protection

**Peanuts**
- USA
- F
- PHI: 480/700
- 14
- 1.2 kg/ha
- 14
- Assessed in Art. 12 MRL review (EFSA, 2012)

**Peanuts**
- USA
- F
- PHI: 480/700
- 14
- 2.52 kg/ha
- 14
- Alternative GAP Application by Syngenta Crop Protection

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
## Appendix B – List of end points

### B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s)       | Application(s) | Sampling (DAT) | Comment/Source                                                                                     |
|-----------------------------------|-------------|---------------|----------------|----------------|--------------------------------------------------------------------------------------------------|
| Fruit crops                       | Tomato      | 3× 2.33 kg as/ha | 1, 7, 14       |                | Foliar applications, ^14^C-phenyl labelled chlorothalonil (EFSA, 2012)                           |
|                                   |             | 1× 1.6 kg as/ha | 0, 14, 21, 28  |                |                                                                                                 |
| Root crops                        | Carrot      | 3× 1.6 kg as/ha | 1, 7, 14, 21   |                |                                                                                                 |
| Leafy crops                       | Lettuce     | 4× 1.75 kg as/ha | 1, 3, 7, 10, 14, 21 |             |                                                                                                 |
|                                   | Celery      | 12× 2.5 kg as/ha | 7, 21          |                |                                                                                                 |
| Cereals                           | Wheat       | 1× 1.0 kg as/ha | 0, 28          |                |                                                                                                 |
| Pulses/oilseeds                   | Snap beans  | 4× 2.46 kg as/ha | 7, 28          |                |                                                                                                 |
|                                   | Pea         | 1× 1.4 kg as/ha | 0, 7, 14, 30, 41 |              |                                                                                                 |

| Rotational crops (available studies) | Crop groups | Crop(s)       | Application(s) | PBI (DAT) | Comment/Source                                                                                     |
|-------------------------------------|-------------|---------------|----------------|-----------|--------------------------------------------------------------------------------------------------|
| Root/tuber crops                    | Carrot*     | * Application rate in kg/ha unknown | 30, 88 |          | * Validity pending demonstration of integrity and reliability (EFSA, 2018a)                        |
| Leafy crops                         | Lettuce*    | Wheat*        |                | 30, 88    | (Netherlands, 2017; EFSA, 2018a)                                                                  |
| Cereal (small grain)                | Wheat       | 1× 7.5 kg as/ha | 30, 120, 365   | (Netherlands, 2017; EFSA, 2018a)                                                                |
| Cereals                             | Lettuce     |               |                | 30, 120, 365 |                                                                                                 |
| Leafy crops                         | Carrot      |               |                | 30, 120, 365 |                                                                                                 |
| Root/tuber crops                    | Barley#     | 1× 1 kg as/ha | 30             | # Supportive (underdosed, low residues limiting sufficient rate of identification, 30d PBI only) (Netherlands, 2017; EFSA, 2018a) |
| Leafy crops                         | Spinach#    |               | 30             |                                                                                                 |
| Root/tuber crops                    | Radish#     |               | 30             |                                                                                                 |
| Other crops see EFSA (2012)         |             |               |                |                                                                                                 |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source                                                                 |
|------------------------------------------|------------|---------|--------------------------------------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4.5)   | Yes        | R182281 (SDS-3701) 1.9% applied radioactivity (EFSA, 2012, 2018a)            |
| Pasteurisation (20 min, 90°C, pH 6)     | Yes        | R182281 (SDS-3701): 5.3% applied radioactivity; R613636 (SDS-19221): 2.8% applied radioactivity (EFSA, 2018a) |
**Processed commodities (hydrolysis study)**

| Conditions                                      | Stable? | Comment/Source                                                                 |
|-------------------------------------------------|---------|---------------------------------------------------------------------------------|
| Baking, brewing and boiling (60 min, 100°C, pH 5°) | No      | R182281 (SDS-3701): 19%-59% applied radioactivity; R613636 (SDS-19221): 3.4%-15% applied radioactivity (EFSA, 2012, 2018a) |
| Sterilisation (20 min, 120°C, pH 6°)             | No      | R182281 (SDS-3701): 48% applied radioactivity; R613636 (SDS-19221): 23% applied radioactivity (EFSA, 2018a) |
| Sterilisation (20 min, 120°C, pH 6°)             | no      | R182281 (SDS-3701): 59% applied radioactivity; R613636 (SDS-19221): 15% applied radioactivity (EFSA, 2018a) |
| Sterilisation (20 min, 120°C, pH 4°)             | no      | R182281 (SDS-3701): 17% applied radioactivity; R613636 (SDS-19221): 2.3% applied radioactivity (EFSA, 2018a) |

- Citrate buffer; Acetate buffer.

**Can a general residue definition be proposed for primary crops?**

- Rotational crop and primary crop metabolism similar?

  - Inconclusive

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

  - Inconclusive

  - Plant residue definition for monitoring (RD-Mo)

  - MRL review (EFSA, 2012):
    1. Chlorothalonil
    2. R182281 (SDS-3701)

  - EFSA conclusion (EFSA, 2018a):
    Primary crops, processed products:
    1. Chlorothalonil (EFSA, 2012; 2018a)
    2. R182281 (SDS-3701) (EFSA, 2012; 2018a)
    Rotational crops:
    1. Chlorothalonil
    2. R182281 (SDS-3701)
    3. R611965 (SDS-46851) (if residues in rotational crops have to be monitored)

  The proposed RDs derived in the EFSA conclusion are provisional; they are applicable to all crops. Residue definition to be finalised pending upon the outcome of the assessment of outstanding data on metabolism study reporting, storage stability and toxicity for all compounds of relevance (EFSA, 2018a)

- Plant residue definition for risk assessment (RD-RA)

  - MRL review (EFSA, 2012):
    1. Chlorothalonil

www.efsa.europa.eu/efsajournal 28 EFSA Journal 2020;18(9):6239
2. R182281 (SDS-3701)

**EFSA conclusion (EFSA, 2018a):**

Primary crops:
1. Chlorothalonil and its conjugates
2. R182281 (SDS-3701) and its conjugates

Processed products:
1. Chlorothalonil and its conjugates
2. R182281 (SDS-3701) and its conjugates
3. R613636 (SDS-19221)
4. Additionally, for processed commodities, the potential inclusion of 4-amino-2,5,6-trichloroisophthalonitrile is pending the outcome of requested information

Rotational crops:
R611965 (SDS-46851)/R417888, and conjugates of metabolites R613636, R613800 (C15) and R611968

Residue definitions derived in the EFSA conclusion are provisional; to be finalised pending upon the outcome of the outstanding data on metabolism study reporting, storage stability and toxicity for all compounds of relevance and rotational crops assessment

---

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

LC–MS/MS (GRM 005.01A), LOQ 0.01 mg/kg (all crop groups) for SDS-3701 (R182281) (preferred method); LOQ 0.01 mg/kg (all crop groups) for both chlorothalonil and SDS-3701 (R182281).

Data on extraction efficiency for dry and high oil content commodities are not available (EFSA, 2018a).

GC–MS (RAM 365/02) requires methylation with trimethyl diazomethane which is not acceptable for enforcement method

---

**B.1.1.2. Stability of residues in plants**

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/ Source |
|-----------------------------------|----------|-----------|--------|-----------------|------------------|-----------------|
|                     | High water content | Tomatoes, cucumbers, carrots, banana and celery | –7 | 48 Months | Parent only | EFSA (2018a) |
|                     | Tomato | Tomatoes | –18 | 24 Months | Parent and SDS-3701 | EFSA (2018a) |
|                     |        |          | –18 | 30 Months | SDS-46851 | EFSA (2018a) |
|                     | High oil content | Olives | ≤ –18 | 24 Months | Parent and SDS-3701 | EFSA (2018a) |
|                     | Peanut oil | Peanut oil | –18 | 24 Months | R613636 | EFSA (2018a) |
| Other commodities see EFSA (2018a) | | |

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; AR: applied radioactivity; DT50: period required for 90% dissipation (define method of estimation); LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; GC–MS: gas chromatography with mass spectrometry.
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/Indoor | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) Chlorothalonil/SDS-3701 | STMR<sup>(c)</sup> (mg/kg) Chlorothalonil/SDS-3701 |
|-----------|---------------|---------------------------------------------------------------|-----------------|------------------------|-----------------------------------------------|-----------------------------------------------|
| **Bananas** | GAP Latin America (10 × 1.5 kg/ha, PHI 0 days) | MRL review: 0.11; 0.24; 0.28; 0.34; 0.59; 1.4; 1.8; 10 | – | Not specified whether trials were in bagged or unbagged bananas | 15/<sup>*</sup> | 10/<sup>*</sup> | 0.47/<sup>*</sup> |
| | New data (bagged bananas): Whole fruits: 8 × < 0.01; < 0.02; Pulp: 8 × < 0.01; < 0.02 | New submitted data Whole fruits: 9 × < 0.01 Pulp: 8 × < 0.01; 1 × < 0.02 | | Residue trials with bagged bananas (Netherlands, 2018) | 0.02*/0.01* | Whole fruit: 0.02*/0.01* Pulp: 0.02*/0.02* | Whole fruit: 0.01*/0.01* Pulp: 0.01*/0.01* |
| | New data (unbagged bananas): Whole fruits: 0.08; 0.05; < 0.01; Pulp: < 0.01; < 0.01; < 0.01 | New submitted data Whole fruits: < 0.01; < 0.01; < 0.01; < 0.01; < 0.01 Pulp: < 0.01; < 0.01 | | Residue trials with unbagged bananas. Number of trials insufficient to derive an MRL proposal for unbagged bananas | – | – | – |
| **Papaya** | GAP Brazil (6 × 1.65 kg/ha, PHI 7 days) | MRL review: Whole fruit: 1.3; 4.5; 4.9; 5.1 Peeled papaya: 0.64; –; –; 0.49 | New submitted data Whole fruit: 3 × < 0.01; 0.01 Peeled papaya: < 0.01; –; –; < 0.01 | Data on SDS-3701 were provided for the trials previously assessed by EFSA (EFSA, 2012) | 15/0.02 | Whole fruit 5.10/0.01* | Whole fruit 4.70/0.01* |
| Commodity | Region/indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | \(\text{HR}^{(b)}\) (mg/kg) | \(\text{STMR}^{(c)}\) (mg/kg) |
|-----------|------------------------|---------------------------------------------------------------|----------------|----------------------|----------------------|----------------------|
| Peanuts   | GAP USA (8 × 1.2 kg/ha, PHI 14 days) | Chlorothalonil 0.01; 2 × 0.01; 12 × < 0.03; 0.05; < 0.1 | No information on the residue concentration of SDS-3701 was provided (EFSA, 2012) | 0.1/– | 0.1/– | 0.03/– |
|           | Re-submitted data 13 × < 0.01 | SDS-3701 New submitted data 13 × < 0.01 | 13 of the residue trials submitted previously (EFSA, 2012) were re-submitted, providing information on SDS-3701. The EMS verified the correctness of the results of the re-submitted residue trials which differed from the results in the MRL review (EFSA, 2012) | \(0.01^*/0.01^*\) | \(0.01^*/0.01^*\) | \(0.01^*/0.01^*\) |

MRL: maximum residue level; GAP: Good Agricultural Practice.
*: 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.
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Yes | Not relevant for this assessment. An assessment was performed during the recent renewal assessment (EFSA, 2018a) |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Yes | Not relevant for this assessment. An assessment was performed during the recent renewal assessment (EFSA, 2018a) |

B.1.2.3. Processing factors

| Processed commodity                  | Number of valid studies\(a\) | Processing Factor (PF)                          | \(\text{CF}_p\)\(b\) | Comment/Source                                                                 |
|--------------------------------------|-------------------------------|------------------------------------------------|-----------------------|--------------------------------------------------------------------------------|
| Banana, peeled                       | 8                             | Individual PFs chlorothalonil: \(<0.02; 0.02; 0.04; 0.05; 0.06; 0.08; 0.09; 0.15\) | 1                     | PF based on chlorothalonil only; metabolite SDS-3701 residues in whole fruit and pulp \(<0.01\ \text{mg/kg}\). It was not specified whether data were derived from bagged or unbagged bananas (EFSA, 2012) |
|                                      |                               | Individual PFs SDS-3701: \(8 \times \leq 1\) |           |                                                                                |
|                                      |                               | Median PF chlorothalonil: \(0.06\) |           |                                                                                |
|                                      |                               | Median PF SDS-3701: \(\leq 1\) |           |                                                                                |
| Banana, peeled (bagged)              | 9                             | Individual PFs chlorothalonil: \(9 \times \leq 1\) | 1                     | New residue data on bagged bananas (see Table B.1.2.1 above) (Netherlands, 2018) |
|                                      |                               | Median PF chlorothalonil: \(\leq 1\) |           | No quantifiable residues in pulp and in whole fruit. No indication of accumulation for chlorothalonil and SDS-3701 |
|                                      |                               | Median PF SDS-3701: \(9 \times \leq 1\) |           |                                                                                |
|                                      |                               | Median PF SDS-3701: \(\leq 1\) |           |                                                                                |
| Banana, peeled (unbagged)           | 3                             | Individual PFs chlorothalonil: \(0.125; 0.20; \leq 1\) | 1                     | New residue data on unbagged bananas (see Table B.1.2.1 above) (Netherlands, 2018) |
|                                      |                               | Median PF chlorothalonil: \(0.2\) |           | Quantifiable residues only in two samples on whole fruit. No indication of accumulation for chlorothalonil and SDS-3701 |
|                                      |                               | Median PF SDS-3701: \(3 \times \leq 1\) |           |                                                                                |
|                                      |                               | Median PF SDS-3701: \(\leq 1\) |           |                                                                                |
| Papaya, peeled                       | 2                             | Individual PFs chlorothalonil: \(0.10; 0.49\) | 1                     | Tentative\(c\) PF based on chlorothalonil only; metabolite SDS-3701 residues in whole fruit and pulp were below the LOQ of \(<0.01\ \text{mg/kg}\) (EFSA, 2012) |
|                                      |                               | Individual PFs SDS-3701: \(2 \times \leq 1\) |           | Number of processing studies is insufficient to derive a reliable PF |
|                                      |                               | Median PF chlorothalonil: \(0.3\) |           |                                                                                |
|                                      |                               | Median PF SDS-3701: \(\leq 1\) |           |                                                                                |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial. During the renewal assessment, a data gap was set for a conversion factor for SDS-3701 (EFSA, 2018a).

(c): A tentative PF is derived based on a limited data set.
### B.2. Residues in livestock

Updated dietary burden calculation according to OECD, 2013 for chlorothalonil.

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup(s) | Most critical commodity | Trigger exceeded (Y/N) | Previous assessment Max. burden (mg/kg DM) |
|-----------------------------|----------------------------|---------------------------|-------------------------|------------------------|------------------------------------------|
|                             | mg/kg bw per day mg/kg DM |                           |                         |                        |                                          |
|                             | Median Maximum               | Median Maximum             |                         |                        |                                          |
| Cattle (all diets)          | 0.000 0.000 0.00 0.00       | Beef cattle               | Peanut meal             | N                      | 10.95                                    |
| Cattle (dairy only)         | 0.000 0.000 0.00 0.00       | Dairy cattle               | Peanut meal             | N                      | 5.73                                     |
| Sheep (all diets)           | 0.000 0.000 0.00 0.00       | Lamb                      | Peanut meal             | N                      | –                                        |
| Sheep (ewe only)            | 0.000 0.000 0.00 0.00       | Ram/Ewe                   | Peanut meal             | N                      | –                                        |
| Swine (all diets)           | 0.000 0.000 0.00 0.00       | Swine (finishing)         | Peanut meal             | N                      | 1.74                                     |
| Poultry (all diets)         | 0.000 0.000 0.00 0.00       | Turkey                    | Peanut meal             | N                      | 0.72                                     |
| Poultry (layer only)        | 0.000 0.000 0.00 0.00       | Poultry layer             | Peanut meal             | N                      | –                                        |
| Fish                        | n.a.                        |                           |                         |                        |                                          |

bw: body weight; DM: dry matter; n.a.: not applicable.

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

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

Dietary burden calculated for SDS-3701 was negligible, similar to the dietary burden of chlorothalonil (see Table above).
### B.3. Consumer risk assessment

#### Chlorothalonil

| ARfD             | 0.05 mg/kg bw (EFSA, 2018a) |
|------------------|-----------------------------|
| Highest IESTI    | Papaya: 433% of ARfD (without peeling)  
                  | 130% of ARfD (with tentative peeling factor)  
                  | Banana: 4% of ARfD  
                  | Peanuts: 0.06% of ARfD  
                  | Peanut butter: 0.1% of ARfD |
| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in raw agricultural commodities under assessment.  
|                  | Calculations with PRIMo rev. 3.1 |
| ADI              | 0.015 mg/kg bw per day (EFSA, 2018a) |
| Highest IEDI, according to EFSA PRIMo | 0.8% ADI  
                  | Contribution of crops assessed:  
                  | Banana: 0.36% of ADI (NL toddler)  
                  | Papaya: 0.5% of ADI (SE general)  
                  | Peanuts: 0.02% of ADI (NL child) |
| Assumptions made for the calculations | The calculation is based on the median residue levels derived for the raw agricultural commodities under assessment and for a previously assessed import tolerance (cranberries (EFSA, 2015)).  
|                  | EU uses which were previously assessed (EFSA, 2012) have not been taken into account, considering that these uses had to be withdrawn following the non-approval of chlorothalonil |

#### Metabolite SDS-3701

| ARfD             | Not established (EFSA, 2018a);  
                  | No risk assessment could be performed. |
| ADI              | Not established (EFSA, 2018a);  
                  | No risk assessment could be performed. |

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

| Code(a) | Commodity        | Existing MRL Chlorothalonil(b) | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation                                                                                                                                 |
|---------|------------------|-------------------------------|-----------------------------|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0130000 | Pome fruit       | 2 (ft1)                       | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised SEU GAP. Uses in third countries have not been reported.                                          |
|         |                  |                               |                             |                       | Codex MRL (CXL) is not in place for pome fruits.                                                                                                          |
|         |                  |                               |                             |                       | Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered.                           |
| 0140010 | Apricots         | 1 (ft1)                       | 0.01*                       | 0.01*                 | The existing MRL is based on the previously authorised SEU GAP.                                                                                         |
| 0140030 | Peaches          |                               |                             |                       | Uses in third countries have not been reported.                                                                                                          |
|         |                  |                               |                             |                       | CXL: 1.5 mg/kg (set by Codex Alimentarius Commission (CAC) in 2016, EU reservation because a separate residue definition for SDS-3701 is considered necessary(c)); |
|         |                  |                               |                             |                       | Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered.                           |
| 0151000 | Table and wine   | 3 (ft2)                       | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised NEU GAPs.                                                                                           |
|         | grapes           |                               |                             |                       | Uses in third countries have not been reported.                                                                                                          |
| 0152000 | Strawberries     | 4 (ft2)                       | 0.01*                       | 0.01*                 | CXLs for grapes (3 mg/kg chlorothalonil), strawberries (5 mg/kg chlorothalonil) and gooseberries (20 mg/kg chlorothalonil) were already in place when the MRL review was performed. Data on SDS-3701 demonstrated that significant residues of the metabolite cannot be excluded for grapes (HR: 0.15 mg/kg); in strawberries and gooseberries residues of SDS-3701 were not analysed(c); Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0154040 | Gooseberries     | 15 (ft2)                      | 0.01*                       | 0.01*                 |                                                                                                                                                         |
| 0163020 | Bananas          | 0.15 (ft3)                    | 0.02* Further risk management considerations required | 0.01*                 | Label information for Latin American countries was provided for Mexico and Brazil, which did not match with the use pattern of the residue trials submitted in support of the application. Based on the submitted trials in bagged bananas, a tentative MRL proposal was derived. For unbagged bananas, the number of trials was insufficient. Further risk management considerations are required whether setting of an MRL at the level of the highest LOQ of the available residue trials in bagged bananas is appropriate Chlorothalonil MRLs in Latin American countries: 15 mg/kg in Costa Rica, 3 mg/kg in Brazil, 0.2 mg/kg pulp in Argentina and 0.01 mg/kg in Chile CXL: 15 mg/kg (set by CAC in 2013, EU reservation because of concerns on metabolite SDS-3701(c)). |

**Existing enforcement residue definition for plants and animals**: Chlorothalonil

**Additional residue definitions for enforcement for plants**: R182281 (SDS-3701) (proposed in the MRL review, not yet implemented)
| Code<sup>(a)</sup> | Commodity | Existing MRL Chlorothalonil<sup>(b)</sup> | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation |
|-------------------|-----------|---------------------------------|-----------------------------|----------------------|--------------------------------|
| 0163040 Papaya    | 15 (ft 3) | 0.01*                           | 0.01*                       | Residue data on chlorothalonil and SDS-3701 were provided reflecting the authorised GAP in Brazil (calculated MRL for chlorothalonil: 15 mg/kg, SDS-3701: 0.02 mg/kg) For chlorothalonil, an acute consumer health risk could not be excluded. The tolerance established in the US and Brazil is 15 mg/kg CXL: 20 mg/kg chlorothalonil (set by CAC in 2011, no EU reservation was noted) The lowering of the existing MRL to the LOQ should be considered |
| 0211000 Potatoes  | 0.01 (ft 3) | 0.01*                          | 0.01*                       | The existing MRL reflects the previously authorised NEU/SEU GAPs Uses in third countries have not been reported Codex MRL is not in place for potatoes Following the non-approval of chlorothalonil in the EU, the MRL at the LOQ of 0.01 mg/kg is appropriate |
| 0213020 Carrots   | 0.3 (ft 3) | 0.01*                           | 0.01*                       | The existing MRL reflects the previously authorised NEU/SEU GAP Uses in third countries have not been reported Codex MRL is not in place for carrots Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
| 0213030 Celeriac  | 1 (ft 3)  | 0.01*                           | 0.01*                       | The existing MRL reflects the previously authorised NEU GAP Uses in third countries have not been reported Codex MRLs are not in place for celeriac Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
| 0213040 Horseradishes | 0.3 (ft 3) | 0.01*                           | 0.01*                       | The existing MRL reflects the previously authorised NEU/SEU GAP Uses in third countries have not been reported CXL: 1 mg/kg for chlorothalonil, set by CAC 2016; EU reservation because of their concern on metabolite SDS-3701 Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
| 0213060 Parsnips  | 0.3 (ft 3) | 0.01*                           | 0.01*                       | The existing MRLs reflect the previously authorised NEU/SEU GAP Uses in third countries have not been reported CXL: 0.3 mg/kg for chlorothalonil set by CAC 2016. EU reservation because a separate residue definition for SDS-3701 is considered necessary Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
| Code | Commodity       | Existing MRL Chlorothalonil | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation                                                                                                                                 |
|------|-----------------|-----------------------------|-----------------------------|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0213110 | Turnips         | 0.3 (ft 1)                  | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised SEU GAP. Uses in third countries have not been reported.
CXL of 0.3 mg/kg for chlorothalonil set by CAC 2016. EU reservation because a separate residue definition for SDS-3701 is considered necessary.
Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0220010 0220020 0220030 | Garlic Onions Shallots | 0.01* (ft 3) | 0.01* | 0.01* | The existing MRL reflects the previously authorised NEU/SEU GAPs.
Uses in third countries have not been reported.
No Codex MRL for garlic; for onions, bulb and shallots CXL of 1.5 mg/kg (set by CAC 2016. EU reservation because a separate residue definition for SDS-3701 is considered necessary).
Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0220040 | Spring onions   | 10 (ft 3)                   | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised NEU/SEU GAP.
Uses in third countries have not been reported.
CXL of 10 mg/kg chlorothalonil (set by CAC 2016. EU reservation because a separate residue definition for SDS-3701 is considered necessary).
Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0231010 | Tomatoes        | 6 (ft 3)                    | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised EU indoor GAP.
Uses in third countries have not been reported.
CXL: 5 mg/kg for chlorothalonil (set by CAC 2016. EU reservation not explicitly mentioned in CCPR report).
Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0231030 | Aubergines      | 6 (ft 3)                    | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised EU indoor GAP.
Uses in third countries have not been reported.
Codex MRL is not in place for aubergines.
Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| Code(a) | Commodity          | Existing MRL Chlorothalonil(b) | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation                                                                                                                                 |
|---------|--------------------|-------------------------------|-----------------------------|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0232000 | Cucurbits-      | 5 (ft 3)                      | 0.01*                       | 0.01*                | The existing MRL reflects the previously authorised EU indoor GAP Uses in third countries have not been reported CXL: 3 mg/kg for chlorothalonil in cucumber, gherkins and courgettes (set by CAC 2011. EU reservation for cucumber (insufficient data set), gherkins, and summer squash (extrapolation practice of JMPR was not agreed by EU) Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
|         | edible peel       |                               |                             |                      |                                                                                                                                                           |
| 0233000 | Cucurbits       | 1 (ft 3)                      | 0.01*                       | 0.01*                | The existing MRL reflects the previously authorised EU indoor/SEU GAP Uses in third countries have not been reported CXL: 2 mg/kg for chlorothalonil for melons (set by CAC 2011; EU reservation because extrapolation practice of JMPR was not agreed by EU) Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
|         | (inedible peel)  |                               |                             |                      |                                                                                                                                                           |
| 0241020 | Cauliflower      | 2 (ft 3)                      | 0.01*                       | 0.01*                | The existing MRL reflects the previously authorised NEU/SEU GAP Uses in third countries have not been reported CXL: 5 mg/kg for chlorothalonil (set by CAC in 2011; no EU reservation was noted) Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
| 0242010 | Brussels sprouts | 3 (ft 3)                      | 0.01*                       | 0.01*                | The existing MRL reflects the previously authorised NEU GAP Uses in third countries have not been reported CXL: 6 mg/kg for chlorothalonil (set by CAC in 2011; EU reservation because a lower MRL of 0.5 mg/kg was suggested when using the OECD calculator) Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
| 0242020 | Head cabbage     | 0.6 (ft 1)                    | 0.01*                       | 0.01*                | The existing MRL reflects the previously authorised SEU GAP Uses in third countries have not been reported Codex MRL is not in place for head cabbage Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
| 0256030 | Celery leaves    | 5 (ft 3)                      | 0.01*                       | 0.01*                | The existing MRLs reflect the previously authorised NEU GAPs Uses in third countries have not been reported Codex MRLs are not in place for celery leaves and parsley Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered |
| 0256040 | Parsley          |                               |                             |                      |                                                                                                                                                           |
| Code        | Commodity         | Existing MRL Chlorothalonil(b) | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation                                                                                                                                                                                                                                                                  |
|------------|-------------------|-------------------------------|----------------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0260010    | Beans (with pods) | 5 (ft 3)                      | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for beans with pods. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered.                                                  |
| 0260020    | Beans (without pods) | 3 (ft 3)                      | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for beans without pods. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered.                                |
| 0260030    | Peas (with pods)  | 5 (ft 3)                      | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for peas with pods. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered.                                      |
| 0260040    | Peas (without pods) | 1 (ft 1)                      | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised SEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for peas without pods. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered.                                        |
| 0260050    | Lentils           | 0.6 (ft 3)                    | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for lentils. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered.                                        |
| 0270010    | Asparagus         | 0.01* (ft 3)                  | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised NEU/SEU GAPs. Uses in third countries have not been reported. Codex MRL is not in place for asparagus. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered.                                  |
| 0270030    | Celeris           | 10 (ft 3)                     | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for celeris. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered.                                   |
| Code       | Commodity   | Existing MRL Chlorothalonil | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation                                                                                                                                 |
|------------|-------------|-----------------------------|----------------------------|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0270060    | Leeks       | 8 (ft 1)                    | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised SEU GAP. Uses in third countries have not been reported. CXL: 40 mg/kg (EFSA, 2011) (EU reservation in CCPR: The EU requested JMPR to perform a short-term dietary risk assessment for leeks). Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0280010    | Cultivated fungi | 0.5 (ft 3)                 | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised EU indoor GAP. Uses in third countries have not been reported. Codex MRL is not in place for cultivated fungi. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0300010    | Beans       | 3 (ft 3)                    | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for beans. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0300020    | Lentils     | 0.2 (ft 3)                  | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for lentils. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0300030    | Peas        | 1 (ft 3)                    | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised SEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for peas. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0300040    | Lupins      | 0.2 (ft 3)                  | 0.01*                      | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for lupins. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
### Evaluation of confirmatory data following the Article 12 MRL review for chlorothalonil

| Code<sup>(a)</sup> | Commodity       | Existing MRL Chlorothalonil<sup>(b)</sup> | Proposed MRL Chlorothalonil | Proposed MRL SDS-3701 | Conclusion/recommendation                                                                                                                                                                                                                                                                                                                                 |
|---------------|-----------------|-------------------------------------------|-----------------------------|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0401020       | Peanuts         | 0.1 (< ft 3)                              | 0.01*                       | 0.01*                 | In response to the confirmatory data request, the applicant submitted 13 trials for chlorothalonil and SDS-3701, representative for the US GAP. Residues were below the LOQ of 0.01 mg/kg for both residue definitions. A US tolerance for peanuts of 0.3 mg/kg is established. Existing CXL: 0.1 mg/kg chlorothalonil (EFSA, 2011). Analytical method for SDS-3701: data gap on extraction efficiency not addressed. |
| 0500010       | Barley          | 0.4 (< ft 3)                              | 0.01*                       | 0.01*                 | The existing MRLs reflect the previously authorised SEU GAP. Uses in third countries have not been reported. Codex MRLs are not in place for barley and oats. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0500090       | Oats            | 0.4 (< ft 3)                              | 0.01*                       | 0.01*                 | The existing MRLs reflect the previously authorised SEU GAP. Uses in third countries have not been reported. Codex MRLs are not in place for barley and oats. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0500070       | Rye             | 0.1 (< ft 3)                              | 0.01*                       | 0.01*                 | The existing MRLs reflect the previously authorised SEU GAP. Uses in third countries have not been reported. Codex MRLs are not in place for rye and wheat. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |
| 0700000       | Hops (dried)    | 60 (< ft 4)                               | 0.01*                       | 0.01*                 | The existing MRL reflects the previously authorised NEU GAP. Uses in third countries have not been reported. Codex MRL is not in place for hops. Following the non-approval of chlorothalonil in the EU, the lowering of the existing MRL to the LOQ should be considered. |

### Residue definitions for enforcement for animal commodities: SDS-3701 (R182281)

| Code<sup>(a)</sup> | Commodity  | Existing MRL SDS-3701 | Proposed MRL SDS-3701 | Conclusion/recommendation                                                                                                                                                                                                                                                                                                                                  |
|-------------------|------------|-----------------------|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1011010           | Swine muscle | 0.02 (< ft 5)        | 0.01*                 | Considering the withdrawal of EU uses in feed, the dietary burden was re-calculated. The requested confirmatory data (a study investigating metabolism of chlorothalonil and metabolite SDS-3701 in pigs) are no longer relevant, since the dietary burden was below the trigger value. The lowering of the existing MRL to the LOQ should be considered. Codex MRLs of 0.02 mg/kg in place for swine meat; lacking data on the toxicological profile of SDS-3701, the consumer risk assessment for this CXL cannot be performed. In addition, the commodity description of the EU and Codex are not compatible (meat vs. muscle). |
Table 1:

| Code(a) | Commodity       | Existing MRL SDS-3701 | Proposed MRL SDS-3701 | Conclusion/recommendation                                                                 |
|--------|-----------------|------------------------|-----------------------|------------------------------------------------------------------------------------------|
| 1011020| Swine fat       | 0.07 (ft 5)            | 0.01*                 | Considering the withdrawal of EU uses in feed, the dietary burden was re-calculated. The requested confirmatory data (a study investigating metabolism of chlorothalonil and metabolite SDS-3701 in pigs) are no longer relevant, since the dietary burden was below the trigger value. The lowering of the existing MRL to the LOQ should be considered. Codex MRLs of 0.07 mg/kg in place for swine fat; lacking data on the toxicological profile of SDS-3701, the consumer risk assessment for this CXL cannot be performed. |
| 1011030| Swine liver     | 0.2 (ft 5)             | 0.01*                 | Considering the withdrawal of EU uses in feed, the dietary burden was re-calculated. The requested confirmatory data (a study investigating metabolism of chlorothalonil and metabolite SDS-3701 in pigs) are no longer relevant, since the dietary burden was below the trigger value. The lowering of the existing MRL to the LOQ should be considered. Codex MRLs of 0.2 mg/kg in place for liver and kidney; lacking data on the toxicological profile of SDS-3701, the consumer risk assessment for this CXL cannot be performed. |
| 1011040| Swine kidney    |                        |                       |                                                                                          |
| 1011050| Swine edible offal |                       |                       |                                                                                          |
| 1016000| (f) Poultry     | 0.01*(ft 5)            | 0.01*                 | Considering the withdrawal of EU uses in feed, the dietary burden was re-calculated. The requested confirmatory data (a study investigating metabolism of chlorothalonil and metabolite SDS-3701 in pigs) are no longer relevant, since the dietary burden was below the trigger value. The existing MRL should be maintained at the LOQ. Codex MRLs of 0.01* mg/kg in place for bird eggs. |
| 1030000| (iii) Bird eggs |                        |                       |                                                                                          |

*: Indicates that the MRL is proposed at the 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.

(c): Risk management decision is required as regards the CXL, considering also the lack of information on the genotoxicity of metabolites/degradation products that may be formed during processing.

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 29 October 2016, or, if that information is not submitted by that date, the lack of it. Moreover, the European Food Safety Authority highlights that the metabolite 2,5,6-trichloro-4-hydroxyphthalonitrile (SDS-3701) has not been taken into account, given that a validated method for enforcement, a complete set of residues trials, storage stability studies and data on processing of SDS-3701, are unavailable for all plant commodities. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1, 2, 3, 4, 9, 10, 11, 12, 13, 14).

ft 2: The European Food Safety Authority identified some information on storage stability 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 29 October 2016, or, if that information is not submitted by that date, the lack of it. Moreover, the European Food Safety Authority highlights that the metabolite 2,5,6-trichloro-4-hydroxyphthalonitrile (SDS-3701) has not been taken into account, given that a validated method for enforcement, a complete set of residues trials, storage stability studies and data on processing of SDS-3701, are unavailable for all plant commodities. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1, 2, 3, 4, 8).

ft 3: The European Food Safety Authority highlights that the metabolite 2,5,6-trichloro-4-hydroxyphthalonitrile (SDS-3701) has not been taken into account, given that a validated method for enforcement, a complete set of residues trials, storage stability studies and data on processing of SDS-3701, are unavailable for all plant commodities. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1, 2, 3, 4).

ft 4: The European Food Safety Authority identified some information on analytical methods and 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 29 October 2016, or, if that information is not submitted by that date, the lack of it. Moreover, the European Food Safety Authority highlights that the metabolite 2,5,6-trichloro-4-hydroxyphthalonitrile (SDS-3701) has not been taken into account, given that a validated method for enforcement, a complete set of
residues trials, storage stability studies and data on processing of SDS-3701, are unavailable for all plant commodities. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 7, 15).

ft 5: The European Food Safety Authority identified some information on pigs metabolism and in TRR in poultry commodities 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 29 October 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 5, 6).
### Chlorothalonil (R)

#### Input values

**Toxicological reference values**

| LOQs (mg/kg) | Range | Source of ADI | Source of ARfD |
|--------------|-------|---------------|---------------|
| 0.01 - 0.05  |       | EFSA          | EFSA          |

#### Year of evaluation

- **2018**

#### No of diets exceeding the ADI

- **---**

#### Substances

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|--------------------------------|----------------------------------|---------------------------------------------|
| Bananas                        | 0.8%                             | 0.12                                         |
| Peanuts/groundnuts             | 0.7%                             | 0.11                                         |
| Bananas                        | 0.7%                             | 0.11                                         |
| Bananas                        | 0.6%                             | 0.09                                         |
| Bananas                        | 0.5%                             | 0.06                                         |
| Bananas                        | 0.4%                             | 0.05                                         |
| Bananas                        | 0.3%                             | 0.01                                         |
| Bananas                        | 0.2%                             | 0.01                                         |
| Bananas                        | 0.1%                             | 0.01                                         |
| Peanuts/groundnuts             | 0.1%                             | 0.01                                         |

#### Calculated exposure (% of ADI)

| Commodity/group of commodities | Exposure resulting from |
|--------------------------------|------------------------|
| Bananas                        | 0.8%                   |
| Peanuts/groundnuts             | 0.7%                   |

### Refined calculation mode

### Chronic risk assessment: JMPR methodology (IEDI/TMDI)

#### Input values

| Commodity/group of commodities | SE general | GEMS/Food G10 | DE child | GEMS/Food G06 | NL child | DE adult | GEMS/Food G11 | FR adult | LT adult | DE women 14-50 yr | FI 6 yr |
|--------------------------------|------------|---------------|----------|---------------|----------|----------|---------------|----------|----------|-------------------|---------|
| Bananas                        | 0.8%       | 0.7%          | 0.6%     | 0.5%          | 0.4%     | 0.3%     | 0.2%          | 0.1%     | 0.1%     | 0.0%              | 0.0%    |
| Peanuts/groundnuts             | 0.7%       | 0.6%          | 0.5%     | 0.4%          | 0.3%     | 0.2%     | 0.1%          | 0.0%     | 0.0%     | 0.0%              | 0.0%    |
| Bananas                        | 0.6%       | 0.5%          | 0.4%     | 0.3%          | 0.2%     | 0.1%     | 0.0%          | 0.0%     | 0.0%     | 0.0%              | 0.0%    |
| Bananas                        | 0.5%       | 0.4%          | 0.3%     | 0.2%          | 0.1%     | 0.0%     | 0.0%          | 0.0%     | 0.0%     | 0.0%              | 0.0%    |
| Bananas                        | 0.4%       | 0.3%          | 0.2%     | 0.1%          | 0.0%     | 0.0%     | 0.0%          | 0.0%     | 0.0%     | 0.0%              | 0.0%    |

#### Conclusions

- **RO general**
- **FR infant**
- **IE child**
- **Peanuts/groundnuts**
- **FRUIT AND TREE NUTS**

#### Comments

- The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
- The long-term intake of residues of Chlorothalonil (R) is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Unprocessed commodities

#### Results for children

| Commodity               | ARfD/ADI Input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------------------|------------------------|---------------------|-----------------------|
| Papayas                 | 15/5.1                 | 216                 | 43%                   |
| Cranberries            | 5/5.4                  | 24                  | 48%                   |
| Bananas                | 0.02/0.02              | 1.9                 | 4%                    |
| Peanuts/groundnuts     | 0.01/0.01              | 0.03                | 0.06%                 |

#### Results for adults

| Commodity               | ARfD/ADI Input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------------------|------------------------|---------------------|-----------------------|
| Papayas                 | 15/5.1                 | 71                  | 144%                  |
| Cranberries            | 5/5.4                  | 6.1                 | 12%                   |
| Bananas                | 0.02/0.02              | 0.42                | 0.8%                  |
| Peanuts/groundnuts     | 0.01/0.01              | 0.02                | 0.05%                 |

#### Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

**Results for children:** 1 commodity exceeding ARfD/ADI

**Results for adults:** 1 commodity exceeding ARfD/ADI

---

### Processed commodities

#### Results for children

| Commodity               | ARfD/ADI Input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------------------|------------------------|---------------------|-----------------------|
| Cranberries/juice       | 5/3.15                 | 18                  | 36%                   |
| Peanuts/peanut butter   | 0.01/0.01              | 0.04                | 0.1%                  |

#### Results for adults

| Commodity               | ARfD/ADI Input (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------------------|------------------------|---------------------|-----------------------|
| Cranberries/dried       | 5/3.15                 | 2.4                 | 5%                    |

---

**Conclusion:**

The estimated short-term intake (IESTI) exceeded the toxicological reference value for 1 commodities.

For processed commodities, no exceedance of the ARfD/ADI was identified.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

| Feed commodity | Median dietary burden | Maximum dietary burden |
|----------------|-----------------------|------------------------|
|                | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment |
| Risk assessment residue definition 1: chlorothalonil | | | | |
| Peanuts        | 0.01* STMR(a)         | 0.01* STMR(a)          | | |
| Risk assessment residue definition 2: SDS-3701 | | | | |
| Peanuts        | 0.01* STMR(a)         | 0.01* STMR(a)          | | |

STMR: supervised trials median residue.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): For peanuts, no default processing factor was applied because chlorothalonil is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

D.2. Consumer risk assessment

| Commodity       | Chronic risk assessment | Acute risk assessment |
|-----------------|-------------------------|-----------------------|
|                 | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| Risk assessment residue definition 1: chlorothalonil | | | | |
| Cranberries     | 3.15 EFSA (2015)        | 5.4 EPSC (2015)       | | |
| Bananas         | 0.01 STMR               | 0.02 HR               | | |
| Papayas         | 4.7 STMR (whole fruit)(b) | 5.1x0.3 HR (whole fruit)(b) | | |
| Peanuts/groundnuts | 0.01 STMR            | 0.01 STMR             | | |
| Risk assessment residue definition 2: SDS-3701 | | | | |
| Cranberries     | 0.02 EFSA (2015)        | 0.02 EPSC (2015)      | | |
| Bananas         | 0.01 STMR               | 0.01 HR               | | |
| Papayas         | 0.01 STMR               | 0.01 HR               | | |
| Peanuts         | 0.01 STMR               | 0.01 STMR             | | |

STMR: supervised trials median residue; HR: highest residue.
(a): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticide, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat, respectively (FAO, 2016).
(b): EFSA also calculated an indicative risk assessment for peeled papayas including the tentative peeling factor of 0.3 (see Section 3.2).
### Appendix E – Used compound codes

| Code/Trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|---------------------------------------|-----------------------|
| chlorothalonil       | Tetrachloroisophthalonitrile            | ![chlorothalonil](image) |
|                      | CRQGFGEAVJUL-UHFFFAOYSA-N              |                       |
|                      | Clc1(c(C#N)(c(Cl)c(c(C#N)(c(Cl)c1Cl       |                       |
| SDS-3701             | 2,4,5-trichloro-6-hydroxybenzene-1,3-dicarbonitrile | ![SDS-3701](image) |
| (R182281)            | Clc1(c(C#N)(c(Cl)c(c(C#N)(c(Cl)c1Cl       |                       |
|                      | MDQKYGOECVSPISW-UHFFFAOYSA-N            |                       |
| SDS-46851            | 3-carbamoyl-2,4,5-trichlorobenzoic acid  | ![SDS-46851](image) |
| (R611965)            | Clc1(c(N)=O)(c(Cl)c(cc1Cl)c(=O)O          |                       |
|                      | XKFUETYLBPNKF-UHFFFAOYSA-N              |                       |
| R613636              | 2,3,4,6-tetrachloro-5-cyanobenamide     | ![R613636](image) |
| SDS-47525            | XTFCOCGBWMNRKW-UHFFFAOYSA-N             |                       |
| M14                  | Clc1(c(N)=O)(c(Cl)c(c(C#N)(c(Cl)c1Cl       |                       |
| SDS-19221            | 2,4,5-trichloro-3-cyano-6-hydroxybenzamide | ![SDS-19221](image) |
| R2                   | Clc1(c(N)=O)(c(Cl)c(=O)c1Cl)(c(N)=O)      |                       |
| Compound 3           | CSPC548417                              |                       |
| R611968              | 2,4,5-trichloro-3-cyano-6-hydroxybenzamide | ![R611968](image) |
| M9                   | Clc1(c(C#N)(c(Cl)c(=O)c1Cl)(c(N)=O)      |                       |
| SDS-47525            | IODGSSFOOWTXKAE-UHFFFAOYSA-N            |                       |
| R5                   | 3-carbamoyl-2,4,5-trichlorobenzoic acid  | ![R611965](image) |
| R611965              | Clc1(c(N)=O)(c(Cl)c(cc1Cl)c(=O)O          |                       |
| M5                   | XKFUETYLBPNKF-UHFFFAOYSA-N              |                       |
| SDS-46851            | 3-carbamoyl-2,4,5-trichlorobenzoic acid  | ![R611965](image) |
| R14                  | Clc1(c(N)=O)(c(Cl)c(cc1Cl)c(=O)O          |                       |
| Compound 4           | XKFUETYLBPNKF-UHFFFAOYSA-N              |                       |

---

www.efsa.europa.eu/efsajournal 47 EFSA Journal 2020;18(9):6239
| Code/Trivial name\(^{(a)}\) | IUPAC name/SMILES notation/InChiKey\(^{(b)}\) | Structural formula\(^{(c)}\) |
|-----------------------------|-------------------------------------------------|-----------------------------|
| R417888 M12 VIS01 R6 U6 CSCC890840 | 2-carbamoyl-3,5,6-trichloro-4-cyanobenzene-1-sulfonic acid  
Clc1c(C#N)c(Cl)c(c(c1Cl)S(=O)(=O)O)C(N)=O  
JNMMKKYUIIPDG-UHFFFAOYSA-N | ![Structural formula](image1.png) |
| R613800 C15 | 2,5-dichloro-4,6-bis(sulfanyl)benzene-1,3-dicarbonitrile  
Sc1c(C#N)c(Cl)c(C#N)c(S)c1Cl  
XVWDIYOGTSEICK-UHFFFAOYSA-N | ![Structural formula](image2.png) |

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

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