

**FINAL** REGISTRATION REPORT

**Part B**

**Section 3**

**Efficacy Data and Information**

Concise summary

Product code: SHA 1100 D

Product name(s): CANDELA

Chemical active substance:

Glyphosate, 540 g/L

Central Zone

Zonal Rapporteur Member State: Poland

**CORE ASSESSMENT**

Applicant: Sharda Cropchem España S.L.

Submission date: February/2018

**MS Finalisation date: 18/10/2022**

## Version history

| When       | What   |
|------------|--|
| 10/2018    | Dossier sent for evaluation to Merit Mark (PL)         |
| March 2019 | Updated with new reports                               |
| 03/2021    | zRMS finalised evaluation                              |
| 10/2022    | Final version prepared by zRMS after Commenting period |

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### **3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)**

**Transformation of the dRR (applicant version) into the RR (zRMS version)**

|                 |  |
|-----------------|--|
| Comment of zRMS | zRMS Assessments of the dRR furnished by applicant was done using boxes across the text. |
|-----------------|--|

#### **3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)**

**Abstract**

**Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)**

| 1  | 2                  | 3  | 4  | 5   | 6                | 7   | 8   | 9  | 10   | 11   | 12                             | 13            | 14   | 15   |
|--|--------------------|--|--|---|------------------|---|---|--|--|--|--------------------------------|---------------|--|--|
| Use-<br>No.<br>*   | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop destination /<br>purpose of crop) | F,<br>Fn,<br>Fnp<br>G,<br>Gn,<br>Gnp<br>or<br>I ** | Pests or Group of<br>pests controlled<br><br>(additionally: develop-<br>mental stages of the<br>pest or pest group) | Application      |   |   |  | Application rate   |  |                                | PHI<br>(days) | Remarks:<br><br>e.g. g safener/<br>synergist per ha,<br>other dose rate<br>expression, dose<br>range (min-max) | zRMS<br>Conclusion<br>(efficacy)                           |
|  |                    |  |  |   | Method /<br>Kind | Timing /<br>Growth stage<br>of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | kg or L product<br>/ ha<br>a) max. rate per<br>appl.<br>b) max. total<br>rate per<br>crop/season | g or kg as/ha<br>a) max. rate per<br>appl.<br>b) max. total<br>rate per<br>crop/season | Water<br>L/ha<br><br>min / max |               |  |  |
| Zonal uses (field or outdoor uses, certain types of protected crops) |                    |  |  |   |                  |   |   |  |  |  |                                |               |  |  |
| 1  | CEU                | Winter cereals<br>(wheat, barley,<br><del>rye, oats</del> , triticale)   | F  | Annual and perennial<br>grass and broadleaved<br>weeds  | Foliar Spray     | Application<br>before seed-<br>ling             | a) 1<br>b) 1  | -  | a) 2<br>b) 2   | a) 1.08<br>b) 1.08   | 200-400                        |               |  | In winter rye<br>and oats is no<br>phytotoxicity<br>trials |
| 2  | CEU                | Winter wheat   | F  | Dessication before<br>harvest   | Foliar Spray     | BBCH 89   | a) 1<br>b) 1  | -  | a) 2<br>b) 2   | a) 1.08<br>b) 1.08   | 200-400                        | 7             |  | Accepted   |
| 3  | CEU                | Winter Oilseed<br>rape   | F  | Annual and perennial<br>grass and broadleaved<br>weeds  | Foliar Spray     | Application<br>before seed-<br>ling             | a) 1<br>b) 1  | -  | a) 2<br>b) 2   | a) 1.08<br>b) 1.08   | 200-400                        |               |  | Accepted   |
| 4  | CEU                | Spring barley,<br>spring wheat   | F  | Annual and perennial<br>grass and broadleaved<br>weeds  | Foliar Spray     | Application<br>before seed-<br>ling             | a) 1<br>b) 1  | -  | a) 2<br>b) 2   | a) 1.08<br>b) 1.08   | 200-400                        |               |  | Accepted   |
| 5  | CEU                | Sunflower  | F  | Annual and perennial<br>grass and broadleaved<br>weeds  | Foliar Spray     | Application<br>before seed-<br>ling             | a) 1<br>b) 1  | -  | a) 2<br>b) 2   | a) 1.08<br>b) 1.08   | 200-400                        |               |  | Accepted   |
| 6  | CEU                | Maize  | F  | Annual and perennial<br>grass and broadleaved<br>weeds  | Foliar Spray     | Application<br>before seed-<br>ling             | a) 1<br>b) 1  | -  | a) 2<br>b) 2   | a) 1.08<br>b) 1.08   | 200-400                        |               |  | Accepted   |
| 7  | CEU                | Pome fruit (Ap-<br>ple, <del>pear</del> )                                | F  | Annual and perennial<br>grass and broadleaved<br>weeds  | Foliar Spray     | Spring appli-<br>cation BBCH<br>31-69           | a) 1<br>b) 1  | -  | a) 2<br>b) 2   | a) 1.08<br>b) 1.08   | 800-1000                       |               |  | In pear is no<br>selectivity<br>trials                     |
| 8  | CEU                | Grapevine  | F  | Annual and perennial<br>grass and broadleaved<br>weeds  | Foliar Spray     | Spring appli-<br>cation BBCH<br>13-69           | a) 1<br>b) 1  | -  | a) 2<br>b) 2   | a) 1.08<br>b) 1.08   | 600-1000                       |               |  | Accepted   |

**Glyphosate 54% SL**

Part B – Section 3 - Core Assessment  
Sharda Poland Sp. z o.o. / Central Zone

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| 1                | 2                  | 3  | 4  | 5   | 6                | 7   | 8   | 9  | 10   | 11   | 12                         | 13            | 14   | 15  |
|------------------|--------------------|--|--|---|------------------|---|---|--|--|--|----------------------------|---------------|--|---|
| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop destination /<br>purpose of crop) | F,<br>Fn,<br>Fnp<br>G,<br>Gn,<br>Gnp<br>or<br>I ** | Pests or Group of<br>pests controlled<br><br>(additionally: develop-<br>mental stages of the<br>pest or pest group) | Application      |   |   |  | Application rate   |  |                            | PHI<br>(days) | Remarks:<br><br>e.g. g safener/<br>synergist per ha,<br>other dose rate<br>expression, dose<br>range (min-max) | zRMS<br>Conclusion<br>(efficacy)                      |
|                  |                    |  |  |   | Method /<br>Kind | Timing /<br>Growth stage<br>of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | kg or L product<br>/ ha<br>a) max. rate per<br>appl.<br>b) max. total<br>rate per<br>crop/season | g or kg as/ha<br>a) max. rate per<br>appl.<br>b) max. total<br>rate per<br>crop/season | Water<br>L/ha<br>min / max |               |  |   |
| 9                | CEU                | Stone fruit<br>(Peach, apricot,<br>plum, cherry)                         | F  | Annual and perennial<br>grass and broadleaved<br>weeds  | Foliar Spray     | Spring appli-<br>cation BBCH<br>31-59           | a) 1<br>b) 1  | -  | a) 2<br>b) 2   | a) 1.08<br>b) 1.08   | 800-1000                   |               |  | In stone fruit<br>is no one<br>phytotoxicity<br>trial |

### 3.2 Efficacy data (KCP 6)

|                  |  |
|------------------|--|
| Comments of zRMS | A detailed summary of efficacy data and information is presented in accordance with required format (Part B Section 3). The comprehensive BAD according to Uniform Principles provided as separate document. |
|------------------|--|

#### Introduction

This document summarises the information related to the efficacy data of the plant protection product **Glyphosate 54% SL** containing the active substance glyphosate, which was included into Annex I of Council Directive 91/414/EEC.

The SANCO report for glyphosate (6511/VI/1999, final) is considered to provide the relevant review information or a reference to where such information can be found.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on glyphosate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 June 2001 shall be taken into account. Consideration of active substances for Annex I inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of glyphosate relating to efficacy.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

**The detailed assessment of the individual trial and study data is located in the following report:**

|                |   |
|----------------|---|
| <b>Report:</b> | <b>KCP 6.0/001 Biological Assessment Dossier Glyphosate 54% SL, Central</b> |
|----------------|---|

#### Description of active substance glyphosate

Glyphosate is a broad-spectrum systemic herbicide and crop desiccant.

Glyphosate was discovered by Monsanto in 1970 and marketed under the trade name Roundup in 1974. It is an organophosphorus compound, specifically a phosphonate.

Glyphosate is absorbed through foliage and minimally through roots, meaning that it is only effective on actively growing plants and cannot prevent seeds from germinating. After application, glyphosate is readily transported around the plant to growing roots and leaves and this systemic activity is important for its effectiveness. While growth stops within hours of application, it takes several days for the leaves to begin turning yellow.

Today, glyphosate is registered and commercialised in several formulations around the world.

**Table 3.2-1: Current approvals of glyphosate in the EU Central zone as well as connected EPPO zones where trials were conducted**

| Country        | Product            | Active ingredient     | Approval number |
|----------------|--------------------|-----------------------|-----------------|
| Czech Republic | Roundup Klasik Pro | glyphosate 360 g/L SL | 4899-0          |
| Latvia         | Roundup Bio        | Glyphosate 360 g/L SL | 0516            |
| Lithuania      | Roundup Bio        | Glyphosate 360 g/L SL | 0173/06         |
|                | Roundup Classic    | Glyphosate 360 g/L SL | 0013H/06        |
| Poland         | Roundup 360 Plus   | Glyphosate 360 g/L SL | R-71/2014       |



## Mode of action

Glyphosate acts by inhibiting a plant enzyme (5-enolpyruvylshikimate-3-phosphate synthase) involved in the synthesis of three aromatic amino acids: tyrosine, tryptophan and phenylalanine. Inhibiting the enzyme causes shikimate to accumulate in plant tissues and diverts energy and resources away from other processes. Due to its primary target site and its chemical family, in the HRAC mode of action classification it is classified as group G (WSSA group 9) herbicide.

**Table 3.2-2: Details of the formulation and the active substance**

|                         |   |
|-------------------------|---|
| Proposed trade name     | Glyphosate 54% SL   |
| A.S. content:           | Glyphosate 540 g/L  |
| Formulation type:       | SL  |
| Synonyms:               | Glyphosate 54% SL   |
|                         |   |
| <b>Active substance</b> | <b>Glyphosate</b>   |
| IUPAC name:             | N-(phosphonomethyl)glycine                                |
| Chemical group:         | Phosphonoglycine  |
| Mode of action:         | inhibition of EPSP synthase                               |
| Plant translocation:    | Systemic, absorbed by foliage and minimally through roots |
| Biological action:      | Non-selective   |

For further physico-chemical properties, please refer to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

## Description of the plant protection product

Glyphosate 54% SL is a Soluble Concentrate (SL) formulation containing 540 g/L glyphosate for use in cereals, oilseed rape, maize and sunflower before sowing as well as for desiccation of winter wheat before harvest. Glyphosate 54% SL is also proposed for use in orchards, to control weeds during the season.

According to the GAP, the proposed application rate of Glyphosate 54% SL is 2.0 L per hectare (L/ha), with one post-emergence application per season, for the control of annual and perennial grasses and broadleaved weeds, and 2.0 L/ha when used for desiccation in winter wheat before harvest. This will deliver 1080 g glyphosate per hectare. In the treated crops, the test product was tested against equivalent dose rates of the glyphosate reference product currently marketed in the countries where the trials were conducted.

The data presented in this dossier fully support the label claim for glyphosate for the control of annual and perennial grasses and broadleaved weeds in a range of field- and orchard crops.

**Table 3.2-3: Simplified table of currently registered uses and requested uses for the product code.**

| Uses                                   |   | Member State | Requested rate(s) | Comments / Other relevant details on GAPs |
|--|---|--------------|-------------------|---|
| Crop(s)                                | Target(s)   |              |                   |   |
| Winter wheat                           | Desiccation   | CEU          | 2.0 L/ha          | BBCH 89                                   |
| Winter cereals and winter oilseed rape | Annual and perennial di- and monocotyledonous weeds | CEU          | 2.0 L/ha          | Before sowing                             |

Continued the following page...

| Uses                               |   | Member State | Requested rate(s) | Comments / Other relevant details on GAPs |
|------------------------------------|---|--------------|-------------------|---|
| Crop(s)                            | Target(s)   |              |                   |   |
| Spring barley, maize, sunflower    | Annual and perennial di- and monocotyledonous weeds | CEU          | 2.0 L/ha          | Before sowing                             |
| Orchards (pome-, stone- and vines) | Annual and perennial di- and monocotyledonous weeds | CEU          | 2.0 L/ha          | During growing season                     |

Further details are in the table “All intended uses” in Part B - Section 0.

### Description of the target pests

All the listed weeds are present throughout or in parts of the Central zone and in relevant EPPO zones. These weed species compete with the crops for light, moisture and nutrients, reducing crop yields and may obstruct harvestability.

**Table 3.2-4: Glossary of pests mentioned in the dossier.**

| EPPO code | Scientific name                                 | Common name               |
|-----------|---|---------------------------|
| ACHMI     | <i>Achillea millefolium</i>                     | Common yarrow             |
| AGRRE     | <i>Elymus repens</i>                            | Couchgrass                |
| AVEFA     | <i>Avena fatua</i>                              | Wild oat                  |
| ARTVU     | <i>Artemisia vulgaris</i>                       | chrysanthemum weed        |
| BRSNX     | <i>Brassica napus</i> (volunteer)               | Oilseed rape (volunteer)  |
| CAPBP     | <i>Capsella bursa-pastoris</i>                  | Shepherd's purse          |
| CENCY     | <i>Cyanus segetum</i>                           | Cornflower                |
| CERAR     | <i>Cerastium arvense</i>                        | Field chickweed           |
| CHEAL     | <i>Chenopodium album</i>                        | Common lambsquarters      |
| CONAR     | <i>Convolvulus arvensis</i>                     | Field morning glory       |
| DESSO     | <i>Descurainia sophia</i>                       | herb sophia               |
| FESRU     | <i>Festuca rubra</i>                            | Red fescue                |
| GALAP     | <i>Galium aparine</i>                           | Cleavers                  |
| GERMO     | <i>Geranium mole</i>                            | Dove's foot cranesbill    |
| GERPU     | <i>Geranium pusillum</i>                        | small-flowered cranesbill |
| GNAUL     | <i>Gnaphalium uliginosum</i>                    | Low cudweed               |
| LAMAM     | <i>Lamium amplexicaule</i>                      | Common deadnettle         |
| LAMPU     | <i>Lamium purpureum</i>                         | Purple deadnettle         |
| LOLPE     | <i>Lolium perenne</i>                           | Perennial ryegrass        |
| LOLMG     | <i>Lolium multiflorum</i> subsp. <i>Gaudini</i> | annual ryegrass           |
| MATMA     | <i>Tripleurospermum maritimum</i>               | False mayweed             |
| MATIN     | <i>Tripleurospermum inodorum</i>                | scentless mayweed         |
| MYOAR     | <i>Myosotis arvensis</i>                        | common scorpiongrass      |
| PAPRH     | <i>Papaver rhoeas</i>                           | Common poppy              |

| EPPO code | Scientific name                      | Common name            |
|-----------|--------------------------------------|------------------------|
| POAAN     | <i>Poa annua</i>                     | Annual bluegrass       |
| POAPR     | <i>Poa pratensis</i>                 | Kentucky bluegrass     |
| POLAV     | <i>Polygonum aviculare</i>           | Prostrate knotweed     |
| POLCO     | <i>Fallopia convolvulus</i>          | Black bindweed         |
| PTLAN     | <i>Potentilla anserina</i>           | silverweed             |
| RUMCR     | <i>Rumex crispus</i>                 | curled dock            |
| SINAR     | <i>Sinapis arvensis</i>              | Charlock               |
| STEME     | <i>Stellaria media</i>               | Common chickweed       |
| SOOCA     | <i>Solidago canadensis</i>           | Canadian goldenrod     |
| TAROF     | <i>Taraxacum officinale</i>          | Common dandelion       |
| THLAR     | <i>Thlaspi arvensis</i>              | Field pennycress       |
| TRFRE     | <i>Trifolium repens</i>              | White clover           |
| TRFAR     | <i>Trifolium arvense</i>             | rabbit-foot clover     |
| TRZAX     | <i>Triticum aestivum</i> (volunteer) | Wheat (volunteer)      |
| VERPE     | <i>Veronica persica</i>              | Common field speedwell |
| VICVI     | <i>Vicia villosa</i>                 | Hairy vetch            |
| VIOAR     | <i>Viola arvensis</i>                | Field violet           |

**Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS).**

| Crop and/or situation | Crop status |       | Pests or group of pests controlled | Pest status |       |
|-----------------------|-------------|-------|------------------------------------|-------------|-------|
|                       | Major       | minor |                                    | Major       | minor |
| Winter cereals        | CEU         | -     | Mono- and dicot weeds              | CEU         | -     |
| Winter oilseed rape   | CEU         | -     | Mono- and dicot weeds              | CEU         | -     |
| Winter triticale      | CEU         | -     | Mono- and dicot weeds              | CEU         | -     |
| Winter wheat          | CEU         | -     | Mono- and dicot weeds              | CEU         | -     |
| Winter barley         | CEU         | -     | Mono- and dicot weeds              | CEU         | -     |
| Spring barley         | CEU         | -     | Mono- and dicot weeds              | CEU         | -     |
| Spring wheat          | CEU         | -     | Mono- and dicot weeds              | CEU         | -     |
| Maize                 | CEU         | -     | Mono- and dicot weeds              | CEU         | -     |
| Sunflower             | CEU         | -     | Mono- and dicot weeds              | CEU         | -     |
| Pome fruit orchard    | CEU         | -     | Mono- and dicot weeds              | CEU         | -     |
| Stone fruit orchard   | CEU         | -     | Mono- and dicot weeds              | CEU         | -     |
| Grapevine orchard     | CEU         | -     | Mono- and dicot weeds              | CEU         | -     |

### Compliance with the Uniform Principles

Comprehensive field trials were conducted in Poland, Lithuania, Latvia and the Czech Republic in 2016, 2017 and 2018. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

### Information on trials submitted (3.1 Efficacy data)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the efficacy part of the current application, 44 efficacy trials were conducted in the North-east (22) and the Maritime (2) EPPO zone.

**Table 3.2-6: Presentation of efficacy trials (efficacy trials, preliminary trials...)**

| Use(s) *             | Target(s)*  | Country          | Years     | Type of trial** | Number of trials<br>(number of valid trials) |       |     |         | GEP, non-<br>GEP,<br>official*** | Comments<br>(any other<br>relevant<br>information) |
|----------------------|---|------------------|-----------|-----------------|--|-------|-----|---------|----------------------------------|--|
|                      |   |                  |           |                 | EPPO zone                                    |       |     |         |                                  |  |
|                      |   |                  |           |                 | MAR  | MED   | S-E | N-E     |                                  |  |
| Desiccation          | Annual and<br>perennial<br>mono- and<br>dicot weeds | Poland           | 2016      | E + S           | -  | -     | -   | 2 (2)   | GEP                              | Winter wheat                                       |
|                      |   |                  | 2017      | E + S           | -  | -     | -   | 2 (2)   | GEP                              | Winter wheat                                       |
|                      |   | Latvia           | 2016      | E + S           | -  | -     | -   | 2 (2)   | GEP                              | Winter wheat                                       |
|                      |   |                  | Lithuania | 2016            | E + S  | -     | -   | -       | 2 (2)                            | GEP  |
|                      |   |                  |           |                 |  | -     | -   | -       | 8 (8)                            | -  |
| Pre-sowing<br>Autumn | Annual and<br>perennial<br>mono- and<br>dicot weeds | Poland           | 2016      | MED + E + S     | -  | -     | -   | 3 (3)   | GEP                              | WW + OSR   |
|                      |   |                  | 2018      | MED + E + S     | -  | -     | -   | 8 (8)   | GEP                              | WB + OSR<br>+WT + WW                               |
|                      |   | Latvia           | 2016      | MED + E + S     | -  | -     | -   | 2 (2)   | GEP                              | Stubble  |
|                      |   | Lithuania        | 2016      | MED + E + S     | -  | -     | -   | 2 (2)   | GEP                              | Oilseed rape                                       |
|                      |   |                  |           |                 |  | -     | -   | -       | 15 (15)                          | -  |
| Pre-sowing<br>Spring | Annual and<br>perennial<br>mono- and<br>dicot weeds | Poland           | 2016      | MED + E + S     | -  | -     | -   | 5 (5)   | GEP                              |  |
|                      |   |                  | 2017      | MED + E + S     |  |       |     | 4 (4)   | GEP                              | SB + Maize<br>+ sunflower                          |
|                      |   | Lithuania        | 2016      | E + S           | -  | -     | -   | 4 (4)   | GEP                              | SB + Maize   |
|                      |   |                  |           |                 |  | -     | -   | -       | 13 (13)                          | -  |
| Orchards             | Annual and<br>perennial<br>mono- and<br>dicot weeds | Lithuania        | 2016      | MED + E + S     | -  | -     | -   | 4 (4)   | GEP                              | Apple  |
|                      |   | Latvia           | 2016      | MED + E + S     | -  | -     | -   | 2 (2)   | GEP                              | Apple  |
|                      |   | Czech Rep.       | 2016      | MED + E + S     | 2 (2)  | -     | -   | -       | GEP                              | Vines  |
|                      |   |                  |           |                 |  | 2 (2) | -   | -       | 6 (6)                            | -  |
|                      |   | Total, all crops |           |                 | 2 (2)  | -     | -   | 42 (42) |                                  |  |

\* According to the GAP table.

\*\* P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

\*\*\* GEP: Good Experimental Practices. Official: carried out by a national official organisation.

### Climatic zones

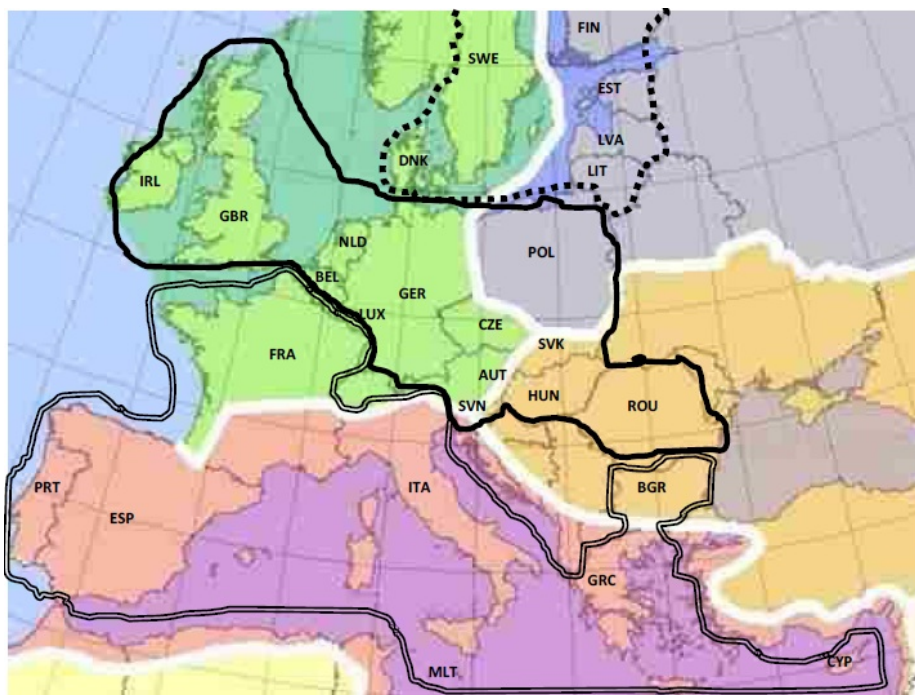
Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy

evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country<sup>1</sup>.

The Czech Republic is located in the EPPO Maritime zone and Poland, Lithuania and Latvia are located in the North-east EPPO zone (Figure 3.2-1).

This document is prepared to support the submission of Glyphosate 54% SL throughout the Central Registration zone, therefore data from the Maritime zone, as well as the North-east EPPO zones are included. The data from each climatic zone is summarised separately.

**Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)**



### **Agronomic conditions**

Cultural conditions of the different crops and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between the Czech Republic, Poland, Lithuania and Latvia. The same glyphosate containing herbicides are already registered and used in all countries to control the same annual and perennial grass- and broadleaved weed species.

#### **(i) Weed physiology**

Annual and perennial grasses and broadleaved weeds are all controlled by Glyphosate 54% SL and are key weeds throughout Central Europe. In each country these weeds are very common and can cause large reductions in yield.

Currently, there are only few reported cases of weed resistance to glyphosate reported from within the EU (Heap, 2018), therefore when treating the same weeds at the same application timing, no difference in level of control should be observed between countries. Therefore, the efficacy results from one country should be valid in another country.

#### **(ii) Site selection**

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<sup>1</sup> Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, E. Bouma, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

Although trials were performed throughout the EU, in each country the sites were carefully selected to ensure that for each weed species the level of control was assessed on a range of populations and application timings. To exert maximum control pressure and to exacerbate treatment differences in each country this included some trials which contained high weed densities. No differences in the level of control were apparent between the different countries or regions in which the trials were conducted.

(iii) *Agronomic practices*

Agronomic practices in autumn and spring sown field crops, as well as orchards crops are similar throughout the Central zone as well as in the countries in the connected EPPO zones where trials were conducted. Winter cereals and winter oilseed rape are sown in the autumn and spring cereals, maize and sunflower are sown in the spring. The levels of inorganic fertilizers and other crop inputs are similar between the countries.

(iv) *Varieties*

Although crop varieties tend to differ between countries, the crop safety of Glyphosate 54% SL has been tested on a wide range of varieties in both the selectivity and efficacy trials. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance and yield data generated in one country is therefore relevant in another Member state.

(v) *Trial methodology*

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(vi) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for cereal production due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

Glyphosate is a foliar acting herbicide with no residual activity. In each country, trials have been conducted on a range of soil types with no difference seen in the level of control.

On the basis that the above factors do not influence the overall performance of Glyphosate 54% SL, it is the applicant's contention that data from the Czech Republic and Poland is equally valid in demonstrating the products performance throughout the Central EU zone and the data from Lithuania and Latvia is valid as supporting data.

Efficacy and crop safety trials were carried out with Glyphosate 54% SL in comparison to the Monsanto reference glyphosate 360 g/L product (Roundup 360 Plus / Roundup Bio / Roundup Classic / Roundup Klasik Pro) in Czech Republic, Poland, Lithuania and Latvia. The trials were carried out on field crops of winter oilseed rape, winter wheat, stubbles (of winter wheat), sunflower, winter triticale, spring barley, spring wheat and maize, as well as in orchards with apples and grapevine.

**Table 3.2-7: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)**

| Trade name       | Formulation | Composition        | Rates [L/ha]                    | Indication                                | Country  | N° of trials |
|------------------|-------------|--------------------|---------------------------------|---|----------|--------------|
| Roundup 360 Plus | SL          | 360 g/L glyphosate | 3.0<br>5.0                      | Control of grasses and broad-leaved weeds | PL       | 24           |
| Roundup Bio      | SL          | 360 g/L glyphosate | 3.0<br>4.0<br>5.0<br>6.0<br>7.0 | Control of grasses and broad-leaved weeds | LT<br>LV | 2<br>6       |



| Trade name         | Formulation | Composition        | Rates [L/ha]      | Indication                                | Country | N° of trials |
|--------------------|-------------|--------------------|-------------------|---|---------|--------------|
| Roundup Classic    | SL          | 360 g/L glyphosate | 4.0<br>5.0<br>7.0 | Control of grasses and broad-leaved weeds | LT      | 10           |
| Roundup Klasik Pro | SL          | 360 g/L glyphosate | 4.0<br>5.0<br>7.0 | Control of grasses and broad-leaved weeds | CZ      | 2            |

|                          |   |
|--------------------------|---|
| <b>Comments of zRMS:</b> | <p>The plant protection product Candela (Glyphosat 54%) is submitted for the authorization in regulatory Central Zone – EPPO Maritime and EPPO North-East.</p> <p>This herbicide containing 540 g/l active substance glyphosate. It is formulated as an soluble (SL). The applicant (Sharda Cropchem Espana SL) has submitted this zonal application in order to register this product in the Central EU. Candela product is proposed for use as a pre-emergence agricultural herbicide in winter cereals (wheat TRZAW, barley HORVW, triticale TLWI), winter oilseed rape, spring barley, maize, sunflower and in orchards in growing season (apple and vines), desiccation before harvest in winter wheat at the dose rate of 2.0 L/ha: for the control of a range of broadleaved and grasses weeds. Candela product has proposed maximum dose in all applications 2, 0 l/ha to deliver 1080 g a.s./ha glyphosate. This product is applied with a water volume 200-400 l/ha. Only one application per season is permitted. In winter cereals, winter oilseed, spring barley, maize, sunflower product may be applied before sowing. In orchards product may be applied in growing season. In winter wheat product may be applied.</p> |
|--------------------------|---|

### 3.2.1 Preliminary tests (KCP 6.1)

The activity of glyphosate is well known, as it has been marketed since the beginning of the 1970's by e.g. Monsanto for broad-spectrum control of annual and perennial mono- and dicotyledonous weeds in a wide range of cropping, utility and industrial situations. Based on the knowledge about the active substance (+40 years) and the experiences with Glyphosate 54% SL in the label claimed crops at similar dose rates, the necessary application rates to obtain sufficient control of the weeds are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

|                          |  |
|--------------------------|--|
| <b>Comments of zRMS:</b> | zRMS agree with applicant argumentation. |
|--------------------------|--|

### 3.2.2 Minimum effective dose tests (KCP 6.2)

To determine the minimum effective dose rate, 32 trials from the North-east zone (26 trials at seeding, i.e. seven autumn trials and five spring trials, and six apple orchard trials) and two trials from the Maritime zone (vine orchard trials), have been included in this section. Data from each zone has been summarized separately.

In the 32 trials, the level of control obtained by Glyphosate 54% SL was assessed on annual and perennial mono- and dicotyledonous weeds present in the trials.

#### Control of annual and perennial grass- and broadleaved weeds with autumn application

To prove and to support the requested dose rate of 2.0 l/ha Glyphosate 54% SL [1080 g glyphosate per hectare] for the control of annual and perennial grass- and broadleaved weeds in field crops before sowing in the autumn, the assessment results of fifteen efficacy trials performed in the North-east EPPO zone in 2016 and 2018 are reported. Glyphosate 54% SL was included in these trials at 2.0 l/ha to demonstrate the recommended dose rate as well as at a lower than recommended dose rate (1.5 l/ha). The rates reflect the proposed label rate and 75% of the full recommended rate of Glyphosate 54% SL, in accordance with the EPPO standard PP 1/225 'Minimum effective dose' and the Central zone efficacy requirements. As the most accurate representation of whole plot product performance, the assessment data at 17-63 days after

the application, obtained by visually estimating control obtained by the applied products are summarised and presented.

The results obtained with Glyphosate 54% SL applied against frequently occurring grasses and broad-leaved weeds in the autumn are presented in Table 3.2-8 for results obtained in the North-east EPPO zone (15 trials).

When evaluating all weed species present in the trials, the average combined control of all the assessed annual and perennial grass- and broadleaved weeds at approx. two to eight weeks after application was 61.1% following an application of Glyphosate 54% SL at 1.5 L/ha, compared to 70.7% achieved by 2.0 L/ha. Statistical evaluation of 57 of 63 assessments revealed that Glyphosate 54% SL at 2.0 l/ha performed significantly better than the 1.5 L/ha dose rate. At the remaining assessments, no significant differences were observed between any of the Glyphosate 54% SL treatments, however, the proposed dose rate of 2.0 L/ha achieved consistently higher levels of control than obtained with the reduced dose rate and the proposed dose rate provided enough efficiency to control annual and perennial grass- and broad-leaved weeds. No statistical evaluation was reported in the last 8 assessments.

**Table 3.2-8:** North-east zone: Minimum effective dose of Glyphosate 54% SL against annual and perennial grasses and broadleaved weeds when applied in the autumn.

| EPPO<br>Code                | Weed<br>Growth<br>stage at<br>application<br>[BBCH] | Total No.<br>of trials | Ground cover<br>(no/m <sup>2</sup> ) | Efficacy obtained with<br>Glyphosate 54% SL at: |                  |                  |
|-----------------------------|---|------------------------|--------------------------------------|---|------------------|------------------|
|                             |   |                        |                                      | Mean (min-max)                                  |                  |                  |
|                             |   |                        |                                      | 1.5 L/ha  | 2.0 L/ha         | 3.5 L/ha         |
| Annual broadleaved weeds    |   |                        |                                      |   |                  |                  |
| BRSNX                       | 11-12   | 1                      | 4.5                                  |   | 59               | 60               |
| GALAP                       | 35-75   | 1                      | 25%                                  |   | 65               | 77.5             |
| LAMAM                       | 10-12   | 1                      | 5                                    |   | 60               | 68               |
| PAPRH                       | 10-12   | 1                      | 14                                   |   | 55               | 66               |
| POLAV                       | 75-95   | 1                      | 8.8%                                 |   | 86               | 90.5             |
| CHEAL                       | 10-12   | 1                      | 4.0                                  | 90.0  | 100              | 100              |
| SETGL                       | 12  | 1                      | 17.0                                 | 80.0  | 100              | 100              |
| CAPBP                       | 10  | 1                      | 6.0                                  | 80.0  | 100              | 100              |
| MYOAR                       | 10  | 1                      | 8.0                                  | 71.0  | 100              | 100              |
| MATIN                       | 10-12   | 1                      | 5.0                                  | 65.0  | 100              | 100              |
| LAMPU                       | 10-12   | 1                      | 4.0                                  | 65.0  | 100              | 100              |
| CAPBP                       | 10-12   | 1                      | 7.0                                  | 78.0  | 100              | 100              |
| CENCY                       | 10-12   | 2                      | 15.5                                 | 26.3  | 57.4 (28.8-86.0) | 59.0 (30.0-88.0) |
| POLCO                       | 10-72   | 2                      | 4.0/11.3%                            |   | 60.6 (55-66.3)   | 68.3 (59-77.5)   |
| SINAR                       | 10-59   | 2                      | 19.8-21%                             |   | 94.1 (93.5-94.8) | 93.6 (92.5-94.7) |
| STEME                       | 10-12   | 4                      | 4.0-7.0                              | 86.0 (82.0-90.0)                                | 78.5 (53.0-100)  | 80.3 (55.0-100)  |
| THLAR                       | 10-14   | 1                      | 3%                                   |   | 98               | 99               |
| VERPE                       | 10-12   | 2                      | 6-7                                  |   | 33.5 (33-34)     | 44.5 (39-50)     |
| MATMA                       | 12-14   | 2                      | 9.0 (6.0-12.0)                       | 34.4 (32.5-36.3)                                | 36.3 (35.0-37.5) | 36.3 (33.8-38.8) |
| VIOAR                       | 09-85   | 7                      | 2-6%/4-7                             | 72.5 (71.0-74.0)                                | 81.8 (46.0-100)  | 83.9 (51.0-100)  |
| GERPU                       | 10-12   | 2                      | 6.5 (6.0-7.0)                        | 68.0 (62.0-74.0)                                | 100              | 100              |
| Mean of all assessments     |   | 36                     | 7.4 (4.0-12.0)                       | 72.6 (26.3-90.0)                                | 78.2 (28.8-100)  | 80.7 (30.0-100)  |
| Perennial broadleaved weeds |   |                        |                                      |   |                  |                  |
| CERAR                       | 12-75   | 1                      | 12%                                  |   | 91.8             | 94.3             |
| TRFRE                       | 11-32   | 1                      | 7.5%                                 |   | 81.3             | 82.5             |
| ARTVU                       | 12-14   | 4                      | 6.0 (5.0-7.0)                        | 29.5 (19.0-34.0)                                | 55.8 (53.0-58.0) | 80.7 (71.0-88.0) |
| RUMCR                       | 12-14   | 4                      | 4.3 (4.0-5.0)                        | 37.5 (29.0-41.0)                                | 58.8 (55.0-64.0) | 81.2 (74.0-88.0) |
| CIRAR                       | 12-14   | 3                      | 5.0 (5.0-5.0)                        | 39.6 (38.0-42.0)                                | 60.0 (54.0-70.0) | 77.3 (71.0-89.0) |
| SOOCA                       | 14  | 3                      | 18.3 (9.0-26.0)                      | 28.3 (26.0-29.0)                                | 52.3 (51.0-55.0) | 65.0 (60.0-72.0) |
| Mean of all assessments     |   | 16                     | 4.0-26.0                             | 37.6 (19.0-74.0)                                | 56.4 (35.0-100)  | 76.2 (33.8-100)  |
| Annual grass weeds          |   |                        |                                      |   |                  |                  |
| TRZAX                       | 10-21   | 4                      | 13-26%                               | -   | 77.2 (57.5-95.7) | 78.5 (60-96)     |
| APESV                       | 12  | 1                      | 4.0                                  | 90.0  | 100              | 100              |
| Mean of all assessments     |   | 5                      |                                      | 90.0  | 81.8 (57.5-100)  | 82.8 (60.0-100)  |
| Perennial grass weeds       |   |                        |                                      |   |                  |                  |
| AGRRE                       | 10-35   | 6                      | 12-44%/ 6-8                          | 31.0 (30.0-32.0)                                | 68.5 (48.0-87.8) | 81.5 (65.0-89.5) |
| Mean of all assessments     |   | 63                     |                                      | 61.1 (19.0-90.0)                                | 70.7 (28.8-100)  | 79.8 (30.0-100)  |

Thus, for Glyphosate 54% SL to consistently achieve satisfactory control against the annual and perennial



weeds claimed, Glyphosate 54% SL has to be applied at 2.0 l/ha on weeds that are actively growing in the late summer/autumn.

### Control of annual and perennial grass- and broadleaved weeds with spring application

To prove and to support the requested dose rate of 2.0 l/ha Glyphosate 54% SL [1080 g glyphosate per hectare] for the control of annual and perennial grass- and broadleaved weeds in field crops at sowing in the spring, the assessment results of nine efficacy trials performed in the North-east EPPO zone in 2016 (1), 2017 (4) and 2018 (4) are reported. Glyphosate 54% SL was included in these trials at 2.0 l/ha to demonstrate the recommended dose rate as well as at lower than recommended dose rate (1.5 l/ha). The rates reflect the proposed label rate and 75% of the full recommended rate of Glyphosate 54% SL, in accordance with the EPPO standard PP 1/225 'Minimum effective dose' and the Central zone efficacy requirements. As the most accurate representation of whole plot product performance, the assessment data at 12-60 days after the application, obtained by visually estimating control obtained by the applied products are summarised and presented.

The results obtained with Glyphosate 54% SL applied against frequently occurring grasses and broadleaved weeds in the spring are presented in Table 3.2-9 for results obtained in the North-east EPPO zone (9 trials).

When evaluating all weed species present in the trials, the average combined control of all the assessed annual and perennial grass- and broadleaved weeds at approx. two to nine weeks after application was 46.2% following an application of Glyphosate 54% SL at 1.5 L/ha, compared to 61.2% achieved by 2.0 L/ha. Statistical evaluation of 37 of 41 assessments revealed that Glyphosate 54% SL at 2.0 l/ha performed significantly better than the 1.5 L/ha dose rate. At the remaining assessments, no significant differences were observed between any of the Glyphosate 54% SL treatments, however, the proposed dose rate of 2.0 L/ha achieved consistently higher levels of control than obtained with the reduced dose rate and the proposed dose rate provided enough efficiency to control annual and perennial grass- and broadleaved weeds.

**Table 3.2-9: North-east zone: Minimum effective dose of Glyphosate 54% SL against annual and perennial grasses and broadleaved weeds when applied in the spring.**

| EPPO Code                        | Weed Growth stage at applica-<br>tion [BBCH] | No. of trials | Ground cover (No./m²) | Efficacy obtained with |                  |                  |
|----------------------------------|--|---------------|-----------------------|------------------------|------------------|------------------|
|                                  |  |               |                       | Glyphosate 54% SL at:  |                  |                  |
|                                  |  |               |                       | Mean (min-max)         |                  |                  |
|                                  |  |               |                       | 1.5 L/ha               | 2.0 L/ha         | 3.5 L/ha         |
| Annual broadleaved weeds         |  |               |                       |                        |                  |                  |
| BRSNX                            | n.r.   | 1             | 12.0                  | 67.5                   | 72.5             | 75               |
| CHEAL                            | n.r.   | 5             | 29.0-50.0             | 36.0 (28.8-43.8)       | 45.0 (40-50)     | 50.3 (31.3-63.8) |
| GALAP                            | n.r.   | 2             | 6.0-29.0              | 23.8 (16.3-31.3)       | 31.9 (21.3-42.5) | 34.4 (23.8-45)   |
| MATMA                            | n.r.   | 1             | 41.0                  | 37.5                   | 46.3             | 47.5             |
| POLAV                            | n.r.   | 2             | 3.0-18.0              | 35.0 (31.3-38.8)       | 50.6 (50-51.3)   | 53.1 (48.8-57.5) |
| POLCO                            | n.r.   | 2             | 4.0-11.0              | 41.3 (38.8-43.8)       | 51.9 (48.8-55)   | 55.0 (51.3-58.8) |
| VERPE                            | 12-14  | 3             | 4.0-5.0               | 32.9 (28.8-36.3)       | 67.4 (32.5-88.5) | 79.1 (38.8-99.3) |
| VIOAR                            | n.r.   | 1             | 10.0                  | 0                      | 2.5              | 6.3              |
| MATIN                            | 12-15  | 4             | 4.0-6.0               | 52.5 (45.0-71.0)       | 73.2 (66.3-77.5) | 96.0 (90-98.8)   |
| STEME                            | 12-14  | 3             | 5.0-6.0               | 78.9 (76.3-83.0)       | 92.3 (92.1-92.5) | 100 (100-100)    |
| CAPBP                            | 14-16  | 3             | 5.0-7.0               | 52.5 (51.3-53.8)       | 70.0 (66.3-75.0) | 97.3 (95.0-98.9) |
| GERPU                            | 14-16  | 2             | 4.0                   | 23.8 (21.3-26.3)       | 56.7 (51.3-62.1) | 88.5 (85.8-91.3) |
| POLPE                            | 12-14  | 1             | 4.0                   | 43.8                   | 55.0             | 91.8             |
| DESSO                            | 14-16  | 1             | 5.0                   | 40.0                   | 71.3             | 90.0             |
| Mean, all assessments            |  | 31            | 4.0-50.0              | 43.8 (0.0-83.0)        | 60.4 (2.5-92.5)  | 70.5 (6.3-100)   |
| Perennial broadleaved weeds      |  |               |                       |                        |                  |                  |
| CIRAR                            | 12-14  | 1             | 5.0                   | 65.0                   | 78.8             | 94.8             |
| Annual grass weeds               |  |               |                       |                        |                  |                  |
| ECHCG                            | n.r.   | 2             | 15-25                 | 28.1 (22.5-33.8)       | 35.0 (32.5-37.5) | 47.5 (38.8-56.3) |
| POAAN                            | 12-13  | 3             | 6.0-7.0               | 62.1 (57.5-68.8)       | 77.1 (74.5-81.8) | 100 (100-100)    |
| Mean, all assessments            |  | 5             | 6.0-25.0              | 48.5 (22.5-68.8)       | 60.3 (32.5-81.8) | 79.0 (38.8-100)  |
| Perennial grass weeds            |  |               |                       |                        |                  |                  |
| AGRRE                            | n.r.   | 4             | 3-20                  | 57.5 (51.3-65)         | 63.8 (57.5-71.3) | 68.8 (60-83.8)   |
| Mean, all assessments, all weeds |  | 41            |                       | 46.2 (0.0-83.0)        | 61.2 (2.5-92.5)  | 71.9 (6.3-100)   |

Thus, for Glyphosate 54% SL to consistently achieve satisfactory control against the annual and perennial weeds claimed, Glyphosate 54% SL has to be applied at 2.0 l/ha on weeds that are actively growing in the spring/early summer.

### Control of annual and perennial grass- and broadleaved weeds in orchards with application during the growing season

to prove and to support the requested dose rate of 2.0 l/ha Glyphosate 54% SL [1080 g glyphosate per hectare] for the control of annual and perennial grass- and broadleaved weeds in orchards during the growing season, the assessment results of eight efficacy trials performed in the North-east (6) EPPO zone and the Maritime (2) EPPO zone in 2016 are reported. Glyphosate 54% SL was included in these trials at 2.0-2.4 and 3.2-4.0 l/ha to demonstrate the recommended dose rate (2.0 l/ha). The rates reflect the proposed label rate and 100% of the full recommended rate of Glyphosate 54% SL, in accordance with the EPPO standard PP 1/225 'Minimum effective dose' and the Central zone efficacy requirements. As the most accurate representation of whole plot product performance, the assessment data at 26-63 days after the application, obtained by visually estimating control obtained by the applied products are summarised and presented.

The results obtained with Glyphosate 54% SL applied against frequently occurring grasses and broadleaved weeds in the summer are presented in Table 3.2-10 and Table 3.2-11 for results obtained in the North-east (6 trials) and the Maritime EPPO zone (2 trials), respectively.

When evaluating all weed species present in the North-eastern apple orchard trials, the average combined control of all the assessed annual and perennial grass- and broadleaved weeds at approx. four to eight weeks after application was 72.5% following an application of Glyphosate 54% SL at 2.0-2.4 L/ha, compared to 86.1% achieved by 3.5 L/ha (3.2-4.0 l/ha, i.e. 3.5 l/ha assessed at 8 assessments, 3.2 l/ha assessed at 10 assessments and 4.0 l/ha assessed on four assessments). Statistical evaluation of the 22 assessments revealed that Glyphosate 54% SL at 3.2-4.0 l/ha performed significantly better than the 2.0-2.4 l/ha dose rate at 11 assessments. At the remaining 11 assessments, no significant differences were observed between any of the Glyphosate 54% SL treatments, however, the proposed dose rate of 2.0 L/ha achieved sufficient levels of control of the annual and perennial grass- and broadleaved weeds.

**Table 3.2-10: North-east zone: Minimum effective dose of Glyphosate 54% SL against annual and perennial grasses and broadleaved weeds when applied during the season in orchards.**

| EPPO<br>Code                       | Weed<br>Growth<br>stage at<br>application<br>[BBCH] | Total No.<br>of trials | Ground cover<br>(no/m <sup>2</sup> ) | Efficacy obtained with |                  |
|------------------------------------|---|------------------------|--------------------------------------|------------------------|------------------|
|                                    |   |                        |                                      | Glyphosate 54% SL at:  |                  |
|                                    |   |                        |                                      | Mean (min-max)         |                  |
|                                    |   |                        |                                      | 2.0-2.4 L/ha           | 3.2-4.0 L/ha     |
| Annual broadleaved weeds           |   |                        |                                      |                        |                  |
| CAPBP                              | 40  | 2                      | 190-224                              | 83.2 (74.5-91.8)       | 89.6 (81.0-98.1) |
| GALAP                              | 11-40   | 3                      | 194-209                              | 82.0 (52-98)           | 87.0 (65.9-98.2) |
| LAMPU                              | 65  | 2                      | 178-272                              | 42.7 (35.1-52.2)       | 61.3 (57.7-64.8) |
| Mean of all assessments            |   | 7                      |                                      | 71.1 (35.1-98)         | 80.4 (57.7-98.2) |
| Perennial broadleaved weeds        |   |                        |                                      |                        |                  |
| ACHMI                              | 18-39   | 1                      | 11.3%                                | 56.3                   | 82.3             |
| CERAR                              | 21-67   | 3                      | 210-218 / 5.8%                       | 77.2 (52.8-99)         | 89.3 (74.4-99)   |
| TAROF                              | 10-99   | 4                      | 254-297 / 26-51%                     | 79.9 (62.8-99.4)       | 90.9 (79.2-100)  |
| TRFRE                              | 10-51   | 1                      | 25%                                  | 48.8                   | 86               |
| Mean of all assessments            |   | 9                      |                                      | 72.9 (48.8-99.4)       | 88.8 (74.4-100)  |
| Annual grass weeds                 |   |                        |                                      |                        |                  |
| POAAN                              | 61  | 2                      | 22-34.5                              | 65.0 (57.5-72.5)       | 80.7 (75-86.3)   |
| Perennial grass weeds              |   |                        |                                      |                        |                  |
| AGRRE                              | 65  | 2                      | 184-216                              | 80.8 (61.5-100)        | 91.2 (82.4-100)  |
| FESRU                              | 12-59   | 1                      | 21.3%                                | 82.3                   | 95.5             |
| POAPR                              | 10-69   | 1                      | 25%                                  | 67.5                   | 93.8             |
| Mean of all assessments            |   | 4                      |                                      | 77.8 (61.5-100)        | 89.8 (82.4-100)  |
| Mean of all assessments, all weeds |   | 22                     |                                      | 72.5 (35.1-100)        | 86.1 (57.7-100)  |

When evaluating all weed species present in the Maritime grapevine trials, the average combined control of all the assessed annual and perennial grass- and broadleaved weeds at approx. three to four weeks after application was 68.9% following an application of Glyphosate 54% SL at 2.0 L/ha, compared to 87.1% achieved by 3.5 L/ha. Statistical evaluation of the 10 assessments revealed that Glyphosate 54% SL at 3.5 l/ha performed significantly better than the 2.0 L/ha dose rate at eight assessments. At the remaining two assessments, no significant differences were observed between either of the two Glyphosate 54% SL treatments, however, also in these, the proposed dose rate of 2.0 L/ha achieved sufficient levels of control of the annual and perennial grass- and broadleaved weeds.

**Table 3.2-11: Maritime zone: Minimum effective dose of Glyphosate 54% SL against annual and perennial grasses and broadleaved weeds when applied during the season in orchards.**

| EPPO<br>Code                       | Weed<br>Growth<br>stage at<br>application<br>[BBCH] | Total No.<br>of trials | Ground cover<br>(no/m <sup>2</sup> ) | Efficacy obtained with |                 |
|------------------------------------|---|------------------------|--------------------------------------|------------------------|-----------------|
|                                    |   |                        |                                      | Glyphosate 54% SL at:  |                 |
|                                    |   |                        |                                      | Mean (min-max)         |                 |
|                                    |   |                        |                                      | 2.0 L/ha               | 3.5 L/ha        |
| Annual broadleaved weeds           |   |                        |                                      |                        |                 |
| GALAP                              | 60  | 1                      | 4.0                                  | 6.3                    | 56.3            |
| GERMO                              | 63  | 2                      | 12.3-16.5                            | 65.6 (35-96.3)         | 88.1 (76.3-100) |
| VICVI                              | 49  | 2                      | 8.8-12.0                             | 71.9 (51.3-92.5)       | 85.0 (70-100)   |
| Mean of all assessments            |   | 5                      |                                      | 56.3 (6.3-96.3)        | 80.5 (56.3-100) |
| Perennial broadleaved weeds        |   |                        |                                      |                        |                 |
| CONAR                              | 60  | 2                      | 9-18.8                               | 66.9 (43.8-90)         | 84.4 (68.8-100) |
| Annual grass weeds                 |   |                        |                                      |                        |                 |
| AVEFA                              | 49  | 1                      | 10.5                                 | 91.3                   | 100             |
| Perennial grass weeds              |   |                        |                                      |                        |                 |
| AGRRE                              | 55  | 1                      | 30.8                                 | 92.5                   | 100             |
| LOLPE                              | 55  | 1                      | 20.5                                 | 90                     | 100             |
| Mean of all assessments            |   | 2                      |                                      | 91.3 (90-92.5)         | 100 (-)         |
| Mean of all assessments, all weeds |   | 10                     |                                      | 68.9 (6.3-96.3)        | 87.1 (56.3-100) |

For Glyphosate 54% SL to consistently achieve satisfactory control against the annual and perennial weeds claimed, Glyphosate 54% SL has to be applied during the growing season at 2.0 l/ha on weeds that are actively growing in the orchards.

### Summary and conclusions on the minimum effective dose

Glyphosate 54% SL applied at 2.0 l/ha to control annual and perennial grasses broadleaved weeds achieved excellent control of all target weeds. As grasses and broadleaved weeds often occur as a complex of several weed species with different susceptibility towards glyphosate, one application of Glyphosate 54% SL at the recommended rates should be used to efficiently control all weeds claimed on the label.

This BAD clearly demonstrates that the efficacy and crop safety of Glyphosate 54% SL is equivalent to that of the standard glyphosate reference product from Monsanto. The applicant therefore wishes to cite the original registrant's data on glyphosate now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

|                          |   |
|--------------------------|---|
| <b>Comments of zRMS:</b> | All of the trials submitted for applications in winter cereals (wheat, barley, triticale) and spring barley followed the EPPO standards PP 1/93, in winter oilseed rape EPPO PP 1/49(3), in sunflower EPPO PP 1/63(3), in maize EPPO PP 1/50(3), in apple EPPO PP 1/90(3), vines EPPO PP 1/64(4), EPPO PP 1/215 "Minimum effective dose" and were conducted in accordance with GEP. Efficacy was tested under the range of environmental conditions to fully challenge the test product. Sufficient evidence to support minimum effective dose was submitted. Appropriate evidence of the GEP status of the organisations that conducted the trials and |
|--------------------------|---|

|  |  |
|--|--|
|  | <p>relevant certificates have been provided.</p> <p>All of the efficacy trials had over 5 plants/m<sup>2</sup> and therefore zRMS considers all of the trials to be sufficiently challenging.</p> <p>Overall, the zRMS considers that the data produced in these trials, support the proposed application rate of 2.0 l/ha Candela product as the MED (Minimum Effective Dose) for the control annual and perennial broadleaved and grass weeds in above mentioned crops.</p> <p>No further information is required.</p> |
|--|--|

### 3.2.3 Efficacy tests (KCP 6.2)

Data from 44 efficacy trials conducted in the North-east EPPO zone (42; Poland (24), Latvia (6) and Lithuania (12)) and the Maritime EPPO zone (2; the Czech Republic) have been included in this biological assessment dossier to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone. Data from each zone has been summarized separately.

In the efficacy trials, the performance of Glyphosate 54% SL was measured against a commercial standard 36% SL formulation of glyphosate currently on the market in Central Europe (Roundup 360 Plus / Roundup Bio / Roundup Classic / Roundup Klasik Pro). The trials were carried out on field crops of winter oilseed rape, winter wheat, winter triticale, winter barley, stubbles (of winter wheat), sunflower, spring barley, spring wheat and maize, as well as in orchards with apples and grapevine.

In the 44 trials, the level of control obtained by Glyphosate 54% SL was assessed on annual and perennial mono- and dicotyledonous weeds present in the trials. Data on each individual weed species is only included from trials in which a minimum of 3 plants per m<sup>2</sup> or 1% ground cover were seen at the timing of the assessment.

**Table 3.2-12: Details on trial methodology**

| Use(s) *             | Target(s)*  | Country   | Years     | Type of trial** | Number of trials<br>(number of valid trials) |     |     |       | GEP, non-<br>GEP,<br>official*** | Comments<br>(any other<br>relevant<br>information) |
|----------------------|---|-----------|-----------|-----------------|--|-----|-----|-------|----------------------------------|--|
|                      |   |           |           |                 | EPPO zone                                    |     |     |       |                                  |  |
|                      |   |           |           |                 | MAR  | MED | S-E | N-E   |                                  |  |
| Desiccation          | Annual and<br>perennial<br>mono- and<br>dicot weeds | Poland    | 2016      | E + S           | -  | -   | -   | 2 (2) | GEP                              | Winter wheat                                       |
|                      |   |           | 2017      | E + S           | -  | -   | -   | 2 (2) | GEP                              | Winter wheat                                       |
|                      |   | Latvia    | 2016      | E + S           | -  | -   | -   | 2 (2) | GEP                              | Winter wheat                                       |
|                      |   |           | Lithuania | 2016            | E + S  | -   | -   | -     | 2 (2)                            | GEP  |
|                      |   |           |           |                 |  | -   | -   | -     | 8 (8)                            | -  |
| Pre-sowing<br>Autumn | Annual and<br>perennial<br>mono- and<br>dicot weeds | Poland    | 2016      | MED + E + S     | -  | -   | -   | 3 (3) | GEP                              | WW + OSR   |
|                      |   |           | 2018      | MED + E + S     | -  | -   | -   | 8 (8) | GEP                              | WB + OSR<br>+WT + WW                               |
|                      |   | Latvia    | 2016      | MED + E + S     | -  | -   | -   | 2 (2) | GEP                              | Stubble  |
|                      |   | Lithuania | 2016      | MED + E + S     | -  | -   | -   | 2 (2) | GEP                              | Oilseed rape                                       |
|                      |   |           |           |                 |  | -   | -   | -     | 15 (15)                          | -  |
| Pre-sowing<br>Spring | Annual and<br>perennial<br>mono- and<br>dicot weeds | Poland    | 2016      | MED + E + S     | -  | -   | -   | 5 (5) | GEP                              |  |
|                      |   |           | 2017      | MED + E + S     |  |     |     | 4 (4) | GEP                              | SB + Maize +<br>sunflower                          |
|                      |   | Lithuania | 2016      | E + S           | -  | -   | -   | 4 (4) | GEP                              | SB + Maize   |
|                      |   |           |           |                 |  | -   | -   | -     | 13 (13)                          | -  |
| Orchards             | Annual and<br>perennial                             | Lithuania | 2016      | MED + E + S     | -  | -   | -   | 4 (4) | GEP                              | Apple  |
|                      |   | Latvia    | 2016      | MED + E + S     | -  | -   | -   | 2 (2) | GEP                              | Apple  |

| Use(s) * | Target(s)*               | Country          | Years | Type of trial** | Number of trials<br>(number of valid trials) |     |     |         | GEP, non-<br>GEP,<br>official*** | Comments<br>(any other<br>relevant<br>information) |
|----------|--------------------------|------------------|-------|-----------------|--|-----|-----|---------|----------------------------------|--|
|          |                          |                  |       |                 | EPPO zone                                    |     |     |         |                                  |  |
|          |                          |                  |       |                 | MAR  | MED | S-E | N-E     |                                  |  |
|          | mono- and<br>dicot weeds | Czech Rep.       | 2016  | MED + E + S     | 2 (2)  | -   | -   | -       | GEP                              | Vines  |
|          |                          |                  |       |                 | 2 (2)  | -   | -   | 6 (6)   | -                                |  |
|          |                          | Total, all crops |       |                 | 2 (2)  | -   | -   | 42 (42) |                                  |  |

### Control of annual and perennial mono- and dicotyledonous weeds with autumn application before sowing

The efficacy trials were conducted to prove the following label claims:

|                    |  |
|--------------------|--|
| Crop, stage        | Winter cereals and winter oilseed rape – before sowing |
| Use rate           | 2.0 L/ha Glyphosate 54% SL                             |
| Use frequency      | 1x   |
| Application timing | Post-emergence to weeds / before emergence of crop     |
| Target weeds       | Annual and perennial grasses and broadleaved weeds     |

The effectiveness of applying Glyphosate 54% SL against mono- and dicotyledonous weeds in the autumn was evaluated in fifteen trials conducted in field crops, i.e. five trials treated before sowing winter oilseed rape (5), winter barley (2), winter triticale (2) or winter wheat (4) and two trials where Glyphosate 54% SL was applied in winter wheat stubbles after harvest. These trials were carried out in 2016 and 2018 in the North-east EPPO zone (15; i.e. Poland (11), Latvia (2) and Lithuania (2)). The objective was to confirm the performance of Glyphosate 54% SL at 2.0 L/ha (i.e. 1080 g glyphosate per hectare) and demonstrate comparability to the reference product. In the trials, one application was applied in the late summer/autumn (August-October), before sowing or after harvest.

In the trials, Glyphosate 54% SL was tested alongside an EU approved glyphosate 36% SL formulation, i.e. Roundup 360 Plus (PL) and Roundup Bio (LV and LT). The summary of efficacy results obtained with the application of Glyphosate 54% SL at 2.0 L/ha and the reference product at comparable dose rates on annual and perennial grasses and broadleaved weeds in the autumn are listed in Table 3.2-13 for results from all trials conducted in the North-east EPPO zone.

**Table 3.2-13: North-east zone: Efficacy of 2.0 L/ha Glyphosate 54% SL and reference product at equivalent dose rate in the efficacy tests 2016 and 2018 – late autumn evaluation, 17-63 DAT.**

| EPPO<br>Code             | Weed<br>Growth<br>stage at<br>application<br>[BBCH] | No.<br>of<br>trials | Ground<br>cover<br>(no/m <sup>2</sup> ) | Efficacy obtained with   |                          |                             | No. of trials where Glyphosate<br>54% SL at 1080 g glyphosate/ha<br>is >, < or =, compared to the<br>glyphosate Ref. product at<br>1800 g glyphosate/ha<br>= : ± 5% control |   |   | Overall |
|--------------------------|---|---------------------|---|--------------------------|--------------------------|-----------------------------|---|---|---|---------|
|                          |   |                     |   | Glyphosate<br>54% SL at: | Glyphosate 54%<br>SL at: | Glyphosate ref.<br>prod. at |   |   |   |         |
|                          |   |                     |   | Mean (min-max)           |                          |                             |   |   |   |         |
|                          |   |                     |   | 2.0 L/ha                 | 3.5 L/ha                 | 5.0 L/ha                    | >   | = | < |         |
| Annual broadleaved weeds |   |                     |   |                          |                          |                             |   |   |   |         |
| BRSNX                    | 11-12   | 1                   | 4.5                                     | 59.0                     | 60                       | 66                          |   |   | 1 | <       |
| GALAP                    | 35-75   | 1                   | 25%                                     | 65.0                     | 77.5                     | 78.8                        |   |   | 1 | <       |
| LAMAM                    | 10-12   | 1                   | 5                                       | 60.0                     | 68                       | 58                          | 1   |   |   | >       |
| PAPRH                    | 10-12   | 1                   | 14                                      | 55.0                     | 66                       | 46                          | 1   |   |   | >       |
| POLAV                    | 75-95   | 1                   | 8.8%                                    | 86.0                     | 90.5                     | 88.3                        |   | 1 |   | =       |
| CHEAL                    | 10-12   | 1                   | 4.0                                     | 100                      | 100                      | 100                         |   | 1 |   | =       |
| SETGL                    | 12  | 1                   | 17.0                                    | 100                      | 100                      | 100                         |   | 1 |   | =       |
| CAPBP                    | 10  | 1                   | 6.0                                     | 100                      | 100                      | 100                         |   | 1 |   | =       |
| MYOAR                    | 10  | 1                   | 8.0                                     | 100                      | 100                      | 100                         |   | 1 |   | =       |
| MATIN                    | 10-12   | 1                   | 5.0                                     | 100                      | 100                      | 100                         |   | 1 |   | =       |

| EPPo<br>Code                | Weed<br>Growth<br>stage at<br>application<br>[BBCH] | No.<br>of<br>trials | Ground<br>cover<br>(no/m <sup>2</sup> ) | Efficacy obtained with   |                          |                             | No. of trials where Glyphosate<br>54% SL at 1080 g glyphosate/ha<br>is >, < or =, compared to the<br>glyphosate Ref. product at<br>1800 g glyphosate/ha<br>= : ± 5% control |    |   | Overall |
|-----------------------------|---|---------------------|---|--------------------------|--------------------------|-----------------------------|---|----|---|---------|
|                             |   |                     |   | Glyphosate<br>54% SL at: | Glyphosate 54%<br>SL at: | Glyphosate ref.<br>prod. at |   |    |   |         |
|                             |   |                     |   | Mean (min-max)           |                          |                             |   |    |   |         |
|                             |   |                     |   | 2.0 L/ha                 | 3.5 L/ha                 | 5.0 L/ha                    | >   | =  | < |         |
| LAMPU                       | 10-12   | 1                   | 4.0                                     | 100                      | 100                      | 100                         |   | 1  |   | =       |
| CAPBP                       | 10-12   | 1                   | 7.0                                     | 100                      | 100                      | 100                         |   | 1  |   | =       |
| CENCY                       | 10-12   | 2                   | 15.5                                    | 57.4<br>(28.8-86.0)      | 59.0<br>(30.0-88.0)      | 57.7<br>(27.5-88.0)         | 1   | 1  |   | >       |
| POLCO                       | 10-72   | 2                   | 4.0/11.3%                               | 60.6<br>(55.0-66.3)      | 68.3<br>(59-77.5)        | 73.6<br>(66-81.3)           |   |    | 2 | <       |
| SINAR                       | 10-59   | 2                   | 19.8-21%                                | 94.1<br>(93.5-94.8)      | 93.6<br>(92.5-94.7)      | 94.0<br>(93.3-94.7)         | 1   | 1  |   | =       |
| STEME                       | 10-12   | 4                   | 4.0-7.0                                 | 78.5<br>(53.0-100)       | 80.3<br>(55.0-100)       | 77.0<br>(54.0-100)          | 1   | 1  |   | >       |
| THLAR                       | 10-14   | 1                   | 3%                                      | 98.0                     | 99                       | 96.8                        |   | 1  |   | =       |
| VERPE                       | 10-12   | 2                   | 6-7                                     | 33.5<br>(33.0-34.0)      | 44.5<br>(39-50)          | 39.0<br>(33-45)             |   | 1  | 1 | =       |
| MATMA                       | 12-14   | 2                   | 6.0-12.0                                | 36.3<br>(35.0-37.5)      | 36.3<br>(33.8-38.8)      | 36.9<br>(33.8-40.0)         |   | 2  |   | =       |
| VIOAR                       | 09-85   | 7                   | 2-6%/4-7                                | 81.8<br>(46.0-100)       | 83.9<br>(51.0-100)       | 78.4<br>(36.0-100)          | 2   | 5  |   | =       |
| GERPU                       | 10-12   | 2                   | 6.0-7.0                                 | 100                      | 100                      | 100                         |   | 2  |   | =       |
| Mean, all assessments       |   | 36                  | 7.4<br>(4.0-12.0)                       | 78.2<br>(28.8-100)       | 80.7<br>(30.0-100)       | 77.5<br>(27.5-100)          | 7   | 22 | 5 | =       |
| Perennial broadleaved weeds |   |                     |   |                          |                          |                             |   |    |   |         |
| CERAR                       | 12-75   | 1                   | 12%                                     | 91.8                     | 94.3                     | 93.8                        |   | 1  |   | =       |
| TRFRE                       | 11-32   | 1                   | 7.5%                                    | 81.3                     | 82.5                     | 87.5                        |   |    | 1 | <       |
| ARTVU                       | 12-14   | 4                   | 6.0<br>(5.0-7.0)                        | 55.8<br>(53.0-58.0)      | 80.7<br>(71.0-88.0)      | 59.0<br>(54.0-66.0)         | 1   | 2  | 1 | =       |
| RUMCR                       | 12-14   | 4                   | 4.3<br>(4.0-5.0)                        | 58.8<br>(55.0-64.0)      | 81.2<br>(74.0-88.0)      | 62.0<br>(54.0-71.0)         |   | 3  | 1 | =       |
| CIRAR                       | 12-14   | 3                   | 5.0<br>(5.0-5.0)                        | 60.0<br>(54.0-70.0)      | 77.3<br>(71.0-89.0)      | 58.3<br>(54.0-66.0)         | 1   | 2  |   | =       |
| SOOCA                       | 14  | 3                   | 18.3<br>(9.0-26.0)                      | 52.3<br>(51.0-55.0)      | 65.0<br>(60.0-72.0)      | 51.0<br>(51.0-51.0)         | 1   | 2  |   | =       |
| Mean, all assessments       |   | 16                  | 4.0-26.0                                | 56.4<br>(35.0-100)       | 76.2<br>(33.8-100)       | 61.9<br>(54.0-93.8)         | 3   | 10 | 3 | =       |
| Annual grass weeds          |   |                     |   |                          |                          |                             |   |    |   |         |
| TRZAX                       | 10-21   | 4                   | 13-26%                                  | 77.2<br>(57.5-95.7)      | 78.5<br>(60-96)          | 84.4<br>(63.8-97.3)         |   | 2  | 2 | =       |
| APESV                       | 12  | 1                   | 4.0                                     | 100                      | 100                      | 100                         |   | 1  |   | =       |
| Mean, all assessments       |   | 5                   |   | 81.8<br>(57.5-100)       | 82.8<br>(60.0-100)       | 87.5<br>(63.8-100)          |   | 3  | 2 | =       |
| Perennial grass weeds       |   |                     |   |                          |                          |                             |   |    |   |         |
| AGRRE                       | 10-35   | 6                   | 12-44%/4-8                              | 68.5<br>(48.0-87.8)      | 81.5<br>(65.0-89.5)      | 71.7<br>(45.0-91.5)         |   | 3  | 3 | =       |

When applied at 2.0 l/ha in the North-east zone, Glyphosate 54% SL obtained good to excellent control when applied to annual and perennial grasses and broadleaved weeds commonly found in cereal- and oilseed rape field crops. In all species evaluated, the effect obtained with Glyphosate 54% SL was similar to the effect obtained with the glyphosate reference product applied in the trials. Statistical evaluation was reported at 41 of 63 assessments evaluated in the table above. At ten of the 41 assessments, Glyphosate 54% SL performed significantly better than the glyphosate reference product applied at comparable dose rates and at ten assessments, the glyphosate reference product performed significantly better than Glyphosate 54% SL. At the remaining 21 assessments, no significant differences were observed between the two tested products. Also in the remaining assessments where no statistical evaluation was reported, both products performed similar.

The combined proposed label claims of the annual and perennial grass- and broadleaved weed spectrum controlled after application of 2.0 l/ha Glyphosate 54% SL post-emergence to weeds are listed in Table 3.2-19.



### Crop desiccation of winter wheat before harvest

The efficacy trials were conducted to prove the following label claims:

|                    |                                  |
|--------------------|----------------------------------|
| Crop, stage        | Winter wheat – before harvest    |
| Use rate           | 2.0 L/ha Glyphosate 54% SL       |
| Use frequency      | 1x                               |
| Application timing | Before harvest (BBCH 89)         |
| Target weeds       | Desiccation of winter wheat crop |

Glyphosate 54% SL is recommended applied for desiccation of winter wheat crops before harvest at 2.0 l/ha, however, the glyphosate applied will also have an effect on the annual and perennial weeds present in the winter wheat field. The effectiveness of applying Glyphosate 54% SL against mono- and dicotyledonous weeds before harvest in winter wheat was evaluated in four trials conducted in winter wheat before harvest. These trials were carried out in 2016 and 2017 in the North-east EPPO zone (8; i.e. Poland (4), Lithuania (2) and Latvia (2)). The objective was to confirm the performance of Glyphosate 54% SL at 2.0 L/ha (i.e. 1080 g glyphosate per hectare) and demonstrate comparability to the reference product. In the trials, one application was applied in the summer (July), before harvest.

In the trials, Glyphosate 54% SL was tested alongside an EU approved glyphosate 36% SL formulation, i.e. Roundup 360 Plus (PL), Roundup Classic (LT) and Roundup Bio (LV). The summary of weed control results obtained with the application of Glyphosate 54% SL at 2.0 L/ha before harvest and the reference product at comparable dose rates on annual and perennial grasses and broadleaved weeds in the summer are listed in Table 3.2-14 for results from all trials conducted in the North-east EPPO zone.

**Table 3.2-14: North-east zone: Efficacy of 2.0 L/ha Glyphosate 54% SL and reference product at equivalent dose rate in the efficacy tests 2016 – late autumn evaluation, 10-42 DAT.**

| EPPO<br>Code                | Weed<br>Growth stage<br>at application<br>[BBCH] | No.<br>of<br>trials | Ground<br>cover<br>(no/m <sup>2</sup> ) | Efficacy obtained with   |                             | No. of trials where Glyphosate 54% SL<br>at 1890 g glyphosate/ha is >, < or =,<br>compared to the glyphosate Ref.<br>product at 1800 g glyphosate/ha<br>= : ± 5% control |   |   | Overall |
|-----------------------------|--|---------------------|---|--------------------------|-----------------------------|--|---|---|---------|
|                             |  |                     |   | Glyphosate 54%<br>SL at: | Glyphosate ref.<br>prod. at |  |   |   |         |
|                             |  |                     |   | Mean (min-max)           |                             |  |   |   |         |
|                             |  |                     |   | 2.0 L/ha                 | 5.0 L/ha                    | >  | = | < |         |
| Annual broadleaved weeds    |  |                     |   |                          |                             |  |   |   |         |
| GNAUL                       | 19-65  | 1                   | 5.0%                                    | 99                       | 99                          |  | 1 |   | =       |
| POLAV                       | 16-65  | 1                   | 6.3%                                    | 99                       | 99                          |  | 1 |   | =       |
| POLCO                       | 35-75  | 1                   | 63.8%                                   | 72.5                     | 71                          |  | 1 |   | =       |
| VIOAR                       | 52-89  | 2                   | 5.0% / 7                                | 91.0 (83-99)             | 86.0 (73-99)                | 1  | 1 |   | =       |
| Mean, all assessments       |  | 5                   |   | 90.5 (72.5-99)           | 88.2 (71-99)                | 1  | 4 |   | =       |
| Perennial broadleaved weeds |  |                     |   |                          |                             |  |   |   |         |
| TRFRE                       | 11-32  | 1                   | 7.3%                                    | 52.5                     | 89                          |  |   | 1 | <       |
| CIRAR                       | 42   | 2                   | 6.5-7.0                                 | 87.8 (87.5-88.0)         | 98.0 (98.0-98.0)            |  | 2 |   | <       |
| Mean, all assessments       |  | 3                   | 6.5-7.0                                 | 76.0 (52.5-88.0)         | 98.0 (98.0-98.0)            |  | 3 |   | <       |
| Perennial grass weeds       |  |                     |   |                          |                             |  |   |   |         |
| AGRRE                       | 11-80  | 8                   | 6.0-84.0                                | 80.9 (53.8-97.3)         | 87.2 (63.8-99.0)            |  | 6 | 2 | =       |

When applied at 2.0 l/ha in the North-east zone, Glyphosate 54% SL obtained good to excellent control when applied to annual and perennial grasses and broadleaved weeds commonly found in cereal field crops. In all species evaluated, the effect obtained with Glyphosate 54% SL was similar to the effect obtained with the glyphosate reference product applied in the trials. At one of the 15 assessments, the glyphosate reference product performed significantly better than Glyphosate 54% SL applied at comparable dose rates. At the remaining 14 assessments, no significant differences were observed between the two tested products.

The proposed label claims of the annual and perennial grass- and broadleaved weed spectrum controlled after application of 2.0 l/ha Glyphosate 54% SL as recommended for desiccation of winter wheat before harvest are listed in Table 3.2-15.

**Table 3.2-15: Annual and perennial grass- and broadleaved weed spectrum controlled by 2.0 L/ha Glyphosate 54% SL after pre-harvest application, proven by testing results of the applicant in 2016**

|  | Botanical name               | EPPO code |
|--|------------------------------|-----------|
| Susceptible (≥ 85% control)                | <i>Elymus repens</i>         | AGRRE     |
|  | <i>Gnaphalium uliginosum</i> | GNAUL     |
|  | <i>Polygonum aviculare</i>   | POLAV     |
|  | <i>Viola arvensis</i>        | VIOAR     |
|  | <i>Cirsium arvense</i>       | CIRAR     |
| Variable or poor controlled (<85% control) | <i>Fallopia convolvulus</i>  | POLCO     |
|  | <i>Trifolium repens</i>      | TRFRE     |

### Control of annual and perennial mono- and dicotyledonous weeds with spring application at sowing

The efficacy trials were conducted to prove the following label claims:

|                    |  |
|--------------------|--|
| Crop, stage        | Spring-sown crops – before sowing                  |
| Use rate           | 2.0 L/ha Glyphosate 54% SL                         |
| Use frequency      | 1x   |
| Application timing | Post-emergence to weeds / before emergence of crop |
| Target weeds       | Annual and perennial grasses and broadleaved weeds |

The effectiveness of applying Glyphosate 54% SL against mono- and dicotyledonous weeds in the spring was evaluated in thirteen trials conducted in field crops, i.e. thirteen trials treated after sowing, but before emergence, of maize (5), sunflower (2), spring barley (4) and spring wheat (2). These trials were carried out in 2016 (5) and 2017 (8) in the North-east EPPO zone (13; i.e. Poland (9) and Lithuania (4)). The objective was to confirm the performance of Glyphosate 54% SL at 2.0 L/ha (i.e. 1080 g glyphosate per hectare) and demonstrate comparability to the reference product. In the trials, one application was applied in the spring (April-May) before emergence of the crop.

In the trials, Glyphosate 54% SL was tested alongside an EU approved glyphosate 36% SL formulation, i.e. Roundup 360 Plus and Roundup Classic. The summary of efficacy results obtained with the application of Glyphosate 54% SL at 2.0 L/ha and the reference product at comparable dose rates on annual and perennial grasses and broadleaved weeds in the autumn are listed in Table 3.2-16 for results from all trials conducted in the North-east EPPO zone.

When applied at 2.0 l/ha in the North-east zone, Glyphosate 54% SL obtained moderate to good control when applied to annual and perennial grasses and broadleaved weeds commonly found in spring-sown field crops. In most species evaluated, the effect obtained with Glyphosate 54% SL was similar to the effect obtained with the glyphosate reference product applied in the trials. At four of the 57 assessments, the glyphosate reference product performed significantly better than Glyphosate 54% SL applied at comparable dose rates. At the remaining 27 of the 57 assessments, no significant differences were observed between the two tested products.

**Table 3.2-16: North-east zone: Efficacy of 2.0 L/ha Glyphosate 54% SL and reference product at equivalent dose rate in the efficacy tests 2016 and 2017 – late spring evaluation, 12-60 DAT.**

| EPPO<br>Code             | Weed<br>Growth<br>stage at<br>application<br>[BBCH] | No.<br>of<br>trials | Ground<br>cover<br>(no/m²) | Efficacy obtained with   |                          |                             | No. of trials where Glyphosate<br>54% SL at 1080 g glyphosate/ha<br>is >, < or =, compared to the<br>glyphosate Ref. product at 1800 g<br>glyphosate/ha<br>=: ± 5% control |   |   | Overall |
|--------------------------|---|---------------------|----------------------------|--------------------------|--------------------------|-----------------------------|--|---|---|---------|
|                          |   |                     |                            | Glyphosate<br>54% SL at: | Glyphosate<br>54% SL at: | Glyphosate<br>ref. prod. at |  |   |   |         |
|                          |   |                     |                            | Mean (min-max)           |                          |                             |  |   |   |         |
|                          |   |                     |                            | 2.0 L/ha                 | 3.5 L/ha                 | 5.0 L/ha                    | >  | = | < |         |
| Annual broadleaved weeds |   |                     |                            |                          |                          |                             |  |   |   |         |
| BRSNX                    | n.r.  | 1                   | 12.0                       | 72.5                     | 75                       | 85                          |  |   | 1 | >       |
| LAMPU                    | 22  | 1                   | 3.5%                       | 77.8                     | 85.0                     | 79.8                        |  | 1 |   | =       |



| Weed Growth stage at application [BBCH]<br>No. of trials |       |    | Ground cover (no/m²) | Efficacy obtained with |                       |                          | No. of trials where Glyphosate 54% SL at 1080 g glyphosate/ha is >, < or =, compared to the glyphosate Ref. product at 1800 g glyphosate/ha = : ± 5% control |    |    | Overall  |
|--|-------|----|----------------------|------------------------|-----------------------|--------------------------|--|----|----|----------|
|  |       |    |                      | Glyphosate 54% SL at:  | Glyphosate 54% SL at: | Glyphosate ref. prod. at |  |    |    |          |
|  |       |    |                      | Mean (min-max)         |                       |                          |  |    |    | 2.0 L/ha |
| EPPO Code  |       |    |                      |                        |                       |                          |  |    |    |          |
| CHEAL  | n.r.  | 8  | 29-50                | 60.8<br>(40.0-92.3)    | 64.4<br>(31.3-95.8)   | 63.5<br>(30.0-93.0)      | 1  | 5  | 2  | ■        |
| GALAP  | n.r.  | 4  | 6.0-29.0             | 56.2<br>(21.3-88.0)    | 63.4<br>(23.8-93.8)   | 65.3<br>(32.5-93.3)      |  | 2  | 2  | ■        |
| MATMA  | n.r.  | 1  | 41.0                 | 46.3                   | 47.5                  | 52.5                     |  |    | 1  | ▲        |
| POLAV  | n.r.  | 2  | 3.0-18.0             | 50.6<br>(50.0-51.3)    | 53.1<br>(48.8-57.5)   | 53.1<br>(47.5-58.8)      |  | 1  | 1  | ■        |
| POLCO  | n.r.  | 2  | 4.0-11.0             | 51.9<br>(48.0-55.0)    | 55.0<br>(51.3-58.8)   | 60.0<br>(53.8-66.3)      |  | 1  | 1  | ■        |
| VERPE  | n.r.  | 3  | 4.0-5.0              | 67.4<br>(32.5-88.5)    | 79.1<br>(38.8-99.3)   | 81.1<br>(47.5-98.5)      |  |    | 3  | ▲        |
| VIOAR  | n.r.  | 2  | 10.0                 | 44.6<br>(6.3-82.8)     | 48.7<br>(6.3-91.0)    | 44.0<br>(2.5-85.5)       |  | 2  |    | ■        |
| MATIN  | 12-51 | 5  | 4.0-6.0              | 78.1<br>(66.3-98.0)    | 94.5<br>(90.0-98.8)   | 91.4<br>(80.0-97.0)      | 1  |    | 4  | ▲        |
| STEME  | 12-14 | 3  | 5.0-6.0              | 92.3<br>(92.1-92.5)    | 100<br>(100-100)      | 100<br>(100-100)         |  |    | 3  | ▲        |
| CAPBP  | 14-30 | 4  | 5.0-7.0              | 78.5<br>(66.3-92.5)    | 96.7<br>(95.0-98.8)   | 95.5<br>(85.0-100)       | 1  |    | 3  | ▲        |
| GERPU  | 14-16 | 2  | 4.0                  | 56.7<br>(51.3-62.1)    | 88.5<br>(85.8-91.3)   | 87.8<br>(85.0-89.8)      |  |    | 2  | ▲        |
| POLPE  | 12-14 | 1  | 4.0                  | 55.0                   | 91.8                  | 94.8                     |  |    | 1  | ▲        |
| DESS0  | 14-16 | 1  | 5.0                  | 71.3                   | 90.0                  | 91.3                     |  |    | 1  | ▲        |
| Mean, all assessments                                    |       | 40 | 3-50                 | 65.9<br>(6.3-98.0)     | 76.0<br>(6.3-100)     | 76.0<br>(2.5-100)        | 3  | 12 | 25 | ▲        |
| Perennial broadleaved weeds                              |       |    |                      |                        |                       |                          |  |    |    |          |
| CIRAR  | 12-40 | 3  | 5.0                  | 87.4<br>(78.8-92.3)    | 96.0<br>(94.8-97.8)   | 96.6<br>(96.0-97.5)      |  | 2  | 1  | ■        |
| ACHMI  | 10-30 | 2  | 2-7.5%               | 94.7<br>(93.0-96.3)    | 97.2<br>(96.8-97.5)   | 96.9<br>(96.3-97.5)      |  | 2  |    | ■        |
| TAROF  | 12-14 | 2  | 4.5-5%               | 91.8<br>(87.5-96.0)    | 96.5<br>(95.0-98.0)   | 96.1<br>(95.0-97.3)      |  | 1  | 1  | ■        |
| PTLAN  | 14-20 | 2  | 3-6.3%               | 90.7<br>(85.0-96.3)    | 86.0<br>(75.0-97.0)   | 90.4<br>(83.8-97.0)      |  | 2  |    | ■        |
| TRFAR  | 31    | 1  | 3.5%                 | 96.5                   | 98.0                  | 98.0                     |  | 1  |    | ■        |
| ARTVU  | 13    | 1  | 7.5%                 | 95.0                   | 98.0                  | 98.0                     |  | 1  |    | ■        |
| Mean, all assessments                                    |       | 11 | 5.0                  | 91.6<br>(78.8-96.5)    | 94.8<br>(75.0-98.0)   | 95.7<br>(83.8-98.0)      |  | 9  | 2  | ■        |
| Annual grass weeds                                       |       |    |                      |                        |                       |                          |  |    |    |          |
| LOLMG  | 21    | 2  | 25-32%               | 92.9<br>(90.5-95.3)    | 95.5<br>(94.0-97.0)   | 95.1<br>(93.8-96.3)      |  | 2  |    | ■        |
| ECHCG  | n.r.  | 2  | 15-25                | 35.0<br>(32.5-37.5)    | 47.5<br>(38.8-56.3)   | 45.6<br>(35-56.3)        |  | 1  | 1  | ■        |
| POAAN  | 12-13 | 3  | 6.0-7.0              | 77.1<br>(74.5-81.8)    | 100<br>(100-100)      | 99.5<br>(99-100)         |  |    | 3  | ▲        |
| Mean, all assessments                                    |       |    | 6.0-25               | 70.8<br>(32.5-92.9)    | 83.7<br>(38.8-100)    | 81.6<br>(35.0-100)       |  | 3  | 4  | ▲        |
| Perennial grass weeds                                    |       |    |                      |                        |                       |                          |  |    |    |          |
| AGRRE  | n.r.  | 6  | 3-20                 | 73.4<br>(57.5-94.3)    | 77.1<br>(60.0-98.0)   | 77.6<br>(60.0-97.8)      |  | 3  | 3  | ■        |

The combined proposed label claims of the annual and perennial grass- and broadleaved weed spectrum controlled after application of 2.0 l/ha Glyphosate 54% SL post-emergence to weeds are listed in Table 3.2-19.

### Control of annual and perennial mono- and dicotyledonous weeds in orchards with application during growing season

The efficacy trials were conducted to prove the following label claims:

|             |  |
|-------------|--|
| Crop, stage | Orchard crops – During growing season<br>Pome fruit: BBCH 31-69<br>Grapevine: BBCH 13-69 |
|-------------|--|

|                    |  |
|--------------------|--|
|                    | Stone fruit: BBCH 31-59                            |
| <b>Use rate</b>    | 2.0 L/ha Glyphosate 54% SL                         |
| Use frequency      | 1x   |
| Application timing | Post-emergence to weeds                            |
| Target weeds       | Annual and perennial grasses and broadleaved weeds |

The effectiveness of applying Glyphosate 54% SL against mono- and dicotyledonous weeds in orchards was evaluated in eight trials conducted in orchards, i.e. six trials conducted in apple orchards and two trials conducted in grapevine orchards. These trials were carried out in 2016 in the North-east EPPO zone (6; i.e. Latvia (2) and Lithuania (4)) and the Maritime EPPO zone (2; i.e. Czech Republic). The objective was to confirm the performance of Glyphosate 54% SL at 2.0 L/ha (i.e. 1080 g glyphosate per hectare) and demonstrate comparability to the reference product. In the orchard trials, one application was applied in the spring/summer (May-June), when the crop was at growth stages ranging between BBCH 55 and BBCH 69.

In the trials, Glyphosate 54% SL was tested alongside an EU approved glyphosate 36% SL formulation, i.e. Roundup Bio (LV), Roundup Classic (LT) and Roundup Klasik Pro (CZ). The summary of efficacy results obtained with the application of Glyphosate 54% SL at 2.0-2.4 L/ha and the reference product at comparable dose rates on annual and perennial grasses and broadleaved weeds during the growing season are listed in Table 3.2-17 and Table 3.2-18 for results from trials conducted in the North-east (6) and the Maritime (2) EPPO zone, respectively.

**Table 3.2-17: North-east zone: Efficacy of 2.0 L/ha Glyphosate 54% SL and reference product at equivalent dose rate in the efficacy tests 2016 – summer evaluation, 26-63 DAT.**

| EPPO Code                   | Weed Growth stage at application [BBCH] | No. of trials | Ground cover (no/m <sup>2</sup> ) | Efficacy obtained with |                       |                          | No. of trials where Glyphosate 54% SL at 1080 g glyphosate/ha is >, < or =, compared to the glyphosate Ref. product at 1800 g glyphosate/ha = : ± 5% control |   |   | Overall |
|-----------------------------|---|---------------|-----------------------------------|------------------------|-----------------------|--------------------------|--|---|---|---------|
|                             |   |               |                                   | Glyphosate 54% SL at:  | Glyphosate 54% SL at: | Glyphosate ref. prod. at |  |   |   |         |
|                             |   |               |                                   | Mean (min-max)         |                       |                          |  |   |   |         |
|                             |   |               |                                   | 2.0-2.4 L/ha           | 3.5 L/ha              | 5.0 L/ha                 | >  | = | < |         |
| Annual broadleaved weeds    |   |               |                                   |                        |                       |                          |  |   |   |         |
| CAPBP                       | 40                                      | 2             | 190-224                           | 83.2 (74.5-91.8)       | 89.6 (81.0-98.1)      | 91.8 (87.8-95.7)         |  | 1 | 1 | =       |
| GALAP                       | 11-40                                   | 3             | 194-209                           | 82.0 (52.0-98.0)       | 87.0 (65.9-98.2)      | 97.1 (92.9-99.5)         |  | 2 | 1 | <       |
| LAMPU                       | 65                                      | 2             | 196-272                           | 42.7 (35.1-50.2)       | 80.3 (64.8-95.7)      | 85.3 (70.6-100)          |  |   | 2 | <       |
| Mean, all assessments       |   | 7             |                                   | 71.1 (35.1-98.0)       | 85.8 (64.8-98.2)      | 92.2 (70.6-100)          |  | 3 | 4 | <       |
| Perennial broadleaved weeds |   |               |                                   |                        |                       |                          |  |   |   |         |
| ACHMI                       | 18-39                                   | 1             | 11.3%                             | 56.3                   | 82.3                  | 88.5                     |  |   | 1 | <       |
| CERAR                       | 21-67                                   | 3             | 170-218                           | 77.2 (52.8-99.0)       | 91.1 (74.4-100)       | 90.0 (71.1-100)          |  | 1 | 2 | <       |
| TAROF                       | 10-99                                   | 4             | 254-297                           | 79.9 (62.8-99.4)       | 90.9 (79.2-100)       | 92.6 (80.8-97.5)         |  | 1 | 3 | <       |
| TRFRE                       | 10-51                                   | 1             | 25%                               | 48.8                   | 86                    | 86                       |  |   | 1 | <       |
| Mean, all assessments       |   | 9             |                                   | 72.9 (48.8-99.4)       | 87.6 (62.8-100)       | 90.5 (71.1-100)          |  | 2 | 7 | <       |
| Annual grass weeds          |   |               |                                   |                        |                       |                          |  |   |   |         |
| POAAN                       | 61                                      | 2             | 22.0-34.5                         | 65.0 (57.5-72.5)       | 80.7 (75.0-86.3)      | 88.4 (85.4-91.3)         |  |   | 2 | <       |
| Perennial grass weeds       |   |               |                                   |                        |                       |                          |  |   |   |         |
| AGRRE                       | 65                                      | 2             | 184-215.5                         | 80.8 (61.5-100)        | 91.2 (82.4-100)       | 90.1 (84.1-96)           |  | 1 | 1 | =       |
| FESRU                       | 12-59                                   | 1             | 21.3%                             | 82.3                   | 95.5                  | 96                       |  |   | 1 | <       |
| POAPR                       | 10-69                                   | 1             | 25%                               | 67.5                   | 93.8                  | 96.5                     |  |   | 1 | <       |
| Mean, all assessments       |   | 4             |                                   | 77.8 (61.5-100)        | 87.7 (61.5-100)       | 93.2 (84.1-96.5)         |  | 1 | 3 | <       |

When applied at 2.0-2.4 l/ha in the North-east zone, Glyphosate 54% SL obtained good to very good control when applied to annual and perennial grasses and broadleaved weeds commonly found in orchards. In all species evaluated, the effect obtained with Glyphosate 54% SL was similar to the effect obtained with the glyphosate reference product applied in the trials. At six of the 22 assessments, the glyphosate reference product performed similar results than Glyphosate 54% SL applied at comparable dose rates. At the remaining 16 assessments, the reference products performed better efficacy, but the proposed dose (2.0L/ha) performed sufficient efficacy for the control of annual and perennial grasses and broadleaved weeds commonly found in orchards.

**Table 3.2-18: Maritime zone: Efficacy of 2.0 L/ha Glyphosate 54% SL and reference product at equivalent dose rate in the efficacy tests 2016 – summer evaluation, 20-28 DAT.**

| EPPO Code                   | Weed Growth stage at application [BBCH] | No. of trials | Ground cover (no/m <sup>2</sup> ) | Efficacy obtained with |                       |                          | No. of trials where Glyphosate 54% SL at 1080 g glyphosate/ha is >, < or =, compared to the glyphosate Ref. product at 1800 g glyphosate/ha = : ± 5% control |   |   | Overall |
|-----------------------------|---|---------------|-----------------------------------|------------------------|-----------------------|--------------------------|--|---|---|---------|
|                             |   |               |                                   | Glyphosate 54% SL at:  | Glyphosate 54% SL at: | Glyphosate ref. prod. at |  |   |   |         |
|                             |   |               |                                   | Mean (min-max)         |                       |                          |  |   |   |         |
|                             |   |               |                                   | 2.0 L/ha               | 3.5 L/ha              | 5.0 L/ha                 | >  | = | < |         |
| Annual broadleaved weeds    |   |               |                                   |                        |                       |                          |  |   |   |         |
| GALAP                       | 60                                      | 1             | 4.0                               | 6.3                    | 56.3                  | 73.8                     |  |   | 1 | ▲       |
| GERMO                       | 63                                      | 2             | 12.3-16.5                         | 65.6<br>(35.0-96.3)    | 88.1<br>(76.3-100)    | 96.3<br>(92.5-100)       | 1  |   | 1 | ▲       |
| VICVI                       | 49                                      | 2             | 8.8-12.0                          | 71.9<br>(51.3-92.5)    | 85.0<br>(70-100)      | 93.8<br>(87.5-100)       |  |   | 2 | ▲       |
| Mean, all assessments       |   | 5             |                                   | 56.3<br>(6.3-96.3)     | 80.5<br>(56.3-100)    | 90.8<br>(73.8-100)       |  | 1 | 4 | ▲       |
| Perennial broadleaved weeds |   |               |                                   |                        |                       |                          |  |   |   |         |
| CONAR                       | 60                                      | 2             | 9-18.8                            | 66.9<br>(43.8-90.0)    | 84.4<br>(68.8-100)    | 93.8<br>(87.5-100)       |  |   | 2 | ▲       |
| Annual grass weeds          |   |               |                                   |                        |                       |                          |  |   |   |         |
| AVEFA                       | 49                                      | 1             | 10.5                              | 91.3                   | 100                   | 100                      |  |   | 1 | ▲       |
| Perennial grass weeds       |   |               |                                   |                        |                       |                          |  |   |   |         |
| AGRRE                       | 55                                      | 1             | 30.8                              | 92.5                   | 100                   | 100                      |  |   | 1 | ▲       |
| LOLPE                       | 55                                      | 1             | 20.5                              | 90.0                   | 100                   | 98.8                     |  |   | 1 | ▲       |
| Mean, all assessments       |   | 2             |                                   | 91.3 (90.92.5)         | 100 (-)               | 99.4 (98.8-100)          |  |   | 2 | ▲       |

When applied at 2.0 l/ha in the Maritime zone, Glyphosate 54% SL obtained good to excellent control when applied to annual and perennial grasses and broadleaved weeds commonly found in orchards. In most species evaluated, the effect obtained with Glyphosate 54% SL was similar to the effect obtained with the glyphosate reference product applied in the trials. At one of the 9 assessments, the glyphosate reference product performed similar results than Glyphosate 54% SL applied at comparable dose rates. At the remaining 8 assessments, the reference products performed better efficacy, but the proposed dose (2.0L/ha) performed sufficient efficacy for the control of annual and perennial grasses and broadleaved weeds commonly found in orchards.

The combined proposed label claims of the annual and perennial grass- and broadleaved weed spectrum controlled after application of 2.0 l/ha Glyphosate 54% SL post-emergence to weeds are listed in Table 3.2-19.

### Summary and conclusion

Based on the results of 44 field trials carried out in 2016, 2017 and 2018, the following can be concluded for the intended use 'Control of annual and perennial grasses and broadleaved weeds' from Glyphosate 54% SL applied on actively growing weeds at the dose rate of 2.0 l/ha and for the use 'Desiccation before harvest' at the dose rate of 2.0 L/ha:

- Glyphosate 54% SL provides a high level control of a wide range of annual and perennial mono- and dicotyledonous weeds when applied to emerged, actively growing weeds with the recommended dose rate of 2.0 l/ha. As weeds often occur as a complex of several weeds with different susceptibility towards glyphosate, one application of Glyphosate 54% SL at the recommended rate 2.0 l/ha rate should be used to efficiently control all weeds claimed on the label.
- A high level of control of weeds may also be obtained if Glyphosate 54% SL is used at 2.0 l/ha for desiccation of winter wheat, before harvest.
- Compared to the glyphosate reference product, the efficacy obtained with GLYPHOSATE 54% SL is comparable against all weed species.

- The trial results are considered valid for all intended Central zone countries.

Glyphosate 54% SL is suitable for the control of annual and perennial weeds in a range of crops, when applied before sowing of cereals, oilseed rape, sunflower, maize in the spring or autumn or when applied during the growing season in orchards.

Glyphosate is a broad-spectrum herbicide and irrespective of the cropping system, the same mono- and dicotyledonous weeds are controlled by glyphosate if the weeds are actively growing. When treating actively growing weeds, the same level of control would be expected irrespective if treated in the spring, summer or autumn and this has been seen in the trials. Therefore, for any label claims not adequately supported for one use, Sharda Cropchem España requests that the Zonal Evaluators reads across to the data on other uses. This BAD also clearly demonstrates that the efficacy and cropsafety of Glyphosate 54% SL is equivalent to the efficacy and cropsafety of the standard glyphosate reference products against which Glyphosate 54% SL was compared. The applicant therefore wishes to cite the original registrant's data on glyphosate now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

The combined proposed label claims across uses, based on control achieved with Glyphosate 54% SL, has been summarized in Table 3.2-19.

**Table 3.2-19: Annual and perennial grass- and broadleaved weed spectrum controlled by 2.0 L/ha Glyphosate 54% SL after post-emergence application, proven by testing results of the applicant in 2016, 2017 and 2018.**

|  | <i>Botanical name</i>                    | <i>EPPO code</i> |
|--|--|------------------|
| <b>Susceptible (≥ 85% control)</b>                   | <i>Elymus repens</i>                     | AGRRE            |
|  | <i>Avena fatua</i>                       | AVEFA            |
|  | <i>Capsella bursa-pastoris</i>           | CAPBP            |
|  | <i>Cyanus segetum</i>                    | CENCY            |
|  | <i>Festuca rubra</i>                     | FESRU            |
|  | <i>Galium aparine</i>                    | GALAP            |
|  | <i>Gnaphalium uliginosum</i>             | GNAUL            |
|  | <i>Lolium perenne</i>                    | LOLPE            |
|  | <i>Polygonum aviculare</i>               | POLAV            |
|  | <i>Sinapis arvensis</i>                  | SINAR            |
|  | <i>Taraxacum officinale</i>              | TAROF            |
|  | <i>Thlaspi arvensis</i>                  | THLAR            |
|  | <i>Trifolium repens</i>                  | TRFRE            |
|  | <i>Triticum aestivum (volunteer)</i>     | TRZAX            |
|  | <i>Viola arvensis</i>                    | VIOAR            |
|  | <i>Chenopodium album</i>                 | CHEAL            |
|  | <i>Setaria gigantea</i>                  | SETGL            |
|  | <i>Myosotis arvensis</i>                 | MYOAR            |
|  | <i>Tripleurospermum inodorum</i>         | MATIN            |
|  | <i>Lamium purpureum</i>                  | LAMPU            |
|  | <i>Capsella bursa-pastoris</i>           | CAPBP            |
|  | <i>Geranium pusillum</i>                 | GERPU            |
|  | <i>Stellaria media</i>                   | STEME            |
|  | <i>Achillea millefolium</i>              | ACHMI            |
|  | <i>Taraxacum officinale</i>              | TAROF            |
|  | <i>Potentilla anserina</i>               | PTLAN            |
|  | <i>Trifolium arvense</i>                 | TRFAR            |
|  | <i>Artemisia vulgaris</i>                | ARTVU            |
|  | <i>Lolium multiflorum subsp. gaudini</i> | LOLMG            |
| <b>Variable or poor controlled (&lt;85% control)</b> | <i>Achillea millefolium</i>              | ACHMI            |
|  | <i>Brassica napus (volunteer)</i>        | BRSNX            |
|  | <i>Lamium amplexicaule</i>               | LAMAM            |
|  | <i>Tripleurospermum maritimum</i>        | MATMA            |
|  | <i>Papaver rhoeas</i>                    | PAPRH            |

|  | <b>Botanical name</b>       | <b>EPPO code</b> |
|--|-----------------------------|------------------|
|  | <i>Fallopia convolvulus</i> | POLCO            |
|  | <i>Convolvulus arvensis</i> | CONAR            |
|  | <i>Geranium mole</i>        | GERMO            |
|  | <i>Vicia villosa</i>        | VICVI            |
|  | <i>Poa pratensis</i>        | POAPR            |
|  | <i>Poa annua</i>            | POAAN            |
|  | <i>Cerastium arvense</i>    | CERAR            |
|  | <i>Artemisia vulgaris</i>   | ARTVU            |
|  | <i>Rumex crispus</i>        | RUMCR            |
|  | <i>Cirsium arvense</i>      | CIRAR            |
|  | <i>Solidago canadensis</i>  | SOOCA            |
|  | <i>Descurainia sophia</i>   | DESSO            |

|                          |   |
|--------------------------|---|
| <b>Comments of zRMS:</b> | <p>A total of 44 efficacy trials were used to evaluate of Candela product (Glyphosate 54%) control of annual and perennial grass- and broadleaved weeds in winter cereals (wheat, barley, triticale), winter oilseed rape, application before sowing and two trials where Glyphosate 54% SL was applied in winter wheat stubbles after harvest, spring barley, maize, spring wheat, sunflower after sowing but before emergence, when applied to emerged, actively growing weeds with the recommended dose rate of 2.0 l/h and in the orchard trials, one application was applied in the spring/summer (May-June), when the crop was at growth stages ranging between BBCH 55 and BBCH 69. Candela is also recommended applied for desiccation of winter wheat crops before harvest at 2.0 l/ha, however, the glyphosate applied will also have an effect on the annual and perennial weeds present in the winter wheat field.</p> <p>Data shows that the test herbicide gives an effective reduction of weeds at least of the performance level if not higher as the standard products. The zRMS considers that the products used are acceptable as reference products. In all of the trials, a randomised complete block design was used, and generally a minimum plot size of 12.0 m<sup>2</sup>.</p> <p>The meteorological conditions observed at application are shown in the BAD.</p> <p>All of the trials submitted for application in autumn and spring followed the EPPO standards and were conducted in accordance with GEP. Appropriate evidence of the GEP of organisations that conducted the trials and relevant certificates have been provided. Infestation in the untreated control was minimum 3 plants/m<sup>2</sup> and therefore zRMS considers all the trials to be sufficiently challenging.</p> <p>Trials conducted for Candela product are sufficient taking into account requirements of EPPO guideline PP 1/214 "Principles of acceptable efficacy".</p> <p>AVEFA, FESRU, GNAUL, LOLPE, THLAR, SEGL, MYOAR, TRFAR, PAPRH, POAPR, DESSO were only in one trial and therefore can't be mentioned on the label. It is expected that relevance of each weed species vary across the Central zone and the zRMS can't exactly confirm how important each weed is in each cMS. Therefore, the cMS use above information to determine appropriate susceptibility claims depending on whether the weed is major or minor in their MS. The zRMS considers that there is sufficient data to support registration Candela product for control grass and broadleaved weeds in winter cereals (wheat, barley triticale), winter oilseed rape, spring barley, spring wheat and orchards (apple, grapevine) in Central zone.</p> <p>No further information is required</p> |
|--------------------------|---|

### 3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

#### 3.3.1 Summary and Conclusions

Resistance is a natural phenomenon embodied in the process of the evolution of biological systems and has been experienced over and over again in the past. According to Heap (2018<sup>2</sup>) resistance is the naturally occurring inheritable ability of some weed biotypes within a population to survive an herbicide treatment that would, under normal conditions of use, effectively control that weed population. Selection of resistant biotypes may eventually result in control failures.

The risk of resistance was analysed following the EPPO-Standard (2015<sup>3</sup>), the classification of the Herbicide Resistance Action Committee (HRAC)<sup>4</sup> and the international Survey of Herbicide Resistant Weeds (Heap 2018). So far, 290 cases in 40 weed species have been reported worldwide to have developed resistance to glyphosate. In Europe, 23 cases of resistance was reported in six weed species. Glyphosate is originally classified as having a low inherent risk of resistance, but excessive use of glyphosate as sole products has greatly increased the incidence of resistance.

The evaluation of the agronomic risk comes to the conclusion, that Glyphosate 54% SL bears a moderate risk of resistance.

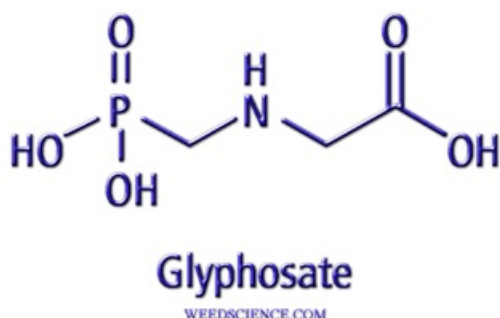
The Registration of Glyphosate 54% SL is endorsed.

#### 3.3.2 Active ingredient

Glyphosate, with the chemical name *N*-(phosphonomethyl)glycine (IUPAC), belongs to the chemical group of the Phosphonoglycines. It is a non-selective herbicide used in a wide range of cropping, utility and industrial situations for broad-spectrum control of grasses and broadleaved weeds. Glyphosate provides contact activity against important annual and perennial grasses and broadleaved weeds across all climatic zones of Europe.

The chemical structure of glyphosate is shown in Figure 3.3-1.

**Figure 3.3-1:** Structure of glyphosate (Source: Heap, I. The International Survey of Herbicide Resistant Weeds. Online. Internet. Saturday, January 20<sup>th</sup>, 2018. Available [www.weedscience.com](http://www.weedscience.com))



#### 3.3.3 Mode of action

Glyphosate is absorbed through foliage and minimally through roots, meaning that it is only effective on actively growing plants and cannot prevent seeds from germinating. After application, glyphosate is readily transported around the plant to growing roots and leaves and this systemic activity is important for

<sup>2</sup> Heap, I. M., 2018: The International Survey of Herbicide Resistant Weeds. Web site visited January 2018. <http://www.weedscience.com>

<sup>3</sup> EPPO 2015: Standard PP 1/213 (4): Resistance risk analysis.

<sup>4</sup> HRAC: <http://www.HRACglobal.com>. Web site visited January 2018.



its effectiveness. It inhibits a plant enzyme (5-enolpyruvylshikimate-3-phosphate synthase) involved in the synthesis of three aromatic amino acids: tyrosine, tryptophan and phenylalanine. Inhibiting the enzyme causes shikimate to accumulate in plant tissues and diverts energy and resources away from other processes. While growth stops within hours of application, it takes several days for the leaves to begin turning yellow.

Due to its primary target site and its chemical family, in the HRAC mode of action classification it is classified as group G (WSSA group 9) herbicide:

- Mode of Action: Inhibition of EPSP synthase
- Chemical family: Phosphonoglycine

### 3.3.4 Status

Currently, 290 cases in 40 weed species have been reported worldwide to have developed resistance to glyphosate (Heap 2018). In Europe, 23 cases of resistance was reported in six weed species. The first report was from Australia in 1996 where *Lolium rigidum* (Rigid ryegrass) evolved resistance towards glyphosate in fields with canola, cereals, fencelines and wheat. Since then, especially during the last 10 years, new weeds has been added to the list and there is no reason to believe that this phenomenon will disappear. Many of the weed species has developed resistant independently in different countries and often with cross-resistance to other group G/9 herbicides as well as other herbicide groups with other sites of action (Heap, 2018). There are many reports from especially US but also Australia, Canada and South America are well represented. However, the below mention examples are from Central Europe. It is important to emphasise that the examples given below is not necessarily the complete picture of glyphosate resistance reported in the given countries but merely examples. Further information and updates regarding resistance and weed populations can be seen on [www.weedscience.org](http://www.weedscience.org).

#### Hungary

In 2016, glyphosate resistant *Conyza canadensis* were reported in Hungary. In Hungary this weed first evolved resistance to Group G/9 herbicides in 2016 and infests Grapes.

#### Czech Republic

Glyphosate resistant horseweed (*Conyza canadensis*) was also reported from the Czech Republic, where this weed first evolved resistance to Group G/9 herbicides in 2007 and infests Railways.

#### Poland

Finally, in Poland, glyphosate resistant horseweed (*Conyza canadensis*) was also reported. In Poland this weed first evolved resistance to Group G/9 herbicides in 2010 and infests Railways.

No glyphosate resistant weeds were reported from any of the other countries in the Central European zone. However, to the South, glyphosate resistance was reported from Spain, Italy, Greece, Portugal, France and Switzerland in perennial ryegrass (*Lolium perenne*), Italian ryegrass (*Lolium perenne* spp. *multiflorum*), Rigid ryegrass (*Lolium rigidum*), Horseweed (*Conyza canadensis*), Hairy fleabane (*Conyza banariensis*) and Sumatran fleabane (*Conyza sumatrensis*).

There are numerous of other cases worldwide, further information and updates on the subject can be seen on [www.weedscience.com](http://www.weedscience.com).

### 3.3.5 Mechanism(s) of resistance

Herbicide resistance can be due to at least three different mechanisms: (1) alterations of the target site; (2) changes in sequestration and/or translocation of the herbicide; (3) changes in rates of metabolism of the herbicide. Currently, two of these mechanisms have been identified as responsible for glyphosate resistance in weeds. Alterations of the target site via a mutation in the EPSPS gene so that it is no longer inhibited by glyphosate or overexpression of EPSP have been documented in goosegrass (*Eleusine indica*), rigid ryegrass (*Lolium rigidum*), Italian ryegrass (*Lolium perenne* ssp. *multiflorum*), Palmer amaranth (*Amaranthus palmeri*) and tall waterhemp (*Amaranthus tuberculatus*). Reduced translocation of glyphosate to the meristems, presumably through sequestration at the site of application, has been identified in

rigid ryegrass, hairy fleabane (*Conyza bonariensis*) and horseweed (*Conyza canadensis*). To date, there have been no resistant weed populations identified with altered glyphosate metabolism.

#### **3.3.5.1 Cross-resistance**

“When a plant expressing resistance to a herbicide also demonstrates resistance to other herbicides that target the same plant process even though the plant has not been exposed to the other herbicides, the resistance is termed cross-resistance” (Prather et al. 2000).

Since glyphosate and other EPSP synthase inhibitors are active towards a single target site, cross resistance is a well-known phenomenon in this group of chemicals. It is therefore important to keep the label recommended limitations concerning the frequency by which glyphosate should be used.

In 1997, one of the first signs of cross resistant weeds were evident, when multiple resistant Goosegrass (*Eleusine indica*) evolved in Malaysian orchards (Heap 2018). Multiple resistance had evolved to herbicides in the Groups A/1, and G/9. These particular biotypes are known to have resistance to fluazifop-P-butyl, and glyphosate and they may be cross-resistant to other herbicides in the Groups A/1, and G/9.

In Europe, multiple cross resistance have been reported in Sumatran fleabane (*Conyza sumatrensis*), Italian ryegrass (*Lolium perenne* spp. *multiflorum*) and Rigid ryegrass (*Lolium rigidum*). In 2008, multiple resistant Italian ryegrass was reported from Italy, being cross-resistant with glyphosate and Clodinafop (ACCase inhibitors, A/1), among others. Later, in 2012, Italian ryegrass was again reported from Italy, being multiple resistant to glyphosate and iodosulfuron (ALS inhibitor, B/2), among others. In 2016, from France, another case of multiple resistance was reported, including glyphosate and an ALS inhibitor (flazasulfuron, iodosulfuron, mesosulfuron, a.o.). The last case of multiple resistance from Europe was observed in 2016 where Rigid ryegrass was resistant to glyphosate as well as Oxyfluorfen (PPO inhibitor, E/14).

There are numerous of other cases worldwide, further information and updates on the subject can be seen on [www.weedscience.com](http://www.weedscience.com).

#### **3.3.5.2 Baseline sensitivity**

Weeds vary in their sensitivity towards herbicides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. EPSP synthase inhibitors have been tested and used worldwide for almost 45 years, it is therefore difficult to find unexposed weed populations. No true base line sensitivity data can therefore be established.

#### **3.3.6 Use pattern**

Glyphosate 54% SL is based on the activity of glyphosate which is a non-selective post-emergence herbicide. In the EU Central zone, the formulation is proposed for use against annual and perennial grasses and broadleaved weeds in a range of crops when applied pre-sowing. Furthermore, Glyphosate 54% SL is proposed for use as a crop desiccant in winter wheat, applied shortly before harvest. **The recommended dose rate is 2.0 (1080 g ai/ha).** The maximum number of applications is one application per growing season.

Glyphosate has been used as straight product as well as in mixtures for many years.

#### **3.3.7 Determination of the Agronomic Risk of Resistance**

Agronomic parameters reducing the risk of a development of resistance are:

- Weed control strategies including chemical, non-chemical, biological and cultural practices.
- No repeated applications in the same crop per season.
- Wide crop rotations
- Low weed pressure
- Applications in mixture with other (different mode of action) active substances.
- Alternation with other (different modes of action) active substances.
- High level of activity on the target weed species.
- Low residual activity.
- Chemical diversity



Agronomic parameters increasing the risk of a development of resistance are:

- Repeated applications during a crop cycle.
- Control of weeds with a sole active ingredient (mostly meaning a single site of action).
- Mono cropping.
- High weed pressure
- Application of sub-lethal concentrations of the herbicide.
- Long lasting residual activity.
- Chemical similarity

With respect to the above mentioned agronomic parameters and an **unrestricted** use pattern, the following can be stated for Glyphosate 54% SL:

Glyphosate 54% SL contains a sole ingredient.

Glyphosate 54% SL provides no residual activity.

At the intended use rate (2.0 L/ha), Glyphosate 54% SL is highly active on the target weed species.

Under unlimited conditions, Glyphosate 54% SL could be applied repeatedly during a crop cycle.

Recommended crop rotations should be employed. When used before seeding, herbicides employing other modes of action should be used during the growing season, if additional weed control is required.

#### **Conclusions:**

Although Glyphosate 54% SL is highly active on the target weed species and provides no residual activity, the agronomic risk for the development of resistance is considered high if the product is used unrestrictedly, since Glyphosate 54% SL contains a sole active ingredient only as well as it could be applied repeatedly during a crop cycle.

#### **3.3.8 Conclusion on inherent and agronomic risk analysis**

Taking into consideration inherent and agronomic risk for resistance development, it can be concluded that measures for resistance management should be established for the control of annual and perennial grasses and broadleaved weeds in the GAP claimed crops.

#### **3.3.9 Resistance management for Glyphosate 54% SL**

To avoid the development of resistance of grasses and broadleaved weed species to Glyphosate 54% SL, the following measures for resistance management should be established:

#### **Modifiers related to the application of the product:**

The number of applications in cereal crops should be limited to 1 application per crop cycle.

#### **Alternations:**

In case of repeated applications of herbicides for grass- and broadleaved weed control within a cropping season or in consecutive cropping seasons, only herbicides with a different mode of action should be used.

#### **Cultural practices:**

Since cross resistance between different modes of action cannot be excluded, application limitations and the alternation of herbicides should be supported by additional agricultural measures. To minimize the weed pressure, deep soil cultivation (plough) and late sowing are recommended.

#### **3.3.10 Implementation of the management strategy**

The basic recommendations for resistance risk management (maximum 1 application) will be clearly recommended on the label. Additional recommendations for product alternations and cultural practices will be given on the label.

### 3.3.11 Monitoring, reporting and reaction to changes in performance

Allegations of weeds control failures in Europe and around the world are monitored.

Sharda will inform the regulatory authorities of any new confirmed occurrence of resistance regarding the use of Glyphosate 54% SL.

|                          |   |
|--------------------------|---|
| <b>Comments of zRMS:</b> | <p>The applicant has provided a resistance risk assessment for grass and broad-leaved weeds in accordance with EPPO standard PP 1/213 and concluded that , the agronomic risk for the development of resistance is considered high if the product is used unrestrictedly, since Candela contains a sole active ingredient only as well as it could be applied repeatedly during a crop cycle.</p> <p>No further information is required.</p> <p>Such precaution should be put on product label:</p> <ul style="list-style-type: none"> <li>- <i>the number of applications in cereals crops should be limited to one application per crop cycle</i></li> <li>- <i>Candela should be used alternately with other compounds (compound change) from different HRAC groups in cereals as well as within the whole crop rotation</i></li> </ul> <p>All possibilities of good agronomic measures should be followed e.g. deep soil cultivation, late sowing time are recommended.</p> |
|--------------------------|---|

### 3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops)

**Table 3.4-1: Presentation of selectivity trials**

| Crop* | Country                           | Type of trial** | Number of trials |     |     |     | Years | GEP, non-GEP, official*** | Comments (any other relevant information) |
|-------|-----------------------------------|-----------------|------------------|-----|-----|-----|-------|---------------------------|---|
|       |                                   |                 | EPPO zone        |     |     |     |       |                           |   |
|       |                                   |                 | MAR              | MED | S-E | N-E |       |                           |   |
| BRSNW | Poland                            | Q + Y + S       | -                | -   | -   | 1   | 2016  | GEP                       | Before sowing, autumn                     |
|       | Poland                            | Q + Y + S       | 1                | 1   | 1   | 1   | 2018  | GEP                       | Before sowing, autumn                     |
|       | Lithuania                         | S               | -                | -   | -   | 1   | 2016  | GEP                       | Before sowing, autumn                     |
|       | Total, Winter oilseed rape (Sel.) |                 | -                | -   | -   | 2   |       |                           |   |
| HELAN | Poland                            | Q + Y + S       | -                | -   | -   | 1   | 2017  | GEP                       | Before emergence, spring                  |
|       | Total, Sunflower (Sel.)           |                 | -                | -   | -   | 1   |       |                           |   |
| TRZAS | Poland                            | Q + Y + S       | -                | -   | -   | 1   | 2017  | GEP                       | Before emergence, spring                  |
|       | Total, Spring wheat (Sel.)        |                 | -                | -   | -   | 1   |       |                           |   |
| TTLWI | Poland                            | Q + Y + S       | 1                | 1   | 1   | 1   | 2017  | GEP                       | Before sowing, autumn                     |
|       | Total, winter triticale (Sel.)    |                 | 1                | 1   | 1   | 1   |       |                           |   |
| TRZAW | Poland                            | Q + Y + S       | -                | -   | -   | 1   | 2016  | GEP                       | Before sowing, autumn                     |
|       | Poland                            | Q + Y + S       | 1                | 1   | 1   | 1   | 2017  | GEP                       | Before sowing, autumn                     |
|       | Total, Winter wheat (Sel.)        |                 | -                | -   | -   | 2   |       |                           |   |
| HORVS | Poland                            | Q + Y + S       | 1                | 1   | 1   | 1   | 2017  | GEP                       | Before sowing, spring                     |
|       | Poland                            | Q + Y + S       | 1                | 1   | 1   | 1   | 2018  | GEP                       | Before sowing, autumn                     |
|       | Total, Spring barley (Sel.)       |                 | 1                | 1   | 1   | 2   |       |                           |   |
| ZEAMX | Poland                            | Q + Y + S       | -                | -   | -   | 2   | 2016  | GEP                       | Before emergence, spring                  |
|       | Poland                            | Q + Y + S       | 1                | 1   | 1   | 1   | 2017  | GEP                       | Before emergence, spring                  |
|       | Total, Sunflower (Sel.)           |                 | -                | -   | -   | 3   |       |                           |   |
|       | Total                             |                 | -                | -   | -   | 13  |       |                           |   |

**Table 3.4-2: Details on selectivity trial methodology**

|                                   |  |  |
|-----------------------------------|--|--|
| <b>Guidelines</b>                 | General guidelines                         | EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4)   |
|                                   | Specific guidelines                        | Winter oilseed rape: EPPO PP 1/49(3)<br>Sunflower: EPPO PP 1/63(3)<br>Spring- and winter wheat and triticale: EPPO PP 1/93(3)<br>Maize: EPPO PP 1/50(3)  |
| <b>Experimental design</b>        | Plot design                                | RCBD (13)  |
|                                   | Plot size                                  | 16.5-33 m <sup>2</sup>   |
|                                   | Number of replications                     | 4 (13)   |
| <b>Crop</b>                       | Trials per crop                            | Winter oilseed rape (3), sunflower (1), spring barley (2), winter triticale (1), spring wheat (1), winter wheat (2) and maize (3)  |
|                                   | Varieties per crop                         | Winter oilseed rape: Poznaniak, Visby, Mercedes<br>Sunflower: Black<br>Spring wheat: Mandaryna<br>Spring barley: KWS Atrika, KWS Kosmos<br>Winter wheat: Julius, Arkadia<br>Maize: Farmstar, Enormo, Mas 17G<br>Winter triticale: Trapero  |
|                                   | Sowing period                              | Autumn-sown crops: from August 28 <sup>th</sup> to October 27 <sup>th</sup><br>Spring-sown crops: from April 19 <sup>th</sup> to May 27 <sup>th</sup>  |
|                                   |  |  |
| <b>Application</b>                | Application period                         | Autumn, pre-sowing: from August 27 <sup>th</sup> to October 24 <sup>th</sup><br>Spring, pre-emergence: from April 25 <sup>th</sup> to May 28 <sup>th</sup>   |
|                                   | Crop stage (BBCH)* at application          | Autumn: Pre-sowing, 0-5 days before sowing<br>Spring: Pre-emergence (BBCH 00), 5-7 days after sowing   |
|                                   | Number of appl.<br>Intervals between appl. | 1 (13 trials)<br>n.a.  |
|                                   | Spray volumes                              | 200 L/ha   |
| <b>Assessment</b>                 | Assessment types                           | <ul style="list-style-type: none"> <li>- Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms.</li> <li>- crop vigour</li> </ul> |
|                                   | Assessment dates                           | As a rule 3 to 4 crop injury ratings   |
| <b>Other relevant information</b> | Soil type                                  | Loam (1), Sandy loam (9), Sandy clay loam (1), Brown soil (2)  |
|                                   | Organic matter content                     | <1.5%(11), 1.5 to 2.49%(0); 2.5 to 3.5%(2), >3.5%(0); not indicated(0)   |
|                                   | pH   | 5.3-7.1  |
|                                   | Natural / artificial inoculation...        | Preferably weed-free conditions  |
|                                   | Field / Greenhouse...                      | Field  |

In selectivity trials, the performance of Glyphosate 54% SL was measured against a commercial standard 36% SL formulation of glyphosate currently on the market in Central Europe (Roundup 360 Plus / Roundup Bio). The trials were carried out on winter oilseed rape, sunflower, spring barley, spring wheat, winter wheat, winter triticale and maize.

The reference products used in the trials are listed in Table 3.4-3.

**Table 3.4-3: Presentation of reference standards used in trials (selectivity trials, transformation trials...)**

| Trade name       | Formulation | Composition        | Rates [l/ha] | Indication                   | Country | N° of trials |
|------------------|-------------|--------------------|--------------|------------------------------|---------|--------------|
| Roundup 360 Plus | SL          | 36% w/v glyphosate | 3.0<br>6.0   | Control of broadleaved weeds | PL      | 12           |
| Roundup Bio      | SL          | 36% w/v glyphosate | 7.0<br>14.0  | Control of broadleaved weeds | LT      | 1            |

### 3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

The crop safety of Glyphosate 54% SL applied before or shortly after seeding was assessed in cereals (winter wheat, spring wheat, winter barley, winter triticale, spring barley and spring oats), winter oilseed rape, maize, sunflower and faba beans in 36 efficacy trials (36 N-E) where Glyphosate 54% SL was applied at dose rates ranging from 1.5 L/ha and up to 4.5 l/ha, and in 13 crop safety trials (6 N-E) where Glyphosate 54% SL was applied at dose rates ranging from 2.0 L/ha and up to 9.0 l/ha.

The crop safety of Glyphosate 54% SL applied during the growing season in orchards was assessed in apple- and grapevine orchards in 8 efficacy trials (6 N-E and 2 MAR) where Glyphosate 54% SL was applied at dose rates ranging from 2.0 L/ha and up to 6.4 l/ha.

The trials were conducted in the North-east zone (55; Poland (35), Lithuania (14) and Latvia (6)) and the Maritime zone (2; Czech Republic) in 2016, 2017 and 2018 to evaluate the crop safety of Glyphosate 54% SL in a range of field- and orchard crops.

#### 3.4.1.1 Winter oilseed rape

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Glyphosate 54% SL was applied before sowing of winter oilseed rape, at the rate of 1.5 to 9.0 l/ha. 9.0 l/ha corresponds to 450% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest (BBCH 89).

#### Phytotoxicity in winter oilseed rape trials, North-east EPPO zone

A total of five efficacy trials and three selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Glyphosate 54% SL when applied as recommended in winter oilseed rape, i.e. before sowing. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and/or vigour were observed in any of the five efficacy trials and in either of the three selectivity trials conducted in the North-east EPPO zone. In the Lithuanian oilseed rape trial, Glyphosate 54% SL was applied at two timings, i.e. 5 days before sowing and 1 day before sowing. No adverse effects were observed with either application timing and the counting of plants emerged confirms this.

Furthermore, results from two winter oilseed rape trial harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

#### 3.4.1.2 Sunflower

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Glyphosate 54% SL was applied before emergence of sunflower, at the rate of 1.5 to 4.0 l/ha. 4.0 l/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest (BBCH 89).

#### Phytotoxicity in sunflower trials, North-east EPPO zone

Three trials, i.e. two efficacy trial and one selectivity trial, were conducted in the North-east EPPO zone to assess the crop safety of Glyphosate 54% SL when applied as recommended in sunflower. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity were observed in any of the trials conducted in the North-east EPPO zone on sunflower. Furthermore, results from one sunflower trial harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

#### **3.4.1.3 Spring oat**

Crop phytotoxicity was evaluated in one efficacy trial where Glyphosate 54% SL was applied in the autumn, in stubbles of a winter wheat crop, and in the following spring, spring oats were sown. In this trial, Glyphosate 54% SL was applied at the rate of 1.5 to 3.5 l/ha. 3.5 l/ha corresponds to 175% of the proposed dose rate. Crop phytotoxicity was assessed in this trial at BBCH 30.

#### **Phytotoxicity in spring oat trials, North-east EPPO zone**

In one efficacy trial conducted in the North-east EPPO zone, the crop safety of Glyphosate 54% SL applied in the autumn was assessed on spring oats planted in the following spring. The trial was conducted on the commercially available variety Scorpion.

No adverse effects in regards to phytotoxicity were observed in the spring oat crop planted the following spring after autumn application. The spring oat trial was not harvested.

#### **3.4.1.4 Spring barley**

Crop phytotoxicity was evaluated in one efficacy trial where Glyphosate 54% SL was applied before emergence of spring barley, at the rate of 1.5 to 4.0 l/ha. 4.0 l/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in the trial at various intervals, from emergence and up to BBCH 33.

#### **Phytotoxicity in spring barley trials, North-east EPPO zone**

Four efficacy trials and two selectivity trial were conducted in the North-east EPPO zone to assess the crop safety of Glyphosate 54% SL when applied as recommended in spring barley. The trial was conducted on the commercially available variety Saldo.

No adverse effects in regards to phytotoxicity were observed in the spring barley crop treated after sowing / before emergence in the spring. Furthermore, results from two spring barley trial harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

#### **3.4.1.5 Spring wheat**

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Glyphosate 54% SL was applied before emergence of spring wheat, at the rate of 1.5 to 4.0 l/ha. 4.0 l/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest (BBCH 89).

#### **Phytotoxicity in spring wheat trials, North-east EPPO zone**

Three trials, i.e. two efficacy trial and one selectivity trial, were conducted in the North-east EPPO zone to assess the crop safety of Glyphosate 54% SL when applied as recommended in spring wheat. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity were observed in any of the trials conducted in the North-east EPPO zone on spring wheat. Furthermore, results from one spring wheat trial harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

#### **3.4.1.6 Faba bean**

Crop phytotoxicity was evaluated in one efficacy trial where Glyphosate 54% SL was applied in the autumn, in stubbles of a winter wheat crop, and in the following spring, faba beans were sown. In this trial, Glyphosate 54% SL was applied at the rate of 1.5 to 3.5 l/ha. 3.5 l/ha corresponds to 175% of the proposed dose rate. Crop phytotoxicity was assessed in this trial at BBCH 11 and BBCH 88.

### Phytotoxicity in faba bean trials, North-east EPPO zone

In one efficacy trial conducted in the North-east EPPO zone, the crop safety of Glyphosate 54% SL applied in the autumn was assessed on faba beans planted in the following spring. The trial was conducted on the commercially available variety Fuego.

No adverse effects in regards to phytotoxicity were observed in the faba bean crop planted the following spring after autumn application. The faba bean trial was not harvested.

#### 3.4.1.7 Winter wheat

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Glyphosate 54% SL was applied before sowing of winter wheat, at the rate of 1.5 to 4.0 l/ha, or shortly before harvest, for desiccation of the crop, at 1.5 and 2.0 L/ha. 4.0 l/ha corresponds to 200% of the proposed dose rate applied pre-sowing and 2.0 L/ha corresponds to 100% of the proposed dose rate when applied for desiccation. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest (BBCH 89).

### Phytotoxicity in winter wheat trials treated before sowing, North-east EPPO zone

A total of four efficacy trials and two selectivity trial were conducted in the North-east EPPO zone to assess the crop safety of Glyphosate 54% SL when applied as recommended in winter oilseed rape, i.e. before sowing. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and/or vigour were observed in any of the six trials conducted in the North-east EPPO zone. Furthermore, results from two winter wheat trial harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

### Phytotoxicity in winter wheat trials treated before harvest, North-east EPPO zone

Six efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Glyphosate 54% SL when applied as recommended in winter wheat, i.e. for desiccation before harvest. The trials were conducted on commercially available varieties.

Besides the most obvious effect, no adverse effects in regards to phytotoxicity were observed in any of the six efficacy trials conducted in the North-east EPPO zone. None of the pre-harvest treated trials were harvested.

#### 3.4.1.8 Maize

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Glyphosate 54% SL was applied before emergence of maize, at the rate of 1.5 to 4.0 l/ha. 4.0 l/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest (BBCH 89).

### Phytotoxicity in maize trials, North-east EPPO zone

A total of five efficacy trials and three selectivity trial were conducted in the North-east EPPO zone to assess the crop safety of Glyphosate 54% SL when applied as recommended in maize, i.e. at seeding. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and/or vigour were observed in any of the eight trials conducted in the North-east EPPO zone. Furthermore, results from three maize trial harvested demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

#### 3.4.1.9 Apple

Crop phytotoxicity was evaluated in efficacy trials where Glyphosate 54% SL was applied during the growing season, at the rate of 2.0 to 6.4 l/ha. 6.4 l/ha corresponds to 320% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest (BBCH 89).



### **Phytotoxicity in apple trials, North-east EPPO zone**

A total of six efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Glyphosate 54% SL when applied as recommended in apple orchards, i.e. during the growing season. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and/or vigour were observed in any of the six trials conducted in the North-east EPPO zone. None of the apple trials were taken to harvest.

#### **3.4.1.10 Grapevine**

Crop phytotoxicity was evaluated in efficacy trials where Glyphosate 54% SL was applied during the growing season, at the rate of 2.0 to 4.5 l/ha. 4.5 l/ha corresponds to 225% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest (BBCH 89).

### **Phytotoxicity in grapevine trials, Maritime EPPO zone**

Two efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Glyphosate 54% SL when applied as recommended in vine orchards, i.e. during the growing season. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and/or vigour were observed in either of the two trials conducted in the Maritime EPPO zone. Furthermore, results from the two Czech grapevine trials harvested demonstrated that the applied treatments did not have any detrimental effects on yield either.

#### **3.4.1.11 Winter barley**

Crop phytotoxicity was evaluated in efficacy trials where Glyphosate 54% SL was applied during the growing season, at the rate of 1.5 to 3.5 l/ha. 3.5 l/ha corresponds to 175% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest (BBCH 89).

### **Phytotoxicity in winter barley trials, North-east EPPO zone**

Two efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Glyphosate 54% SL when applied as recommended in winter barley, i.e. during the growing season. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and/or vigour were observed in either of the two trials conducted in the North-east EPPO zone.

#### **3.4.1.12 Winter triticale**

Crop phytotoxicity was evaluated in efficacy trials where Glyphosate 54% SL was applied during the growing season, at the rate of 2.0 to 4.0 l/ha. 4.0 l/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals from application and up to harvest (BBCH 89).

### **Phytotoxicity in winter triticale trials, North-east EPPO zone**

Two efficacy and one selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Glyphosate 54% SL when applied as recommended in winter triticale, i.e. during the growing season. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and/or vigour were observed in either of the three trials conducted in the North-east EPPO zone. Furthermore, results from the one winter triticale trial harvested demonstrated that the applied treatments did not have any detrimental effects on yield either.

**Table 3.4-4: Phytotoxicity of product**

| Number of trials with...                            |             | Selectivity trials (13 trials) |          |            |          | Efficacy trials (44 trials) |            |
|---|-------------|--------------------------------|----------|------------|----------|-----------------------------|------------|
|   |             | Test product                   |          | Standard 1 |          | Test product                | Standard 1 |
|   |             | 2.0 L/ha                       | 4.0 L/ha | 3.0 L/ha   | 6.0 L/ha | 3.5 L/ha                    | 5.0 L/ha   |
| Maximum of phytotoxicity recorded during the trials | 0% to 5%    | 13                             | 13       | 13         | 13       | 44                          | 44         |
|   | >5% to 10%  | 0                              | 0        | 0          | 0        | 0                           | 0          |
|   | >10% to 15% | 0                              | 0        | 0          | 0        | 0                           | 0          |
|   | >15 %       | 0                              | 0        | 0          | 0        | 0                           | 0          |
| Level of symptoms at the last assessments           | 0% to 5%    | 13                             | 13       | 13         | 13       | 44                          | 44         |
|   | >5% to 10%  | 0                              | 0        | 0          | 0        | 0                           | 0          |
|   | >10% to 15% | 0                              | 0        | 0          | 0        | 0                           | 0          |
|   | >15 %       | 0                              | 0        | 0          | 0        | 0                           | 0          |

### 3.4.1.13 Overall conclusion

Cereal-, oilseed rape-, maize- and sunflower field crops as well as orchard fruit- and berry crops are claimed on the label. The claims of crop safety on these crops are supported with a total of 57 trials conducted in Poland, Lithuania, Latvia and the Czech Republic. Glyphosate 54% SL applied at the maximum proposed rate and dose rates of up to 3.6n overlapping rate is safe when used as recommended in the GAP claimed crops.

As this BAD also clearly demonstrates, then the efficacy and crop safety of Glyphosate 54% SL is equivalent to the standard glyphosate product to which it was compared. The applicant wishes to cite the original registrant's data on glyphosate now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

|                          |  |
|--------------------------|--|
| <b>Comments of zRMS:</b> | <p>The phytotoxicity assessment in the package submitted by the applicant with this dossier prove that Candela is selective in cereals, winter oilseed rape, maize, sunflower and apple orchard and vines when it is applied in dose 2,0 l/ha. Application of 2,0 l/ha in effective trials had no adverse effect on the crop. The trials were conducted in the North-east zone (55; Poland (35), Lithuania (14) and Latvia (6) and the Maritime zone (2; Czech Republic) in 2016, 2017 and 2018 to evaluate the crop safety of Glyphosate 54% SL in a range of field- and orchard crops</p> <p>The amount of performed selectivity trials and information from efficacy trials meets requirements containing in the EPPO guideline PP 1/226 "Number of efficacy trials". Selectivity trials were done according to EPPO guideline PP 1/135. Mentioned above crops were selective for Candela used in 2N dose.</p> <p>No further information is required.</p> |
|--------------------------|--|

### 3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

To evaluate the effect of Glyphosate 54% SL on the yield of cereals, maize, oilseed rape, sunflower and orchard crops, the results obtained in 14 trials, i.e. two efficacy trials and twelve selectivity trials conducted in 2016, 2017 and 2018 have been included to support the registration of Glyphosate 54% SL in the label claimed crops.

The 14 trials were conducted on spring barley (2 sel.), winter triticale (1 sel.), winter oilseed rape (2 sel.), sunflower (1 sel.), spring wheat (1 sel.), winter wheat (2 sel.), maize (3 sel.) and grapevine (2 eff.). With one application, glyphosate was applied before seeding or shortly after seeding, before emergence, in selectivity trials, and in the two efficacy trials, glyphosate was applied during the growing season, when the vines were at BBCH 57. All trials presented in this section of the Biological Assessment Dossier were located within the North-east or the Maritime EPPO zone as defined by EPPO Standard PP1/241(1).



### 3.4.2.1 Materials and methods

Plot yields, as fresh weight plant material in kg/plot, were measured at harvest and in selectivity trials converted to t/ha. The data of the treated plots are presented as relative values in relation to the fresh weight for the untreated plots. For further information on materials and methods please refer to section KCP 6.4.2.

### 3.4.2.2 Summary and evaluation of the field trials conducted in autumn-sown crops, treated with single application at seeding

A summary of the mean yield assessments (yield and/or quality) expressed as %-relative of the untreated, from trials treated once, conducted in the North-east EPPO zone, are presented in Table 3.4-5.

#### Winter oilseed rape

Two selectivity trials in winter oilseed rape were harvested. The trials were conducted in Poland in season 2016/17 and 2017/18. Glyphosate 54% SL was applied pre-sowing in the autumn at 2.0 l/ha and 4.0 l/ha.

Neither Glyphosate 54% SL nor the glyphosate reference product (Roundup 360 Plus) significantly affected the yield (Table 3.4-5) when applied at the recommended dose rate (2.0 L/ha) and higher (4.0 l/ha) in the Polish selectivity trials. The results obtained in this trial supports the label claim that Glyphosate 54% SL is safe to be applied at the recommended dose rates to winter oilseed rape before sowing in the autumn.

#### Winter wheat

Two selectivity trials in winter wheat were harvested. The trials were conducted in Poland in season 2016/17. Glyphosate 54% SL was applied pre-sowing in the autumn at 2.0 l/ha and 4.0 l/ha.

Neither Glyphosate 54% SL nor the glyphosate reference product (Roundup 360 Plus) significantly affected the yield (Table 3.4-5) when applied at the recommended dose rate (2.0 L/ha) and higher (4.0 l/ha) in the Polish selectivity trials. The results obtained in this trial supports the label claim that Glyphosate 54% SL is safe to be applied at the recommended dose rates to winter wheat before sowing in the autumn.

#### Winter triticale

One selectivity trial in winter triticale was harvested. The trial was conducted in Poland in season 2016/17. Glyphosate 54% SL was applied pre-sowing in the autumn at 2.0 l/ha and 4.0 l/ha.

Neither Glyphosate 54% SL nor the glyphosate reference product (Roundup 360 Plus) significantly affected the yield (Table 3.4-5) when applied at the recommended dose rate (2.0 L/ha) and higher (4.0 l/ha) in the Polish selectivity trial. The results obtained in this trial supports the label claim that Glyphosate 54% SL is safe to be applied at the recommended dose rates to winter triticale before sowing in the autumn.

**Table 3.4-5: North-East zone – Crop yield (t/ha) of winter oilseed rape, winter triticale and winter wheat treated with Glyphosate 54% SL, single application before sowing in the autumn, as % of untreated (Untreated = 100%)**

| Crop, trial type           | No. of trials | Untreated      | Glyphosate 54% SL at:                       |                            | Glyphosate Ref. prod. at:  |                            |
|----------------------------|---------------|----------------|---|----------------------------|----------------------------|----------------------------|
|                            |               |                | % relative, compared to untreated (min-max) |                            |                            |                            |
|                            |               | Mean (min-max) | 2.0 L/ha<br>[1080 g ai/ha]                  | 4.0 L/ha<br>[2160 g ai/ha] | 3.0 L/ha<br>[1080 g ai/ha] | 6.0 L/ha<br>[2160 g ai/ha] |
| North-east zone            |               |                |   |                            |                            |                            |
| Winter oilseed rape (t/ha) | 2             | 2.67           | 94.0  | 105                        | 88.0                       | 102                        |
| Winter triticale (t/ha)    | 1             | 6.19           | 104   | 105                        | 106                        | 102                        |
| Winter wheat (t/ha)        | 2             | 7.42           | 97.5  | 103                        | 96.5                       | 97.2                       |

### 3.4.2.3 Summary and evaluation of the field trials conducted in spring-sown crops, treated with single application at seeding

A summary of the mean yield assessments (yield and/or quality) expressed as %-relative of the untreated, from trials treated once, conducted in the North-east EPPO zone, are presented in Table 3.4-6.

#### Sunflower

One selectivity trial conducted in a sunflower field in Poland in 2017 was harvested. Glyphosate 54% SL was applied pre-emergence of the crop in the spring at 2.0 l/ha and 4.0 l/ha.

Neither Glyphosate 54% SL nor the glyphosate reference product (Roundup 360 Plus) significantly affected the yield (Table 3.4-6) when applied **at the recommended dose rate** (2.0 L/ha) and higher (4.0 l/ha) in the Polish selectivity trial. The results obtained in this trial supports the label claim that Glyphosate 54% SL is safe to be applied at the recommended dose rates to sunflower before emergence of the crop in the spring.

**Table 3.4-6: North-East zone – Crop yield (t/ha) of Sunflower, **spring barley**, spring wheat and maize treated with Glyphosate 54% SL, single application before sowing in the spring, as % of untreated (Untreated = 100%)**

| Crop, trial type     | No. of trials | Untreated      | Glyphosate 54% SL at:                       |                            | Glyphosate Ref. prod. at:  |                            |
|----------------------|---------------|----------------|---|----------------------------|----------------------------|----------------------------|
|                      |               |                | % relative, compared to untreated (min-max) |                            |                            |                            |
|                      |               | Mean (min-max) | 2.0 L/ha<br>[1080 g ai/ha]                  | 4.0 L/ha<br>[2160 g ai/ha] | 3.0 L/ha<br>[1080 g ai/ha] | 6.0 L/ha<br>[2160 g ai/ha] |
| North-east zone      |               |                |   |                            |                            |                            |
| Sunflower (t/ha)     | 1             | 2.0            | 108   | 112                        | 108                        | 109                        |
| Spring wheat (t/ha)  | 1             | 3.7            | 110   | 112                        | 109                        | 107                        |
| Maize (t/ha)         | 3             | 38.0           | 102   | 99.7                       | 98.1                       | 103                        |
| Spring barley (t/ha) | 2             | 7.10           | 101   | 100                        | 101                        | 100                        |

#### Spring wheat

One selectivity trial conducted in a spring wheat field in Poland in 2017 was harvested. Glyphosate 54% SL was applied pre-emergence of the crop in the spring at 2.0 l/ha and 4.0 l/ha.

Neither Glyphosate 54% SL nor the glyphosate reference product (Roundup 360 Plus) significantly affected the yield (Table 3.4-6) when applied **at the recommended dose rate** (2.0 L/ha) and higher (4.0 l/ha) in the Polish selectivity trial. The results obtained in this trial supports the label claim that Glyphosate 54% SL is safe to be applied at the recommended dose rates to spring wheat before emergence of the crop in the spring.

#### Maize

**Three** selectivity trial conducted in a maize field in Poland **and Lithuania** in 2016 **and 2017** **were** harvested. Glyphosate 54% SL was applied pre-emergence of the crop in the spring at 2.0 l/ha and 4.0 l/ha.

Neither Glyphosate 54% SL nor the glyphosate reference product (Roundup 360 Plus and **Roundup Classic**) significantly affected the yield (Table 3.4-6) when applied **at the recommended dose rate** (2.0 L/ha) and higher (4.0 l/ha) in the selectivity trials. The results obtained in this trials supports the label claim that Glyphosate 54% SL is safe to be applied at the recommended dose rates to maize before emergence of the crop in the spring.

#### Spring barley

**Two** selectivity trial conducted in spring barley field in Poland in 2017 and 2018 **were** harvested. Glyphosate 54% SL was applied pre-emergence of the crop in the spring at 2.0 l/ha and 4.0 l/ha.

**Neither** Glyphosate 54% SL nor the glyphosate reference product (Roundup 360 Plus and Roundup Classic) significantly affected the yield (Table 3.4-6) when applied at the recommended dose rate (2.0 L/ha) and higher (4.0 l/ha) in the selectivity trials. The results obtained in this trials supports the label claim that

Glyphosate 54% SL is safe to be applied at the recommended dose rates to spring barley before emergence of the crop in the spring.

### 3.4.2.4 Summary and evaluation of the field trials conducted in fruit orchards, treated with single application during growing season

A summary of the mean yield assessments (yield and/or quality) expressed as %-relative of the untreated, from trials treated once, conducted in the Maritime EPPO zone, are presented in Table 3.4-7.

#### Grapevine

Two efficacy trials conducted in grapevine orchards were harvested. The trials were conducted in the Czech Republic in 2016. Glyphosate 54% SL was applied during the growing season (June), when the crop was at growth stage BBCH 57, at 2.0 l/ha, 2.5 l/ha and 3.5 l/ha in one trial and 2.0 l/ha, 3.5 l/ha and 4.5 l/ha in the other. In Table 3.4-7, the results obtained in the efficacy trials when treated with 2.0 and 3.5 L/ha are presented.

Neither Glyphosate 54% SL nor the glyphosate reference product (Roundup Klasik Pro) significantly affected the yield (Table 3.4-7) when applied at the recommended dose rate (2.0 L/ha) and higher (4.0 l/ha) in the Czech trials. The results obtained in these trials support the label claim that Glyphosate 54% SL is safe to be applied at the recommended dose rates to fruit orchards during the season.

**Table 3.4-7: Maritime zone – Crop yield (kg/plot) of grapes from vine orchards treated with Glyphosate 54% SL, single application during growing season in the early summer, as % of untreated (Untreated = 100%)**

| Parameter evaluated  | Total No. of trials | Untreated        | Glyphosate 54% SL at: |          | Glyphosate Ref. prod. at: |
|----------------------|---------------------|------------------|-----------------------|----------|---------------------------|
|                      |                     | Mean (range)     | % -relative (min-max) |          |                           |
|                      |                     | t/ha             | 2.0 l/ha              | 3.5 l/ha | 5.0 l/ha                  |
| <b>Maritime zone</b> |                     |                  |                       |          |                           |
| Grapes (kg/plot)     | 2                   | 31.0 (28.9-33.1) | 100 (-)               | 100 (-)  | 100 (99-100)              |

### 3.4.2.5 Conclusion

Glyphosate 54% SL applied at the recommended dose rate did not affect crop yield of the crop yield significantly in the any of the fourteen trials taken to harvest. In all trials, Glyphosate 54% SL applied at dose rates higher than the recommended rate – representative for sprayer overlap – did not significantly affect the crop yield.

Furthermore, the data obtained in trials harvested demonstrate that Glyphosate 54% SL is as safe to the crop as the reference products used in the trials.

As this BAD clearly demonstrates, the efficacy and crop safety of Glyphosate 54% SL is equivalent to the standard glyphosate product to which it was compared. The applicant therefore wishes to cite the original registrant's data on glyphosate now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

|                          |   |
|--------------------------|---|
| <b>Comments of zRMS:</b> | <p>The data submitted by applicant with this dossier prove that Candela has no negative impact on yield of winter wheat, winter barley, winter oilseed rape, winter triticale, spring barley, spring wheat, sunflower, maize, apple orchard and grapevine for which registration is applied when it is used according to the GAP.</p> <p>The amount of performed selectivity trials meets requirements containing in EPPO guideline PP 1/226. Selectivity trials were done according to guideline PP 1/135. Such information should be put on the label:</p> <p><i>“Avoid spray overlaps.”</i></p> <p>No further information is required.</p> |
|--------------------------|---|

### 3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Twelve selectivity trials and two efficacy trials treated with Glyphosate 54% SL were harvested and yields recorded. In these, assessments were conducted on the potential impact of treatment on a range of quality parameters including oil content, protein content, hectolitre weight and thousand grain weight.

#### Winter oilseed rape

The results obtained from assessments on the quality of the harvested winter oilseed rape seeds are presented in Table 3.4-8

**Table 3.4-8: North-east zone – Quality of harvested winter oilseed rape seeds – crop treated with Glyphosate 54% SL with single application in the autumn, as % of untreated (Untreated = 100%)**

| Crop, trial type         | No. of trials | Untreated      | Glyphosate 54% SL at:                       |                            | Glyphosate Ref. prod. at:  |                            |
|--------------------------|---------------|----------------|---|----------------------------|----------------------------|----------------------------|
|                          |               |                | % relative, compared to untreated (min-max) |                            |                            |                            |
|                          |               | Mean (min-max) | 2.0 L/ha<br>[1080 g ai/ha]                  | 4.0 L/ha<br>[2160 g ai/ha] | 3.0 L/ha<br>[1080 g ai/ha] | 6.0 L/ha<br>[2160 g ai/ha] |
| North-east zone          |               |                |   |                            |                            |                            |
| Oil content (%)          | 2             | 41.8           | 102   | 101                        | 101                        | 102                        |
| Thousand Seed Weight (g) | 2             | 5.2            | 97.5  | 100                        | 101                        | 98.8                       |
| Protein content (%)      | 1             | 22.1           | 100   | 101                        | 101                        | 101                        |

In the trial evaluated, Glyphosate 54% SL had no detrimental effect on the quality parameters assessed on the harvested oilseed rape seeds. When comparing the results obtained with Glyphosate 54% SL against the results obtained with the Glyphosate reference product at comparable dose rates, both products performed statistically similar.

#### Sunflower

The results obtained from assessments on the quality of the harvested sunflower seeds are presented in Table 3.4-9.

**Table 3.4-9: North-east zone – Quality of harvested sunflower seeds – crop treated with Glyphosate 54% SL with single application in the spring, as % of untreated (Untreated = 100%)**

| Crop, trial type         | No. of trials | Untreated      | Glyphosate 54% SL at:                       |                            | Glyphosate Ref. prod. at:  |                            |
|--------------------------|---------------|----------------|---|----------------------------|----------------------------|----------------------------|
|                          |               |                | % relative, compared to untreated (min-max) |                            |                            |                            |
|                          |               | Mean (min-max) | 2.0 L/ha<br>[1080 g ai/ha]                  | 4.0 L/ha<br>[2160 g ai/ha] | 3.0 L/ha<br>[1080 g ai/ha] | 6.0 L/ha<br>[2160 g ai/ha] |
| North-east zone          |               |                |   |                            |                            |                            |
| Thousand Seed Weight (g) | 1             | 48.4           | 103   | 105                        | 103                        | 104                        |

In the trial evaluated, Glyphosate 54% SL had no detrimental effect on the quality parameters assessed on the harvested sunflower seeds. When comparing the results obtained with Glyphosate 54% SL against the results obtained with the Glyphosate reference product at comparable dose rates, both products performed statistically similar.

#### Spring wheat

The results obtained from assessments on the quality of the harvested spring wheat grains are presented in Table 3.4-10.

**Table 3.4-10: North-east zone – Quality of harvested spring wheat grains – crop treated with Glyphosate 54% SL with single application in the spring, as % of untreated (Untreated = 100%)**

| Crop, trial type          | No. of trials | Untreated      | Glyphosate 54% SL at:                       |                            | Glyphosate Ref. prod. at:  |                            |
|---------------------------|---------------|----------------|---|----------------------------|----------------------------|----------------------------|
|                           |               |                | % relative, compared to untreated (min-max) |                            |                            |                            |
|                           |               | Mean (min-max) | 2.0 L/ha<br>[1080 g ai/ha]                  | 4.0 L/ha<br>[2160 g ai/ha] | 3.0 L/ha<br>[1080 g ai/ha] | 6.0 L/ha<br>[2160 g ai/ha] |
| North-east zone           |               |                |   |                            |                            |                            |
| HectoLitre Weight (kg/hL) | 1             | 71.0           | 100   | 102                        | 101                        | 103                        |
| Thousand Seed Weight (g)  | 1             | 42.0           | 102   | 102                        | 101                        | 101                        |

In the trial evaluated, Glyphosate 54% SL had no detrimental effect on the quality parameters assessed on the harvested spring wheat grains. When comparing the results obtained with Glyphosate 54% SL against the results obtained with the Glyphosate reference product at comparable dose rates, both products performed statistically similar.

### Winter wheat

The results obtained from assessments on the quality of the harvested winter wheat grains are presented in Table 3.4-11.

**Table 3.4-11: North-east zone – Quality of harvested winter wheat grains – crop treated with Glyphosate 54% SL with single application in the autumn, as % of untreated (Untreated = 100%)**

| Crop, trial type          | No. of trials | Untreated      | Glyphosate 54% SL at:                       |                            | Glyphosate Ref. prod. at:  |                            |
|---------------------------|---------------|----------------|---|----------------------------|----------------------------|----------------------------|
|                           |               |                | % relative, compared to untreated (min-max) |                            |                            |                            |
|                           |               | Mean (min-max) | 2.0 L/ha<br>[1080 g ai/ha]                  | 4.0 L/ha<br>[2160 g ai/ha] | 3.0 L/ha<br>[1080 g ai/ha] | 6.0 L/ha<br>[2160 g ai/ha] |
| North-east zone           |               |                |   |                            |                            |                            |
| Protein content (%)       | 2             | 11.3           | 99  | 99                         | 98.5                       | 99                         |
| HectoLitre Weight (kg/hL) | 2             | 77.0           | 100   | 100                        | 99.9                       | 99.8                       |
| Thousand Seed Weight (g)  | 2             | 43.7           | 98.3  | 101                        | 99.6                       | 101                        |

In the trial evaluated, Glyphosate 54% SL had no detrimental effect on the quality parameters assessed on the harvested winter wheat grains. When comparing the results obtained with Glyphosate 54% SL against the results obtained with the Glyphosate reference product at comparable dose rates, both products performed statistically similar.

### Maize

The results obtained from assessments on the quality of the harvested maize grains are presented in Table 3.4-12.

**Table 3.4-12: North-east zone – Quality of harvested maize grains – crop treated with Glyphosate 54% SL with single application in the spring, as % of untreated (Untreated = 100%)**

| Crop, trial type         | No. of trials | Untreated      | Glyphosate 54% SL at:                       |                            | Glyphosate Ref. prod. at:  |                            |
|--------------------------|---------------|----------------|---|----------------------------|----------------------------|----------------------------|
|                          |               |                | % relative, compared to untreated (min-max) |                            |                            |                            |
|                          |               | Mean (min-max) | 2.0 L/ha<br>[1080 g ai/ha]                  | 4.0 L/ha<br>[2160 g ai/ha] | 3.0 L/ha<br>[1080 g ai/ha] | 6.0 L/ha<br>[2160 g ai/ha] |
| North-east zone          |               |                |   |                            |                            |                            |
| Thousand Seed Weight (g) | 2             | 413.0          | 98.7  | 96.5                       | 98.2                       | 99.0                       |

In the trial evaluated, Glyphosate 54% SL had no detrimental effect on the quality parameters assessed on the harvested maize seeds. When comparing the results obtained with Glyphosate 54% SL against the results obtained with the Glyphosate reference product at comparable dose rates, both products performed statistically similar.

### Spring barley

The results obtained from assessments on the quality of the harvested spring barley grains are presented in Table 3.4-13.

**Table 3.4-13: North-east zone – Quality of harvested spring barley grains – crop treated with Glyphosate 54% SL with single application in the spring, as % of untreated (Untreated = 100%)**

| Crop, trial type          | No. of trials | Untreated      | Glyphosate 54% SL at:                       |                            | Glyphosate Ref. prod. at:  |                            |
|---------------------------|---------------|----------------|---|----------------------------|----------------------------|----------------------------|
|                           |               |                | % relative, compared to untreated (min-max) |                            |                            |                            |
|                           |               | Mean (min-max) | 2.0 L/ha<br>[1080 g ai/ha]                  | 4.0 L/ha<br>[2160 g ai/ha] | 3.0 L/ha<br>[1080 g ai/ha] | 6.0 L/ha<br>[2160 g ai/ha] |
| North-east zone           |               |                |   |                            |                            |                            |
| Protein content (%)       | 1             | 13.7           | 100   | 100                        | 99                         | 99                         |
| HectoLitre Weight (kg/hL) | 2             | 62.8           | 100   | 99.5                       | 100                        | 100                        |
| Thousand Seed Weight (g)  | 2             | 45.8           | 101   | 102                        | 102                        | 102                        |

In the trial evaluated, Glyphosate 54% SL had no detrimental effect on the quality parameters assessed on the harvested spring barley seeds. When comparing the results obtained with Glyphosate 54% SL against the results obtained with the Glyphosate reference product at comparable dose rates, both products performed statistically similar.

### Winter triticale

The results obtained from assessments on the quality of the harvested winter triticale grains are presented in Table 3.4-14.

**Table 3.4-14: North-east zone – Quality of harvested winter triticale grains – crop treated with Glyphosate 54% SL with single application in the autumn, as % of untreated (Untreated = 100%)**

| Crop, trial type          | No.<br>of<br>trials | Untreated      | Glyphosate 54% SL at:                       |                            | Glyphosate Ref. prod. at:  |                            |
|---------------------------|---------------------|----------------|---|----------------------------|----------------------------|----------------------------|
|                           |                     |                | % relative, compared to untreated (min-max) |                            |                            |                            |
|                           |                     | Mean (min-max) | 2.0 L/ha<br>[1080 g ai/ha]                  | 4.0 L/ha<br>[2160 g ai/ha] | 3.0 L/ha<br>[1080 g ai/ha] | 6.0 L/ha<br>[2160 g ai/ha] |
| North-east zone           |                     |                |   |                            |                            |                            |
| Protein content (%)       | 1                   | 10.43          | 105   | 104.8                      | 102                        | 100                        |
| HectoLitre Weight (kg/hL) | 1                   | 63.7           | 108   | 108                        | 108                        | 107                        |
| Thousand Seed Weight (g)  | 1                   | 46.7           | 92.0  | 96.6                       | 94.2                       | 96.6                       |

In the trial evaluated, Glyphosate 54% SL had no detrimental effect on the quality parameters assessed on the harvested winter triticale seeds. When comparing the results obtained with Glyphosate 54% SL against the results obtained with the Glyphosate reference product at comparable dose rates, both products performed statistically similar.

#### 3.4.3.1 Conclusion

Glyphosate 54% SL applied at the recommended dose rate did not affect crop yield nor the quality of the crop yield significantly in the any of the **fourteen** trials taken to harvest. In all trials, Glyphosate 54% SL applied at dose rates higher than the recommended rate – representative for sprayer overlap – did not significantly affect the crop yield.

Furthermore, the data obtained in trials harvested demonstrate that Glyphosate 54% SL is as safe to the crop as the reference products used in the trials.

As this BAD clearly demonstrates, the efficacy and crop safety of Glyphosate 54% SL is equivalent to the standard glyphosate product to which it was compared. The applicant therefore wishes to cite the original registrant's data on glyphosate now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator ex-

trapolate from those data.

|                          |   |
|--------------------------|---|
| <b>Comments of zRMS:</b> | zRMS considers that provided data demonstrates that there is no detrimental effect on the yield quality in above mentioned crops after treatment with the test product N and 2N doses.<br>No further information is required. |
|--------------------------|---|

#### **3.4.4 Effects on transformation processes (KCP 6.4.4)**

Glyphosate 54% SL is composed of glyphosate which has been widely used for a number years on a range of crops without identifying any quality problems on the treated crops.

Glyphosate 54% SL is recommended applied early in the season (before seeding) or as a desiccant of winter wheat before harvest (BBCH 89). When applied early in the season or as a desiccant before harvest, it is not expected that any significant amounts of residues are present in the grains at harvest. This was also confirmed with data presented in the RAR on glyphosate, section 7.7.2 (Renewal Assessment Report (2013), Vol. III, B7), where results obtained with a number of residue trials are presented.

For further information on residues, please refer to Part B, Section 4: Metabolism and residues.

|                          |  |
|--------------------------|--|
| <b>Comments of zRMS:</b> | zRMS agree with applicant argumentation. |
|--------------------------|--|

#### **3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)**

Special tests to investigate this purpose are not required.

### **3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)**

#### **3.5.1 Impact on succeeding crops (KCP 6.5.1)**

In orchards, the impact on succeeding crops is not relevant since pome fruit orchards, stone fruit orchards and grapevine orchards are perennial crops.

In field crops, glyphosate is recommended applied at sowing. As per the RAR for glyphosate (Renewal Assessment Report (2013), Vol. III, B8), average DT<sub>50</sub> is 18.7 days (range 1-67.7, n=17), therefore no studies are needed according to guidelines. Data from soil dissipation studies conducted in Germany and Switzerland (average: 23.8 days; range: 5.7-40.9 days; n=8) confirm that the DT<sub>50</sub> is less than 100 days. According to EFSA (EFSA Journal 2015; 13(11):4302), then glyphosate and AMPA residues are not expected in rotational crops, based on the supported uses. Thus, the peer review concluded that there was no need to propose risk mitigating measures, considering the overall low residue situation in succeeding and rotational crops.

Hence, no significant residue levels are to be expected in rotational crops following application of glyphosate according to the proposed GAP.

|                          |  |
|--------------------------|--|
| <b>Comments of zRMS:</b> | zRMS agree with applicant argumentation. |
|--------------------------|--|

#### **3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)**

During the conduct of efficacy trials and phytotoxicity trials no observations about negative or positive effects on other plants or neighbouring crops were reported.

Glyphosate 54% SL is a non-selective herbicide. Therefore, drift to adjacent plants and other crops should always be avoided.

EPPO guidelines PP1/256 is intended to examine whether the active substance of a plant protection product can cause negative effects on crop which would be in contact with that product. Based on the actual drift value calculated with the Ganzelmeier model and on the bio assay results from the Vegetative vigour test and from the seedling emergence study TER values are obtained.



- If the active substance has no activity against plants at the highest doses tested in the bioassays. Then field trials are unnecessary.
- If the TER values are  $> 1$ . Then no further testing is necessary.
- If the TER values are  $\leq 1$ . Damage to the relevant succeeding crop is possible and further field testing is necessary as described in the EPPO guideline.

In the studies summarized in the DAR, 10 representative species were tested and the results obtained will be used in the above table to assess the TER and compare it to the trigger value of 1.

These studies are presented in the tables below.

**Table 3.5-1: Effects of glyphosate on vegetative vigour (foliar application) (RAR B.9.9.1 [Glyphosate acid])**

| Crop            | Endpoint (kg/a.s./ha) at Day 21 |                  |              |                  |                  |                  |
|-----------------|---------------------------------|------------------|--------------|------------------|------------------|------------------|
|                 | Survival                        |                  | Plant height |                  | Plant dry weight |                  |
|                 | NOER                            | ER <sub>50</sub> | NOER         | ER <sub>50</sub> | NOER             | ER <sub>50</sub> |
| <i>Ryegrass</i> | 1.232                           | 4.592            | 0.627        | 2.352            | 0.627            | 1.344            |
| <i>Corn</i>     | 0.627                           | 1.680            | 0.627        | 0.918            | 0.627            | 0.750            |
| <i>Onion</i>    | 5.040                           | $> 5.040$        | 0.627        | $> 5.040$        | 0.627            | 1.792            |
| <i>Oat</i>      | 2.576                           | $> 5.040$        | 0.627        | 1.344            | 0.157            | 0.874            |
| <i>Soybean</i>  | 5.040                           | $> 5.040$        | 0.627        | 1.568            | 0.314            | 0.974            |
| <i>Lettuce</i>  | 1.232                           | 2.800            | 0.627        | 1.344            | 0.314            | 0.762            |
| <i>Cucumber</i> | 2.576                           | 4.032            | 0.314        | 1.456            | 0.314            | 0.896            |
| <i>Cabbage</i>  | 1.232                           | 4.592            | 0.627        | 1.456            | 0.157            | 0.739            |
| <i>Radish</i>   | 0.314                           | 0.918            | 0.078        | 0.358            | 0.039            | 0.246            |
| <i>Tomato</i>   | 0.314                           | 0.515            | 0.039        | 0.336            | 0.039            | <b>0.146</b>     |

Visual phytotoxicity, plant height and plant dry weight of all crops were significantly affected by glyphosate treatments. Except for soybean and onion, a significant effect on mortality was observed for all species exposed to glyphosate.

The lowest 21 day ER<sub>50</sub> values were observed for tomato plants and were calculated to be 0.1457 kg a.s./ha for plant dry weight. This ER<sub>50</sub> value was considered by EFSA as the value relevant for the risk assessment.

### Risk assessment

The risk was assessed by calculation of the toxicity to exposure ratio (TER), and comparison of this value with the EPPO trigger of 1.

Results are presented in the table below:

**Table 3.5-2: Effects on non-target plants**

| Test substance | Buffer distance (m) | Application rate (g a.s./ha) | Drift value <sup>a</sup> (%) | Timing         | ER <sub>50</sub> (g a.s./ha) | TER | Trigger |
|----------------|---------------------|------------------------------|------------------------------|----------------|------------------------------|-----|---------|
| Glyphosate     | 1                   | 1890                         | 2.77                         | Post-emergence | 145.7                        | 2.8 | 1       |

<sup>a</sup> Drift estimates are based on 90<sup>th</sup> percentile values for field crops (BBA 2000); ER<sub>50</sub> values on tomato, as the worst case

The calculated TER values above the trigger of 1, indicating no potential risk to non-target plants. Therefore, no specific risk mitigation measures are necessary.

### Conclusion

The non-target plant studies show that there is a potential risk to adjacent crops from an application of Glyphosate 54% SL, therefore care should be taken to avoid drift onto adjacent crops. The results above confirm that no further testing is necessary and that no negative impact on adjacent crops is expected, if applied as proposed.

Please, for more information, refer to Registration Report, Part B, Section 6.

|                          |   |
|--------------------------|---|
| <b>Comments of zRMS:</b> | zRMS agree with applicant argumentation.<br>The following statement should be included on Candela product label:<br><i>“Apply product only under calm weather conditions. Respect good spraying practices to avoid any spray drift on adjacent crops. If possible, use anti-drift nozzles</i> |
|--------------------------|---|

### 3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

From the experimentation carried out with Glyphosate 54% SL in 2016, 2017 and 2018, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 6.

### Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

### 3.6 Other/special studies

No other studies were conducted

### 3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified, and the trials were conducted according to GEP guidelines.

**Table 3.7-1: List of test facilities**

| Testing facility                               | Zone | Country | Year and trial type |             |          |             |          |             |  |
|--|------|---------|---------------------|-------------|----------|-------------|----------|-------------|--|
|  |      |         | 2016                |             | 2017     |             | 2018     |             |  |
|  |      |         | Efficacy            | Selectivity | Efficacy | Selectivity | Efficacy | Selectivity |  |
| Winter oilseed rape – pre-sowing, Autumn appl. |      |         |                     |             |          |             |          |             |  |
| IOR-PIB, Poznan                                | N-E  | PL      | 1                   | 1           |          |             |          |             |  |
| LRCAF  | N-E  | LT      | 2                   | 1           |          |             |          |             |  |
| IOSPC  | N-E  | PL      |                     |             | 1        | 1           | 2        | 1           |  |
| Winter wheat – pre-sowing, Autumn appl.        |      |         |                     |             |          |             |          |             |  |
| IOR-PIB, Poznan                                | N-E  | PL      | 2                   | 1           |          |             |          |             |  |
| IOSPC  | N-E  | PL      |                     |             |          |             | 1        |             |  |
| Winter wheat – pre-harvest, Summer appl.       |      |         |                     |             |          |             |          |             |  |
| LPPRC  | N-E  | LV      | 2                   |             |          |             |          |             |  |
| IOR-PIB, Poznan                                | N-E  | PL      | 2                   |             |          |             |          |             |  |
| IOSPC  | N-E  | PL      |                     |             | 2        |             |          |             |  |
| LAMMC  | N-E  | LT      | 2                   |             |          |             |          |             |  |
| Winter wheat – Stubble, Summer/Autumn appl.    |      |         |                     |             |          |             |          |             |  |
| LPPRC  | N-E  | LV      | 2                   |             |          |             |          |             |  |
| Winter triticale – pre-sowing, Autumn appl.    |      |         |                     |             |          |             |          |             |  |
| IOSPC  | N-E  | PL      |                     |             | 1        | 1           |          |             |  |
| Winter barley– pre-sowing, Autumn appl.        |      |         |                     |             |          |             |          |             |  |
| IOSPC  | N-E  | PL      |                     |             |          |             | 2        |             |  |
| Sunflower – pre-emergence, Spring appl.        |      |         |                     |             |          |             |          |             |  |
| IOR-PIB, Poznan                                | N-E  | PL      |                     |             | 1        | 1           |          |             |  |
| IOSPC  | N-E  | PL      |                     |             | 1        |             |          |             |  |
| Spring barley – pre-emergence, Spring appl.    |      |         |                     |             |          |             |          |             |  |
| IOR-PIB, Poznan                                | N-E  | PL      |                     |             | 1        |             |          |             |  |
| IOSPC  | N-E  | PL      |                     |             | 1        | 1           |          |             |  |
| LAMMC  | N-E  | LT      | 2                   |             |          |             |          |             |  |
| Spring barley – pre-emergence, Autumn appl.    |      |         |                     |             |          |             |          |             |  |
| IOSPC  | N-E  | PL      |                     |             |          |             |          | 1           |  |
| Spring wheat – pre-emergence, Spring appl.     |      |         |                     |             |          |             |          |             |  |
| IOR-PIB, Poznan                                | N-E  | PL      |                     |             | 1        | 1           |          |             |  |

|  |     |    |    |   |    |   |   |   |
|--|-----|----|----|---|----|---|---|---|
| IOSPC  | N-E | PL |    |   | 1  |   |   |   |
| Maize – pre-emergence, Spring appl.                |     |    |    |   |    |   |   |   |
| IOR-PIB, Poznan                                    | N-E | PL | 1  | 1 | 1  |   |   |   |
| IOSPC  | N-E | PL |    |   | 1  | 1 |   |   |
| LAMMC  | N-E | LT | 2  | 1 |    |   |   |   |
| Apple Orchard – during season, Spring/Summer appl. |     |    |    |   |    |   |   |   |
| LPPRC  | N-E | LV | 2  |   |    |   |   |   |
| LRCAF  | N-E | LT | 4  |   |    |   |   |   |
| Vine Orchard – during season, Spring/Summer appl.  |     |    |    |   |    |   |   |   |
| PP Trial s.r.o.                                    | MAR | CZ | 2  |   |    |   |   |   |
| Total, All crops                                   |     |    | 26 | 5 | 12 | 6 | 5 | 2 |

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not                            | Vertebrate<br>study<br>Y/N | Owner |
|------------|-----------|------|--|----------------------------|-------|
| CP 6.0-001 | Anonymous | 2018 | Biological Assessment Dossier: Glyphosate 54% SL (540 g/L glyphosate) – EU Central zone<br>Sharda Cropchem España<br>-, -<br>Unpublished | N                          | SHA   |