|  |
| --- |
| REGISTRATION REPORT  Part A  Risk Management |
| Product code: ADM.09250.H.1.A  Product name: 2,4-D 95 SP  Chemical active substance:  2,4-dichlorophenoxy acetic acid, 80.4% or 804 g/kg |
| Central Zone  Zonal Rapporteur Member State: Poland |
| NATIONAL ASSESSMENT Poland  (authorization) |
| Applicant: XXXX  Sponsor: XXXX  Submission date: March 2023  Evaluation date: December 2023  MS Finalisation date: March 2024 |

Version history

|  |  |
| --- | --- |
| When | What |
| March 2023 | 1st applicant version |
| December 2023 | Initial version of RR |
|  |  |
|  |  |

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PART A

RISK MANAGEMENT

# Details of the application

This is an application from XXXX for the registration of ADM.0950.H.1.A (containing 2,4-D (950 g/kg as sodium salt monohydrate) formulated as an SP), according to Art 33 of Regulation (EC) N° 1107/2009, to be used as an herbicide in spring wheat.

Part of this assessment is based on the ongoing evaluation by the Polish Authority of ADM.3304.H.1.A / Tricera.

## Application background

The submission is made to the Central zone, ZRMS and only cMS Poland.

## Letters of Access

The newly submitted studies are owned by XXXX so no Letter of Access were included in this submission.

## Justification for submission of tests and studies

The formulation toxicity studies provided were generated in 2011 to support registration outside of the EU, thus are provided and summarised for information only.  In accordance with paragraph 69 of [2019/C 229/01 Commission Notice — Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Feur-lex.europa.eu%2Flegal-content%2FEN%2FTXT%2FPDF%2F%3Furi%3DOJ%3AC%3A2019%3A229%3AFULL%26from%3DEN&data=05%7C01%7Cclaudia.studart%40erm.com%7Cfa6067f74e6041cb8c0408daf491c249%7Cf2fe6bd39c4a485bae69e18820a88130%7C0%7C0%7C638091204109542388%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=V%2F4sS90W6AlOoIGaLItSnVdRVuYPrUCNrH8EG18%2FVsA%3D&reserved=0), full details of product classification using the calculation method are given in Part C, and outcomes reported in B6.

## Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4. The period of protection for eligible studies should be for 10 years from the date of authorization in each Member State.

# Details of the authorization decision

## Product identity

| Product code | ADM.09250.H.1.A |
| --- | --- |
| Product name in MS | Pielik 95 SP |
| Authorization number | To be confirmed |
| Function | herbicide |
| Applicant | XXXX |
| Active substance(s)  (incl. content) | 2,4-D; 804 g/kg |
| Formulation type | Soluble Powder [SP] |
| Packaging | PET12/MPET12/LLDPE  professional use |
| Coformulants of concern for national authorizations | None |
| Restrictions related to identiy | Dioxins and furans: free phenols (expressed as 2,4 DCP): not more than 3 g/kg  TCDD toxic equivalents /TEQ): not more than 10 µg/kg. |
| Mandatory tank mixtures | None |
| Recommended tank mixtures | None |

## 

## Conclusion

The evaluation of the application for ADM.09250.H.1.A resulted in the decision to grant the authorization. All uses applied for were authorised (see 2.6).

## Substances of concern for national monitoring

Not relevant.

## Classification and labelling

### Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

|  |  |
| --- | --- |
| Hazard class(es), categories: | Acute Tox. 4  STOT SE 3  Aquatic acute 1 (H400), Aquatic chronic 1 (H410) |

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the label:

|  |  |  |
| --- | --- | --- |
| Hazard pictograms: | | ~~GHS05~~  GHS07  GHS09 |
| Signal word: | | Warning ~~Danger~~ |
| Hazard statement(s): | | H302 - Harmful if swallowed  ~~H318 - Causes serious eye damage~~  H335 - May cause respiratory irritation  H410 - Very toxic to acuatic life with long lasting effects |
| Precautionary statement(s): | | P102: Keep out of reach of children  P261: Avoid breathing dust/spray  P264: Wash hands thoroughly after handling  P270: DO not eat, drink or smoke when using this product.  ~~P280: Wear protective gloves and eye protection/face protection.~~  P301+P312- IF SWALLOWED: Call a POISON CENTER/doctor.  ~~P302+P352-IF ON SKIN: Wash with plenty of water and soap.~~  P304+P340-IF INHALED: Remove person to fresh air and keep comfortable for breathing.  ~~P305+P351+P338-IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.~~  P391: Collect spillage  P405: Store locked up.  P501: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation |
| Additional labelling phrases: | | Repeated exposure may cause skin dryness or cracking [EUH066]  To avoid risks to man and the environment, comply with the instructions for use. [EUH401] |
| Special rule for labelling of plant protection product (PPP): | | |
| - | - | |
| Further labelling statements under Regulation (EC) No 1272/2008: | | |
| - | - | |

**See Part C for justifications of the classification and labelling proposals.**

### Standard phrases under Regulation (EU) No 547/2011

|  |  |
| --- | --- |
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
| Spe 3 | To protect non-target plants respect an unsprayed buffer zone of 5 m or an unsprayed buffer zone of 1 m in combination with 75% drift reducing technices. |

### 

### Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

|  |  |
| --- | --- |
|  | None required. |

## 

## Risk management

### Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

|  |  |
| --- | --- |
| Operator protection: | |
|  | Workwear (arms, body and legs covered), gloves and face mask/respiratory protection (FP2, P2 and similar) during mixing/loading.  Workwear (arms, body and legs covered) and gloves during application. |
| Worker protection: |  |
|  | Workwear (arms, body and legs covered) |
| Integrated pest management (IPM)/sustainable use: | |
|  | None required. |
| Environmental protection | |
| P501 | Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. |
| Spe 3 | To protect non-target plants respect an unsprayed buffer zone of 5 m or an unsprayed buffer zone of 1 m in combination with 75% drift reducing technices. |
| Other specific restrictions | |
| EUH401 | To avoid risks to man and the environment, comply with the instructions for use. |

The authorization of the PPP is linked to the following conditions (voluntary labelling):

|  |  |
| --- | --- |
| Integrated pest management (IPM)/sustainable use: | |
|  | - |

### 

### Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

|  |  |  |
| --- | --- | --- |
| Integrated pest management (IPM)/sustainable use: | | Relevant for use no. |
|  | - |  |
| Environmental protection: | | Relevant for use no. |
|  | - |  |

## Intended uses (only NATIONAL GAP)

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | GAP January 2023 |
| PPP (product name/code): | 2,4-D 95 SP / ADM.09250.H.1.A | Formulation type: | SP, Soluble Powder |
| Active substance 1: | 2,4-D (2,4-dichlorophenoxy acetic acid 80.4%) | Conc. of as 1: | 950 g/kg |
| Safener: | - | Conc. of safener: | - |
| Synergist: | - | Conc. of synergist: | - |
| Applicant: | XXXX | Professional use: |  |
| Zone(s): | Central | Non professional use: |  |
| Verified by MS: | no |  |  |
|  |  |  |  |
| Field of use: | herbicide |  |  |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Use-No. (e) | Member state(s) | Crop and/ or situation  (crop destination / purpose of crop) | F, Fn, Fpn G, Gn, Gpn or I | Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks:   e.g. g safener/synergist per ha  (f) |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | kg or L product / ha  a) max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min / max |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | |
| 1 | Poland | Spring Wheat | F | Broadleaf Weeds  CENCY, VERPE, BRSNW, THLAR, CAPBP | Overall, Broadcast foliar spray | BBCH 15-25 | 1 | (-) | 0.9328 kg product (2,4-D acid)/ha | 0.75 | 200 -300 | - | - |

|  |  |  |  |
| --- | --- | --- | --- |
| Remarks  table heading: | (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  (b) Catalogue of pesticide formulation types and international coding system CropLife  International Technical Monograph n°2, 6th Edition Revised May 2008  (c) g/kg or g/l |  | (d) Select relevant  (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use. |
|  |  |  |  |
| Remarks  columns: | 1 Numeration necessary to allow references  2 Use official codes/nomenclatures of EU Member States  3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)  4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. |  | 7 Growth stage at first and 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  8 The maximum number of application possible under practical conditions of use must be provided.  9 Minimum interval (in days) between applications of the same product  10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.  13 PHI - minimum pre-harvest interval  14 Remarks may include: Extent of use/economic importance/restrictions |

# Background of authorization decision and risk management

## 

## Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of white powder. It is not explosive, has no oxidising properties. The product is not highly flammable and does not readily combust. It does not have a self-ignition temperature under the conditions of the test. In aqueous solution, it has a pH value around 7.2. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in 300 g laminated heat-sealed sachets. Its technical characteristics are acceptable for a SP formulation.

The intended concentration of use is 0.311% to 0.466%. w/v.

## Efficacy (Part B, Section 3)

ADM.09250.H.1.A is a water soluble powder formulation containing 950 g of 2,4 D (sodium salt) for use on spring wheat. The proposed maximum rate of ADM.09250.H.1.A is 0,79 kg/ha, which will deliver 750g 2,4 D(sodium salt) per hectare. ADM.09250.H.1.A is absorbed by the leaves of the weeds, causing deformation and inhibition of growth dicotyledonous plants. It is most effective in destroying weeds in the 2-6 leaf phase.

## Efficacy data

Sales formulations containing 2,4 D (sodium salt) as single active substance are well-known and widely used in post-emergence on cereal crops including spring wheat to control broadleaved weeds. Therefore, no preliminary range-finding tests have been carried out.

Minimum effective dose rates were tested in all 15 trials. Results of last assessment at BBCH 51-89 (DAA 42-77) dose response between treatments is clearly visible for all presented weed plants. According to the presented results, the target dose rate for 0,79 kg/ha should be considered as effective against a selected range of broad leaf weeds present on trial locations.

In total 15 efficacy trials carried between 2021-2022 in spring wheat have generated valid data on the efficacy of ADM.09250.H.1.A. Applied solo at dose rates: 0, 79 kg/ha– 1N (target dose rate), 0,42 kg/ha – 0,5 N (53% of target dose rate), 0,526 kg/ha – 0,7N (66 % of target dose rate). ADM.09250.H.1.A was applied post emergence, at BBCH 14-25, on growing weeds, at single spring application.

*Sensitive weeds*: BRSNW, CENCY, CAPBP

*Moderately Susceptible weeds*: CHEAL, MATIN, THLAR, VIOAR, VERSS

*Moderately Tolerant weeds*: GALAP, STEME

*Tolerant weeds*: MATCH

### Information on the occurrence or possible occurrence of the development of resistance

2,4 D belongs to HRAC group 4 (WSSA) legacy HRAC group 4 (legacy O) – Auxin Mimics, it’s structurally similar to IAA (indole-3-acetic acid).

Considering the experiences with the practical use of 2,4 D solo product, overall the resistance risk evaluation can be summarized as low to medium for the test product ADM.09250.H.1.A. The introduction of this product will not result in a significant change of the resistance risk situation.

No specific restrictions except for general remark on good agricultural practice are required on the label.

### Adverse effects on treated crops

Total of 8 selectivity trials have been carried out between 2021 (4) and 2022 (4), in NE EPPO zone (Po-land), specifically to determinate crop safety and possibility of adverse impact on quality and quantity of yield , after application of ADM.09250.H.1.A. ADM.09250.H.1.A was applied at dose rate: 0,9 kg/ha which is higher than recommended target dose rate 0,79 kg/ha: 1N, also double dose rate: 1,8 kg/ha is higher than 2N rate of recommended dose rate.

No phytotoxicity symptom caused by product ADM.09250.H.1.A applied at 1N dose rate (0,9 kg/ha) and double dose rate 2N (1.8 kg/ha) was recorded in any of trials at any of assessments.

All selectivity trials were harvested, and the harvested crop was assessed for quality parameters. The assessed quality parameters were MOICON (moisture content), HLW (hectolitres weight), TKW (thousand grain weight). For none of the parameters tested there was a significant negative impact on the quality of the treated plants when test product or standard were applied at N or 2N application rate.

Based on these long-time experiences with the active ingredient a negative impact on transformation processes for cereals can be excluded.

Due to results can be concluded that is not expected ADM.09250.H.1.A could have negative impact on treated plants use for propagation.

### Observations on other undesirable or unintended side-effects

There is no need for restrictions of the selection of succeeding crops on fields that have been treated with ADM.09250.H.1.A at targeted application rate. All typically grown crops can be established. There is no need to impose specific restrictions on the label.

For early crop replacement due to a crop failure, after pre-sowing cultivation, all crops can be sown or planted. For uses planned near to broad leaf crop fields, it is sufficient to follow good agricultural practice in order to reduce drift to the neighbouring crops. No specific additional measure has to be applied to protect the neighbouring crops.

Following of good agricultural practices is also sufficient as an advice for tank cleaning on the product label.

The purpose of this section is to evaluate efficacy data submitted for authorization of ADM.09250.H.1.A. as a post-emergence herbicide applied in spring against different annual dicotyledonous weeds (TTTDS) in spring wheat.

**Preliminary range-finding tests**

No data is therefore presented in this section.

The applicant stated that a large number of trials have been completed and many years of commercial experience have been gained prior to and since its introduction into the market. The performance of the active ingredient is well known. The evaluator supports this statement.

**Minimum effective dose tests**

The minimum effective rate of 0.79 kg/ha ADM.09250.H.1.A. can be justified. Overall efficacy is improved for each weed species presented for post-emergent applications against *Brassica napus, Cyanus segetum, Capsella bursa-pastoris, Chenopodium album, Tripleurospermum inodorum, Thlaspi arvense, Viola arvensis and Veronica persica*. Each weed is an important weed in spring sown cereal crops in the North-East EPPO zone. Where data is available, a clear dose response could be seen.

**Efficacy tests**

The presented data correspond with the requirements of the EPPO Standards PP 1/135 (4) *Phytotoxicity assessment*; PP 1/152 (4) *Design and analysis of efficacy evaluation trials*; PP 1/181 (4) *Conduct and reporting of efficacy evaluation trials including good experimental practice* and PP 1/93 (3) *Weeds in cereals.*

ADM.09250.H.1.A. was applied post emergence at BBCH 14-25 at the recommended label rate of 0.79 kg/ha with water volume of 200-300 l/ha at single spring application. Overall data from all of the trial reports show that ADM.09250.H.1.A. gave good control (>85%) of the annual broadleaved weeds BRSNW (n=12), CENCY (n=12), CAPBP (n=8).

In these trials ADM.09250.H.1.A. does not appear to be effective against CHEAL (n=13), MATIN (n=3), THLAR (n=3), VIOAR (n=8), VERSS (n=6) and therefore the acceptability of a 'Moderately Susceptible' claim against these weeds should be considered.

GALAP, STEME, LAMPU and MATCH were insufficiently controlled by ADM.09250.H.1.A.

**Information on the occurrence or possible occurrence of the development of resistance**

According to the applicant, the risk of development of resistance is considered to be acceptable and no anti-resistance measures in addition to the standard ‘Guideline to the Management of Herbicide Resistance’ are required.

**Adverse effects on treated crops**

Specific selectivity trials were conducted in weed-free conditions to assess the crop safety of ADM.09250.H.1.A. The phytotoxicity data indicate that the proposed uses are unlikely to cause significant injury to the crops. No phytotoxicity was observed in any of the efficacy and phytotoxicity trials in North-East EPPO zone. Additionally, these trials demonstrate that the uses of ADM.09250.H.1.A. are unlikely to have a negative impact on the yield, quality, processing and transformation, or plant parts for propagation.

**Impact on succeeding crops**

The ADM.09250.H.1.A decomposes in the soil during the growing season without posing a threat to plants succeeded. In the situation of the need for early liquidation of the plantation treated with ADM.09250.H.1.A as a result damage to plants by frosts, diseases or pests, after pre-sowing cultivation, all crops can be sown or planted.

Based on this submitted data and on expert knowledge about 2,4D it can be concluded to accept the information provided by the applicant. Additionally, this is further supported by the data discussed in the Ecotox section.

**Impact on other plants including adjacent crops**

Based on the intended use of 2,4-D 95 SP on spring wheat, acceptable risk is demonstrated to non-target terrestrial plants with mitigation of either 75% Drift Reducing Nozzles (DRT) or a 5 m buffer strip. Additionally, data discussed in the Ecotox section “Effects on non-target terrestrial plants.”

## Methods of analysis (Part B, Section 5)

### Analytical method for the formulation

The analysis of 2,4-D in ADM.09250.H.1.A was performed by high performance liquid chromatography (HPLC). Analysis was performed using HPLC with UV detection employing an Ultrasphere ODS, 5µm column (150 x 4.6 mm) at 284 nm using external calibration standards.

### Analytical methods for residues

Different methods of analysis suitable as monitoring methods to enable compliance with MRLs have been developed for the determination of residues in different matrices.

Methods for the determination of 2,4-D (and metabolites) in ADM.09250.H.1.A exist for food of plant origin (HPLC-MS-MS, LOQ 0.01 mg/kg), in food of animal origin (HPLC-MS-MS, LOQ 0.01 mg/kg), in soil (HPLC-MS-MS, LOQ 0.05 mg/kg), in water (HPLC-MS-MS, LOQ 0.1 µg/L) in air (HPLC-MS-MS, LOQ 4.5 µg/m3) and in body fluids (HPLC-MS-MS, LOQ 0.05 mg/kg) have been developed and validated.

zRMS: accepted.

## Mammalian toxicology (Part B, Section 6)

### Acute toxicity

A summary of the toxicological evaluation for ADM.09250.H.1.A/2,4-D 95 SP is given in the following table:

| Type of test, species, model system (Guideline) | Result | Acceptability | Classification  (acc. to the criteria in Reg. 1272/2008) | Reference |
| --- | --- | --- | --- | --- |
| Acute oral toxicity: Rat, (OECD 423 (2001) | LD50>300 – <2000 mg/kg bw | Yes | Acute Tox. 4, H302 | Satyavani G., 2011a |
| Acute dermal toxicity: Rat, (OECD 402 (1987) | Not acutely toxic  LD50>2000mg/kg bw | Yes | None | Satyavani G., 2011b |
| Acute inhalation toxicity: Rat, (OECD 403 (2009) | Not acutely toxic  LC50>1.36 mg/L air/4h | Yes | None | Jagan Mohan Rao, P., 2011 |
| Skin irritation: Rabbit (OECD 404 (2002)) | Non-irritant | Yes | None | Satyavani G., 2011c |
| Eye irritation: Rabbit (OECD 405 (2002)) | Mild-irritant | Yes | None | Satyavani G., 2011d |
| Skin sensitisation: guinea pig (OECD 406 (1992), Buehler (3 inductions) | Non-sensitising | **No** | None - based on no classification for skin sesnsitisation of a.s. 2,4-D (according to EFSA Journal 2014;12(9):3812) | Satyavani G., 2011e |
| Supplementary studies for combinations of plant protection products | No data – not required | | | |

Toxicological classification of the active substance – 2,4-D, relevant for classification of the product ADM.09250.H.1.A: STOT SE 3, H335 ‘May cause respiratory irritation’.

### Operator exposure

According to the EFSA model calculations (2022), it can be concluded that the risk for the operator using ADM.09250.H.1.A/2,4-D 95 SP for the proposed uses up to 0.750 kg a.s./ha is acceptable when considering workwear (arms, body and legs covered) and protective gloves during application as well as during mixing/loading. Additionally, a face mask/ respiratory protection (FP2, P2 and similar) are during mixing/loading. The acceptable operator exposure level (AOEL) will not be exceeded when the aforementioned personal protective equipment (PPE) is used.

### Worker exposure

According to the EFSA model calculations (2022), the estimated worker exposure to ADM.09250.H.1.A/2,4-D 95 SP is less than the systemic AOEL when workwear is considered when the product is applied at 0.750 kg a.s./ha.

### Bystander and resident exposure

According to the EFSA model calculations (2022), it can be concluded that the risk for bystander and residents exposed to 2,4-dichlorophenoxy acetic acid is acceptable following application to field crops. This has no labelling implications.

## Residues and consumer exposure (Part B, Section 7)

The preparation ADM.09250.H.1.A. is composed of 2,4-D. The formulation is used as a foliar treatment on spring wheat.

### Residues

For the uses proposed for aminopyralid in ADM.09250.H.1.A, all relevant residue data and assessments are provided. New data on the magnitude of the residues are submitted in the framework of this application. Magnitude of residue studies are provided and summarized.

Field uses N-EU:

Wheat is a major crop in northern Europe (SANTE/2019/12752) and therefore, generally requires a minimum of eight trials in the residue region. The intended critical GAP for ADM.09250.H.1.A is less critical than the GAP used to confirm the MRL in wheat (EFSA, 2011). A total of 20 trials conducted on range of cereals (wheat, barley and oat) at an exaggerated rate were submitted for wheat during the renewal process (Greece, 2014). According to SANTE/2019/12752, extrapolation from other cereals is considered possible because the application was performed before forming the edible part. Additionally, two new trials are also available. These trials are in the 25% tolerance rule and could be used to support the cGAP. The data submitted show that no exceedance of the MRL will occur. The proposed use is considered acceptable.

### Consumer exposure

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo 3.1 | 114% (based on DK child) |
| IEDI (% ADI) according to EFSA PRIMo 3.1 | 31 % (based on NL toddler) |
| IESTI RAC (% ARfD) according to EFSA PRIMo 3.1 | Wheat: 1 % (based on UK 4-6 years)  Rye: 0.5 % (based on UK infant)  Barley: 0.4 % (based on UK 7-10 years) |
| IESTI Processed (% ARfD) according to EFSA PRIMo 3.1 | Wheat /milling (flour): 0.9 % (based on DE child)  Wheat /milling (wholemeal): 0.4 % (based on NL child)  Rye/boiled: 0.3 % (based on NL child) |

The proposed uses of 2,4-D in the formulation ADM.09250.H.1.A do not represent unacceptable acute and chronic risks for the consumer.

**zRMS**: accepted – see also B7

## Environmental fate and behaviour (Part B, Section 8)

The data used in the assessment of 2,4-D and its metabolites 2,4-DCP, 2,4-DCA and 4-CP were reviewed in the EU review. Appropriate endpoints from the EU review were used to calculate Predicted Environmental Concentrations (PECs) for 2,4-D, and its metabolites in soil, surface water and groundwater.

### Predicted environmental concentrations in soil (PECsoil)

The predicted environmental concentration in soil (PECSOIL) values of 2,4-D and its metabolites 2,4-DCP, 2,4-DCA, and 4-CP in soil have been assessed based on FOCUS guidance, following application 2,4-D 95 SP (750 g/L) to spring wheat at a maximum use rate of 1 x 750 g a.s./ha of 2,4-D, assuming a crop interception of 0%. The overall maximum initial PECSOIL of 2,4-D was calculated to be 1.000 mg/kg. As the field DT90 of 2,4-D in soil is <365 days, there is no risk of accumulation expected and therefore no accumulation calculations were performed.

For the metabolites 2,4-DCP, 2,4-DCA, and 4-CP, the worst-case use pattern will lead to maximum initial PECSOIL of 0.0642, 0.120, and 0.192 mg/kg, respectively. As the DT90 of 2,4-DCP, 2,4-DCA, and 4-CP in the soil are <365 days, there is no risk of accumulation expected and therefore no accumulation calculations were performed.

As the formulation PECSOIL values were not needed for the ecotoxicological risk assessment, they have not been calculated.

The results for PECSOIL for the active substance and its metabolites were considered for the ecotoxicological risk assessment.

### Predicted environmental concentrations in groundwater (PECgw)

The predicted environmental concentrations in groundwater (PECGW) values of 2,4-D in groundwater have been assessed with all crop-relevant FOCUS groundwater scenarios in the FOCUS PEARL (version 5.5.5), and FOCUS PELMO (version 6.6.4) groundwater models.

The simulations were based on maximum applications of 2,4-D 95 SP (750 g/L) in the GAP table, to produce a worst-case groundwater assessment, for use on spring wheat at 1 x 750 g a.s./ha. The simulations assumed foliar application with 0% crop interception for all applications.

The predicted 80th percentile average annual concentrations for 2,4-D following application to spring wheat were lower than the 0.1 µg/L regulatory threshold in groundwater at 1 m depth for all scenario combinations.

The PECGW values for metabolites 2,4-DCA, 2,4-DCP and 4-CP following annual application 2,4-D to crops were also lower than the 0.1 µg/L regulatory threshold in groundwater at 1 m depth for all the available scenario combinations.

Based on the assessment, there is an acceptable risk to groundwater from the use of 2,4-D according to the proposed use pattern for 2,4-D 95 SP (750 g/L).

### Predicted environmental concentrations in surface water (PECsw)

The predicted environmental concentrations in surface water (PECSW) values of 2,4-D and its metabolites 2,4-DCP, 2,4-DCA, 4-CP and 1,2,4-benzenetriol have been assessed with the FOCUS surface water models. The PECSW values of 2,4-D in surface water were calculated according to FOCUS Steps 1 to 3 based on maximum applications of 2,4-D 95 SP (750 g/L) in the critical GAP table.

The FOCUS Step 3 PECsw value for D1 (risk envelop approach) was considered in the evaluation for CEU. This approach had no impact on the conclusions of the evaluation as risk mitigation measures are not required.

The maximum overall PECSW value at Step 3 for 2,4-D has been calculated to be 4.867 µg/L following application to spring wheat (BBCH 15-25).

The maximum PEC values at Step 2 of the 2,4-D metabolites 2,4-DCP, 2,4-DCA, 4-CP and 1,2,4-benzenetriol have been calculated to be 10.861 µg/L for 2,4-DCP, 4.951 µg/L for 2,4-DCA, 1.892 µg/L for 4-CP, and 9.605 µg/L for 1,2,4-benzenetriol, following application to spring wheat (BBCH 15-25).

As the formulation PECSW values were not needed for the ecotoxicological risk assessment, they have not been calculated.

The results of the PECSW for 2,4-D and its metabolites were considered for the ecotoxicological risk assessment.

### Predicted environmental concentrations in air (PECair)

Due to the low vapour pressure of 2,4-D (< 10-5) Pa at 20°C and the Henry’s Law constant of 1.3 x 10-5 Pa m3/mol, the compound is regarded as non-volatile. In addition, the atmospheric half-life for 2,4-D was calculated to be 1.6 days, which demonstrates that 2,4-D is not persistent in the atmosphere and would not be subject to significant concerns related to long-range transport and atmospheric deposition.

## Ecotoxicology (Part B, Section 9)

### Effects on terrestrial vertebrates

Based on the intended use of 2,4-D 95 SP on spring wheat, acceptable risk is demonstrated to birds and mammals at Tier 1. The risk to birds and mammals *via* drinking water is deemed low, and due to the low potential of 2,4-D to bioaccumulate the risk from secondary poisoning is considered acceptable.

The risk of secondary poisoning from the relevant metabolites 2,4-DCP and 2,4-DCA to earthworm-eating and fish-eating birds and mammals is also considered acceptable.

There is currently no guidance addressing terrestrial life stages of amphibians and reptiles in ecotoxicological risk assessments. Therefore, the risk assessment provided for birds and mammals is considered protective of terrestrial amphibian and reptile species.

### Effects on aquatic species

For the intended use of 2,4-D 95 SP on spring wheat, calculated PECSW/RAC ratios have indicated an acceptable risk to aquatic organisms using FOCUS Step 3 for the parent and Steps 1 to 2 for the metabolites 2,4-DCP, 2,4-DCA and 4-chlorophenol. No risk assessment has been conducted for metabolite 1,2,4-benzenetriol due to the transient nature of the metabolite.

The FOCUS Step 3 PECsw value for D1 (risk envelop approach) was considered in the evaluation for CEU. This approach had no impact on the conclusions of the evaluation as risk mitigation measures are not required.

### Effects on bees

Based on the intended use of 2,4-D 95 SP on spring wheat, the acute oral and acute contact risk to bees is deemed acceptable at the first tier.

### Effects on other arthropod species other than bees

Based on the intended use of 2,4-D 95 SP on spring wheat, acceptable in-field and off-field risk was demonstrated to non-target arthropods at the first tier.

### Effects on soil organisms

Based on the intended use of 2,4-D 95 SP on spring wheat, the risk to earthworms and other non-target soil macrofauna is deemed acceptable at the first tier.

The risk to soil micro-organisms is also deemed acceptable with no significant effects (>25%) observed at concentrations greater than the predicted maximum soil concentrations.

### Effects on non-target terrestrial plants

Based on the intended use of 2,4-D 95 SP on spring wheat, acceptable risk is demonstrated to non-target terrestrial plants with mitigation of either 75% DRT or a 5 m buffer strip.

### Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

## Relevance of metabolites (Part B, Section 10)

The metabolites 2,4-DCP. 2,4-DCA and 4-CP are not predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR Part B Section 8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

# Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

2,4-D 95 SP contains 2,4-D which is not approved as a candidate for substitution thus no comparative assessment is required.

# Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Physicochemical properties:

The two-year study is ongoing. It has to be provided for evaluation in Poland when available. It is required to confirm the two-year shelf life.

1. Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

1. Copy of the product label

MS assessor to present a copy of the approved product label for MS country.

1. Letter of Access

As indicated in section 1.2 above, no Letter of Access will be included in this submission.

1. Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
| --- | --- | --- | --- | --- | --- | --- | --- |
| XXXX | XXXX | XXX | XXXX | XX | XX | XXXX | XXXX |

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
| --- | --- | --- | --- | --- | --- | --- | --- |
| XXXX | XXXX | XXX | XXXX | XX | XX | XXXX | XXXX |
| As the majority of the endpoints for 2,4-D and the relevant metabolites were taken from the EU review (EFSA Journal 2014;12(9):3812), for the list of respective studies please refer to Volume 2 of the RAR (2013). | | | | | | | |

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
| --- | --- | --- | --- | --- | --- | --- | --- |
| XXXX | XXXX | XXX | XXXX | XX | XX | XXXX | XXXX |
|  |  |  |  |  |  |  |  |

List of data relied on and not submitted by the applicant but necessary for evaluation

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
| --- | --- | --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report No  Source  GLP/Not GLP/GEP/Not GEP, Published/Unpublished | Y/N | Y/N | Data/study report never submitted before to <insert MS> If previously submitted in **this** MS: Data protection started with: <insert authorization number of first authorization> | Owner |
|  |  |  |  |  |  |  |  |