

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 7**

#### **Metabolism and Residues**

Detailed summary of the risk assessment

Product code: SHA6100A

Product name(s): ALIVE

Chemical active substance:

Propaquizafop, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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## Version history

| When         | What                      |
|--------------|---------------------------|
| October 2020 | Submission                |
| May 2021     | Updated by applicant      |
| June 2021    | ZRMS evaluated the dRR    |
| January 2022 | Updated by applicant      |
| March 2022   | Assessment of updated dRR |

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## 7 Metabolism and residue data (KCA section 6)

### 7.1 Summary and zRMS Conclusion

#### Storage stability

Storage stability of propaquizafop residues in plant matrices was investigated during the peer review (Italy, 2005).

The 2 year storage period covers the groups of high water content (tomatoes, sugar beet (leaves)), high starch content (sugar beet roots and carrots) and high oil content (rape seed, soya seed). Additional studies are required as to cover the high acid, high protein content (dry legume vegetables/pulses) commodities and animal commodities.

Applicant provided new storage stability study.

Regarding the residues of total quizalofop before and during the storage period, no degradation higher than 30 % of total quizalofop residues was observed in pea whole plant (-11.4%), pea dry seed (-11.4%), oil seed rape grain (-20.5%) and grape (-8.0%) after storage for 12 months at -18°C. Total quizalofop residues are therefore stable in pea whole plant, pea dry seed, oil seed rape grain and grape for at least 12 months at -18°C.

#### Metabolism in plants and animals

The metabolism of propaquizafop has been investigated during first peer review in cotton, soybean, lettuce and sugar beet, representing three groups of crops; oilseed/pulse crops, leafy crops and root/tuber crops. According to OECD 501 guideline as results of these three metabolism groups studies indicate comparable metabolic route, extrapolation is also applicable to fruits, and no additional study is needed.

The metabolism of propaquizafop in rotational crops was investigated in sugar beet, spinach and wheat.

EFSA Journal 2019;17(7):5747: *Studies investigating the effect of processing on the nature of residues were performed with quizalofop (acid); these studies demonstrated that quizalofop (acid) is stable under conditions representative for pasteurisation, sterilisation and baking/brewing/boiling. Studies with propaquizafop are not available. In the framework of the MRL review, it was decided that the studies with quizalofop (acid) are sufficient to conclude that propaquizafop is not expected to degrade under standard processing conditions (EFSA, 2017).*

| Endpoints   |  |
|---|--|
| Plant groups covered  | Root and tuber vegetables (sugar beets...)<br>Leafy vegetables (lettuce..)<br>Pulses and oilseeds (cotton, soya beans..)<br>Fruits (citrus, olive..) |
| Rotational crops covered  | Root and tuber vegetables (sugar beets)<br>Leafy vegetables (spinach)<br>Cereals (spring wheat)  |
| Metabolism in rotational crops similar to metabolism in primary crops?          | Yes  |
| Processed commodities   | Not applicable   |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Yes  |
| Plant residue definition for monitoring   | Reg. (EU) 2019/973: Quizalofop (sum of quizalofop, its salts, its  |

|  |   |
|--|---|
|  | esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers))  |
| Plant residue definition for risk assessment | Propaquizafop<br>Provisional:<br>Sum propaquizafop and quizalofop expressed as quizalofop (sum of isomers) (EFSA, 2008)<br>Sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers) (EFSA, 2017) |
| Conversion factor from enforcement to RA     | Not applicable  |

## Magnitude of residues in plants

### Sugar beet

Proposed uses:

1 application, BBCH 12-35, 0.050 – 0.150 kg as/ha, PHI: 28 days

or

2 application (interval 12 days), BBCH 12-35, 0.060 kg as/ha, PHI: 28 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014). Residue trials were evaluated at the European Community level too.

Trials GAP: 1x 0.15-0.2 kg as/ha, BBCH 37, PHI 91

GAP supported by available data *Propaquizafop, SANCO/131/08 final, 26 May 2009*:

1x 0.2 kg as/ha, BBCH 12-39, PHI na

PHI evaluated under review of the existing maximum residue levels for quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop according to Article 12 of Regulation (EC) No 396/2005 for sugar beet was 60 days. Therefore, 60 days is proposed.

Available data can cover the proposed use.

The residues arising from the proposed uses will not exceed the MRLs established for sugar beets (0.06 mg/kg, Reg. (EU) 2019/973).

Uses are accepted.

### Fodder beet; Beetroot

According to the SANTE/2019/12752 extrapolation from sugar beet to fodder beet and beetroot is possible. The residues arising from the proposed uses will not exceed the MRLs established for beetroot (0.06 mg/kg, Reg. (EU) 2019/973). Uses are accepted. Accepted PHI: 60 days.

### Oilseed rape

Proposed uses:

1 application, BBCH 12-35, 0.050 – 0.150 kg as/ha, PHI: 42 days

or

2 application (interval 12 days), BBCH 12-35, 0.060 kg as/ha, PHI: 42 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

GAP on which EU a.s. assessment is based: 1x 0.2 kg as/ha, BBH 31, PHI 90

GAP evaluated under review of the existing maximum residue levels: 1x 0.20 kg as/ha, BBH 11-31, PHI 90

GAP supported by available data *Propaquizafop, SANCO/131/08 final, 26 May 2009*:

1x 0.2 kg as/ha, BBCH 12-39, PHI na

PHI evaluated under review of the existing maximum residue levels for quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop according to Article 12 of Regulation (EC) No 396/2005 for oilseed rape was 90 days. Therefore, 90 days is proposed.

Available data can cover the proposed use.

The residues arising from the proposed uses will not exceed the MRLs established for oilseed rape (2.0 mg/kg, Reg. (EU) 2019/973).

Uses are accepted.

According to the SANTE/2019/12752 extrapolation from oilseed rape to poppy seed and flax is possible.

The residues arising from the proposed uses will not exceed the MRLs established for linseeds (0.3 mg/kg) and poppy seeds (0.7 mg/kg).

#### Potatoes

Proposed uses:

1 application, BBCH 10-35, 0.050 – 0.150 kg as/ha, PHI: 40 days

or

2 application (interval 12 days), BBCH 10-35, 0.060 kg as/ha, PHI: 40 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

Trials GAP: 1 x 0.2 kg a.s./ha, PHI: 49-171d

GAP evaluated under review of the existing maximum residue levels: 1x 0.15 kg as/ha, BBH 11-31, PHI 30

Available data can cover the proposed use.

The residues arising from the proposed uses will not exceed the MRLs established for potatoes (0.1 mg/kg, Reg. (EU) 2019/973).

Uses are accepted.

#### Onion

Proposed uses:

1 application, BBCH 9-53, 0.050 – 0.150 kg as/ha, PHI: 30 days

or

2 application (interval 12 days), BBCH 9-53, 0.060 kg as/ha, PHI: 30 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

GAP evaluated under review of the existing maximum residue levels: 1x 0.20 kg as/ha, PHI 30

Available data can cover the proposed use.

The residues arising from the proposed uses will not exceed the MRLs established for onion (0.04 mg/kg, Reg. (EU) 2019/973).

Uses are accepted.

According to the SANTE/2019/12752 extrapolation from onion to garlic and shallot is possible.

The residues arising from the proposed uses will not exceed the MRLs established for garlic and shallot (0.04 mg/kg, Reg. (EU) 2019/973).

#### Bean

Proposed uses:

1 application, BBCH 13-30, 0.050 – 0.150 kg as/ha, PHI: 45 days

or

2 application (interval 12 days), BBCH 13-30, 0.060 kg as/ha, PHI: 45 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

Study Schwager L., 1991 (90003816):

This study was performed on been for dry seed (pulses). **Storage stability data are required as to verify the validity of the results.**

The data included in the Registration Report are not sufficient as to perform an evaluation.

Heyer R., 1995a – Analytical report; Beinhauer K., 1994a – Field report:

This study was performed on been for dry seed (pulses). **Storage stability data are required as to verify the validity of the results.**

The data included in the Registration Report are not sufficient as to perform an evaluation.

Uses are not accepted.

#### Green peas; Peas for dry seeds

Proposed uses:

1 application, BBCH 13-30, 0.050 – 0.150 kg as/ha, PHI: 45 days

or

2 application (interval 12 days), BBCH 13-30, 0.060 kg as/ha, PHI: 45 days

Only two trials are referenced (on fresh peas) in the RR Agil 100 EC.

The data included in the Registration Report are not sufficient as to perform an evaluation the uses on fresh and dry peas.

Uses are not accepted. **Additionally storage stability data for High protein content matrices are required.**

Alfalfa; Yellow alfalfa; Black medic; Red clover; White clover; Crimson clover; Common sainfoin;  
Vetch; Little white bird's-foot; Lentil; White melilot; Yellow melilot; Grass pea

The data included in the Registration Report (RR Agil 100 EC) are not sufficient as to perform an evaluation the uses on above crops.

#### Head cabbage

Proposed uses:

1 application, BBCH 13-30, 0.050 – 0.150 kg as/ha, PHI: 28 days

or

2 application (interval 12 days), BBCH 13-30, 0.060 kg as/ha, PHI: 28 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

GAP on which EU a.s. assessment is based: 1x 0.15 kg as/ha, BBCH 29, PHI 30

Available data can cover the proposed use.

The residues arising from the proposed uses will not exceed the MRLs established for head cabbage (0.6 mg/kg, Reg. (EU) 2019/973).

PHI = 30 days is proposed by zRMS. Use is accepted.

#### Broccoli; Brussels sprouts

According to the SANTE/2019/12752 extrapolation from head cabbage to broccoli and brussels sprouts is not possible. Uses are not accepted.

Carrot; Parsley

Proposed uses:

1 application, BBCH 12-30, 0.050 – 0.150 kg as/ha, PHI: 28 days

or

2 application (interval 12 days), BBCH 12-30, 0.060 kg as/ha, PHI: 28 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

GAP on which EU a.s. assessment is based: 1x 0.15 kg as/ha, BBCH 29, PHI 30

Available data can cover the proposed use on carrot.

The residues arising from the proposed uses will not exceed the MRLs established for carrot (0.2 mg/kg, Reg. (EU) 2019/973).

PHI = 30 days is proposed by zRMS. Use on carrot is accepted.

According to the SANTE/2019/12752 extrapolation from carrot to parsley is possible. Use on parsley is accepted (PHI: 30 days).

The residues arising from the proposed uses will not exceed the MRLs established for parsley (0.2 mg/kg, Reg. (EU) 2019/973).

Root celery; Parsnip; Swedes

According to the SANTE/2019/12752 extrapolation from carrot to Whole subgroup (c ) other root and tuber vegetables except sugar beets (0213000) is possible.

MRLs for

Carrots: 0.2 mg/kg

Celeriacs/turnip rooted celeries: 0.08 mg/kg

Parsnip: 0.2 mg/kg

Swedes: 0.06 mg/kg

Use on parsnip is accepted. The residues arising from the proposed uses will not exceed the MRLs established for head parsnip (0.2 mg/kg, Reg. (EU) 2019/973).

Use on root celery and swedes are not accepted (when extrapolation is from carrot). The residues arising from the proposed uses may exceed the MRLs established for root celery and swedes (Reg. (EU) 2019/973).

Despite this, extrapolation from sugar beets to celery root and swedes is possible.

MRL for sugar beet is 0.06 mg/kg. Then, the residues arising from the proposed uses will not exceed the MRLs established for root celery and swedes.

Uses are accepted. PHI proposed: 60 days (see sugar beet).

Jerusalem Artichokes; Horseradish; Black radish; Japanese radish (daikon); Radish; Salsify; White turnip;

Black turnip

MRLs:

Jerusalem Artichokes: 0.08 mg/kg - not accepted (extrapolation from sugar beet is not possible)

Horseradish: 0.08 mg/kg - accepted extrapolation from sugar beet with PHI: 60 days

Black radish: 0.2 mg/kg - accepted extrapolation from carrots with PHI: 30 days

Japanese radish (daikon): 0.2 mg/kg - accepted extrapolation from carrots with PHI: 30 days

Radish: 0.2 mg/kg - accepted extrapolation from carrots with PHI: 30 days  
Salsify: 0.2 mg/kg - accepted extrapolation from carrots with PHI: 30 days  
White turnip: 0.08 mg/kg: - accepted extrapolation from sugar beet with PHI: 60 days  
Black turnip: 0.08 mg/kg: - accepted extrapolation from sugar beet with PHI: 60 days

#### Strawberry

Proposed uses:

1 application, BBCH 13-30, 91-92, 0.050 – 0.150 kg as/ha, PHI: na

or

2 application (interval 12 days), BBCH 13-16, 91-92, 0.060 kg as/ha, na

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

The data included in the Registration Report (RR Agil 100 EC) are not sufficient as to perform an evaluation the uses on strawberry. Additionally the storage stability data are required as to cover the high acid commodities.

Uses at BBCH 13-30 are not accepted. Use at BBCH 91-92 is accepted.

#### **Magnitude of residues in livestock**

Regarding available data, there is no risk for animal MRL to be exceeded.

#### **Processing studies**

Further processing studies are not required in this case as they are not expected to affect the outcome of the risk assessment.

#### **Estimation of exposure through diet and other means**

Accepted uses of propaquizafop in the formulation SHA 6100A do not represent unacceptable chronic or acute risk for the consumer

#### **Conclusions**

**Uses not accepted (insufficient data on field trials / possibility of extrapolation):**

Bean

Green peas;

Peas for dry seeds

~~Jerusalem Artichokes~~

Broccoli,

Brussels sprouts;

Broad beans;

Faba bean;

Field peas;

White lupine;

Yellow lupine;

Narrow-leaved lupine

Alfalfa;

Yellow alfalfa;  
Black medic;  
Red clover;  
White clover;  
Crimson clover;  
Common sainfoin;  
Vetch;  
Little white bird's-foot;  
Lentil;  
White melilot;  
Yellow melilot;  
Grass pea

#### Jerusalem Artichokes

In this case extrapolation from carrots is possible.

MRL for carrots is 0.2 mg/kg.

MRL for Jerusalem Artichokes is 0.08 mg/kg

The residues in Jerusalem Artichokes after application of the Alive will not exceed the MRL set for this crop.

Therefore use is acceptable.

#### Uses with the changed by evaluator PHI:

Sugar beet, Root celery, Swedes, Fodder beet, Beetroot, Turnips, Horseradish (proposed PHI: 60 days)

Winter oilseed rape, Spring oilseed rape, Opium poppy, Common flax, Linen flax; (proposed PHI: 90 days)

Cabbage, Carrot, Parsley, Parsnip, Black radish, Japanese radish (daikon), Radish, Salsify (proposed PHI: 30 days)

#### Uses with restricted BBCH:

Uses at BBCH 13-30 are not accepted. Use at BBCH 91-92 is accepted.

### 7.1.1 Critical GAP(s) and overall conclusion

#### Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation Propaquizafop 10% EC are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone/EU for crop 1. A list of all intended uses within the central zone is given in Part B, Section 0.

#### Justification for the selection of the critical GAP

#### Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of **xxx** mg/kg for Propaquizafop as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of Propaquizafop residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the intended use(s).

According to available data, **no specific mitigation measures should apply.**

Or

According to available data, **the following specific mitigation measures are recommended:** ...

#### Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

#### Noticed data gaps are:

- Uses not accepted (insufficient data on field trials / possibility of extrapolation):  
Bean, Green peas, Peas for dry seeds, **Jerusalem Artichokes**, Broccoli, Brussels sprouts, Broad beans Faba bean, Field peas, White lupine Yellow lupine Narrow-leaved lupine, Alfalfa, Yellow alfalfa, Black medic, Red clover, White clover, Crimson clover, Common sainfoin, Vetch, Little white bird's-foot, Lentil, White melilot, Yellow melilot, Grass pea
- Strawberry (trials at proposed BBCH)
- ~~Storage stability studies are required as to cover the high acid, high protein content (dry legume vegetables/pulses) commodities and animal commodities.~~

**Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)**

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>Fpn<br>G,<br>Gn,<br>Gpn<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) | Conclusion |
|------------------|--------------------|--|--|---|---------------|--|---|--|--|---|-----------------------------|---------------|------------|
|                  |                    |  |  |   | Method / Kind | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br><br>min / max |               |            |

| Use-<br>No.<br>*   | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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)       | Conclusion |
|--|--------------------|--|---|---|-----------------------|--|---|--|--|---|-------------------------|---------------------|------------|
|  |                    |  |   |   | Method / Kind         | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |                     |            |
| <b>PL uses (field or outdoor uses, certain types of protected crops)</b> |                    |  |   |   |                       |  |   |  |  |   |                         |                     |            |
| 1.   | PL                 | <b>Sugar beet</b>  | F   | Common barnyardgrass ( <i>Echinochloa crus-galli</i> );<br><br>Spring wild-oat ( <i>Avena fatua</i> );<br><br>Red fingergrass ( <i>Digitaria sanguinalis</i> );<br><br>Yellow bristlegrass ( <i>Setaria pumila</i> );<br><br>Green bristlegrass ( <i>Setaria viridis</i> );<br><br>Perennial ryegrass ( <i>Lolium perenne</i> ) | Broadcast<br>spraying | BBCH 13-29*<br>BBCH 12-35**                  | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | <del>28</del><br>60 | A          |
| 2  | PL                 | <b>Sugar beet</b>  | F   | Silky bentgrass ( <i>Apera spica-venti</i> );<br><br>self-seeding of cereals  | Broadcast<br>spraying | BBCH 13-21*<br>BBCH 25-30**<br>BBCH 12-35*** | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | <del>28</del><br>60 | A          |
| 3  | PL                 | <b>Sugar beet</b>  | F   | Couch grass ( <i>Agropyron repens</i> )   | Broadcast<br>spraying | BBCH 13-16*<br>BBCH 12-35**                  | a) 1<br>b) 1<br><br>OR<br>a) 1<br>b) 2              | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br>a) 0.6<br>b) 1.2                                   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br>a) 0.060<br>b) 0.120          | 200-300                 | <del>28</del><br>60 | A          |
| 4.   | PL                 | <b>Winter<br/>oilseed rape</b>   | F   | Common barnyardgrass ( <i>Echinochloa crus-galli</i> );   | Broadcast<br>spraying | BBCH 13-29*<br>BBCH 12-30**                  | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | <del>42</del><br>90 | A          |



| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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) | Conclusion |
|------------------|--------------------|--|---|--|-----------------------|--|---|--|--|---|-------------------------|---------------|------------|
|                  |                    |  |   |  | Method / Kind         | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |               |            |
| 5.               | PL                 | Winter<br>oilseed rape   | F   | Silky bentgrass ( <i>Apera<br/>spica-venti</i> );<br><br>self-seeding of cereals   | Broadcast<br>spraying | BBCH 13-21*<br>BBCH 25-30**<br>BBCH 12-30*** | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | 42<br>90      | A          |
| 6.               | PL                 | Winter<br>oilseed rape   | F   | Couch grass ( <i>Agropyron<br/>repens</i> )  | Broadcast<br>spraying | BBCH 13-16*<br>BBCH 12-30**                  | a) 1<br>b) 1<br><br>OR<br>a) 1<br>b) 2              | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br>a) 0.6<br>b) 1.2                                   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br>a) 0.060<br>b) 0.120          | 200-300                 | 42<br>90      | A          |
| 7.               | PL                 | Potato   | F   | Common barnyardgrass<br>( <i>Echinochloa crus-<br/>galli</i> );<br><br>Spring wild-oat ( <i>Avena<br/>fatua</i> );<br><br>Red fingergrass ( <i>Digi-<br/>taria sanguinalis</i> );<br><br>Yellow bristlegrass<br>( <i>Setaria pumila</i> );<br><br>Green bristlegrass<br>( <i>Setaria viridis</i> );<br><br>Perennial ryegrass<br>( <i>Lolium perenne</i> ) | Broadcast<br>spraying | BBCH 13-29*<br>BBCH 10-35**                  | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | 40            | A          |
| 8.               | PL                 | Potato   | F   | Silky bentgrass ( <i>Apera<br/>spica-venti</i> );<br><br>self-seeding of cereals   | Broadcast<br>spraying | BBCH 13-21*<br>BBCH 25-30**<br>BBCH 10-35*** | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | 40            | A          |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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) | Conclusion |
|------------------|--------------------|--|---|---|--------------------|--|---|--|--|---|-------------------------|---------------|------------|
|                  |                    |  |   |   | Method / Kind      | Timing / Growth<br>stage of crop &<br>season                   | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |               |            |
| 9.               | PL                 | Potato   | F   | Couch grass ( <i>Agropyron repens</i> )   | Broadcast spraying | BBCH 13-16*<br>BBCH 10-35**                                    | a) 1<br>b) 1<br><br>OR<br>a) 1<br>b) 2              | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br>a) 0.6<br>b) 1.2                                   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br>a) 0.060<br>b) 0.120          | 200-300                 | 40            | A          |
| 10.              | PL                 | Onion  | F   | Common barnyardgrass ( <i>Echinochloa crus-galli</i> );<br><br>Spring wild-oat ( <i>Avena fatua</i> );<br><br>Red fingergrass ( <i>Digitaria sanguinalis</i> );<br><br>Yellow bristlegrass ( <i>Setaria pumila</i> );<br><br>Green bristlegrass ( <i>Setaria viridis</i> );<br><br>Perennial ryegrass ( <i>Lolium perenne</i> ) | Broadcast spraying | BBCH 13-29*<br>BBCH 11-12**<br>BBCH 09-53***                   | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | 30            | A          |
| 11.              | PL                 | Onion  | F   | Silky bentgrass ( <i>Apera spica-venti</i> );<br><br>self-seeding of cereals  | Broadcast spraying | BBCH 13-21*<br>BBCH 25-30**<br>BBCH 11-12***<br>BBCH 09-53**** | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | 30            | A          |
| 12.              | PL                 | Onion  | F   | Couch grass ( <i>Agropyron repens</i> )   | Broadcast spraying | BBCH 13-16*<br>BBCH 11-12**<br>BBCH 09-53***                   | a) 1<br>b) 1<br><br>OR                              |  | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR                                  | 200-300                 | 30            | A          |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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) | Conclusion |
|------------------|--------------------|--|---|---|---------------|--|---|--|--|---|-------------------------|---------------|------------|
|                  |                    |  |   |   | Method / Kind | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |               |            |
|                  |                    |  |   |   |               |  | a) 1<br>b) 2  | 12   | a) 0.6<br>b) 1.2   | a) 0.060<br>b) 0.120  |                         |               |            |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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) | Conclusion |
|------------------|--------------------|--|---|---|--------------------|--|---|--|--|---|-------------------------|---------------|------------|
|                  |                    |  |   |   | Method / Kind      | Timing / Growth<br>stage of crop &<br>season   | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |               |            |
| 13.              | PL                 | <b>Bean</b>  | F   | Common barnyardgrass ( <i>Echinochloa crus-galli</i> );<br><br>Spring wild-oat ( <i>Avena fatua</i> );<br><br>Red fingergrass ( <i>Digitaria sanguinalis</i> );<br><br>Yellow bristlegrass ( <i>Setaria pumila</i> );<br><br>Green bristlegrass ( <i>Setaria viridis</i> );<br><br>Perennial ryegrass ( <i>Lolium perenne</i> ) | Broadcast spraying | BBCH 13-29*<br>min. BBCH 13**                  | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | 45            | N          |
| 14.              | PL                 | <b>Bean</b>  | F   | Silky bentgrass ( <i>Apera spica-venti</i> );<br><br>self-seeding of cereals  | Broadcast spraying | BBCH 13-21*<br>BBCH 25-30**<br>min. BBCH 13*** | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | 45            | N          |
| 15.              | PL                 | <b>Bean</b>  | F   | Couch grass ( <i>Agropyron repens</i> )   | Broadcast spraying | BBCH 13-16*<br>min. BBCH 13**                  | a) 1<br>b) 1<br><br>OR<br>a) 1<br>b) 2              | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br>a) 0.6<br>b) 1.2                                   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br>a) 0.060<br>b) 0.120          | 200-300                 | 45            | N          |
| 16.              | PL                 | <b>Green peas;<br/>Peas for dry<br/>seeds</b>  | F   | Common barnyardgrass ( <i>Echinochloa crus-galli</i> );<br><br>Spring wild-oat ( <i>Avena</i>   | Broadcast spraying | BBCH 13-29*<br>min. BBCH 12**                  | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | 45            | A          |



| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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)                           | Conclusion |
|------------------|--------------------|--|---|--|-----------------------|--|---|--|--|---|-------------------------|---|------------|
|                  |                    |  |   |  | Method / Kind         | Timing / Growth<br>stage of crop &<br>season   | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |   |            |
| 17.              | PL                 | <b>Green peas;<br/>Peas for dry<br/>seeds</b>  | F   | Silky bentgrass ( <i>Apera<br/>spica-venti</i> );<br><br>self-seeding of cereals   | Broadcast<br>spraying | BBCH 13-21*<br>BBCH 25-30**<br>min. BBCH 12*** | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | 45                                      | A          |
| 18.              | PL                 | <b>Green peas;<br/>Peas for dry<br/>seeds</b>  | F   | Couch grass ( <i>Agropyron<br/>repens</i> )  | Broadcast<br>spraying | BBCH 13-16*<br>min. BBCH 12**                  | a) 1<br>b) 1<br><br>OR<br>a) 1<br>b) 2              | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br>a) 0.6<br>b) 1.2                                   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br>a) 0.060<br>b) 0.120          | 200-300                 | 45                                      | A          |
| 19.              | PL                 | <b>Cabbage</b>   | F   | Common barnyardgrass<br>( <i>Echinochloa crus-<br/>galli</i> );<br><br>Spring wild-oat ( <i>Avena<br/>fatua</i> );<br><br>Red fingergrass ( <i>Digi-<br/>taria sanguinalis</i> );<br><br>Yellow bristlegrass<br>( <i>Setaria pumila</i> );<br><br>Green bristlegrass<br>( <i>Setaria viridis</i> );<br><br>Perennial ryegrass<br>( <i>Lolium perenne</i> ) | Broadcast<br>spraying | BBCH 13-29*<br>min. BBCH 13**                  | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | Growth<br>stage<br>restricted<br><br>30 | A          |
| 20.              | PL                 | <b>Cabbage</b>   | F   | Silky bentgrass ( <i>Apera<br/>spica-venti</i> );<br><br>self-seeding of cereals   | Broadcast<br>spraying | BBCH 13-21*<br>BBCH 25-30**<br>min. BBCH 13*** | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | 28<br>30                                | A          |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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)       | Conclusion |
|------------------|--------------------|--|---|---|--------------------|--|---|--|--|---|-------------------------|---------------------|------------|
|                  |                    |  |   |   | Method / Kind      | Timing / Growth<br>stage of crop &<br>season   | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |                     |            |
| 21.              | PL                 | <b>Cabbage</b>   | F   | Couch grass ( <i>Agropyron repens</i> )   | Broadcast spraying | BBCH 13-16*<br>min. BBCH 13**                  | a) 1<br>b) 1<br><br>OR<br>a) 1<br>b) 2              | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br>a) 0.6<br>b) 1.2                                   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br>a) 0.060<br>b) 0.120          | 200-300                 | <del>28</del><br>30 | A          |
| 22.              | PL                 | <b>Carrot;<br/>Parsley</b>   | F   | Common barnyardgrass ( <i>Echinochloa crus-galli</i> );<br><br>Spring wild-oat ( <i>Avena fatua</i> );<br><br>Red fingergrass ( <i>Digitaria sanguinalis</i> );<br><br>Yellow bristlegrass ( <i>Setaria pumila</i> );<br><br>Green bristlegrass ( <i>Setaria viridis</i> );<br><br>Perennial ryegrass ( <i>Lolium perenne</i> ) | Broadcast spraying | BBCH 13-29*<br>min. BBCH 12**                  | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | <del>28</del><br>30 | A          |
| 23.              | PL                 | <b>Carrot;<br/>Parsley</b>   | F   | Silky bentgrass ( <i>Apera spica-venti</i> );<br><br>self-seeding of cereals  | Broadcast spraying | BBCH 13-21*<br>BBCH 25-30**<br>min. BBCH 12*** | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | <del>28</del><br>30 | A          |
| 24.              | PL                 | <b>Carrot;<br/>Parsley</b>   | F   | Couch grass ( <i>Agropyron repens</i> )   | Broadcast spraying | BBCH 13-16*<br>min. BBCH 12**                  | a) 1<br>b) 1<br><br>OR                              |  | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR                                  | 200-300                 | <del>28</del><br>30 | A          |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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) | Conclusion |
|------------------|--------------------|--|---|---|---------------|--|---|--|--|---|-------------------------|---------------|------------|
|                  |                    |  |   |   | Method / Kind | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |               |            |
|                  |                    |  |   |   |               |  | a) 1<br>b) 2  | 12   | a) 0.6<br>b) 1.2   | a) 0.060<br>b) 0.120  |                         |               |            |

| Use-<br>No.<br>*                                       | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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) | Conclusion                     |
|--|--------------------|--|---|--|-----------------------|--|---|--|--|---|-------------------------|---------------|--------------------------------|
|  |                    |  |   |  | Method / Kind         | Timing / Growth<br>stage of crop &<br>season                       | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |               |                                |
| 25.  | PL                 | <b>Strawberry</b>  | F   | Common banyardgrass ( <i>Echinochloa crus-galli</i> );<br><br>Spring wild-oat ( <i>Avena fatua</i> );<br><br>Red fingergrass ( <i>Digitaria sanguinalis</i> );<br><br>Yellow bristlegrass ( <i>Setaria pumila</i> );<br><br>Green bristlegrass ( <i>Setaria viridis</i> );<br><br>Perennial ryegrass ( <i>Lolium perenne</i> ) | Broadcast<br>spraying | <del>BBCH 13-29*</del><br>BBCH 91-92**                             | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | N.A.          | A<br>Use only at<br>BBCH 91-92 |
| 26.  | PL                 | <b>Strawberry</b>  | F   | Silky bentgrass ( <i>Apera spica-venti</i> );<br><br>self-seeding of cereals   | Broadcast<br>spraying | <del>BBCH 13-21*</del><br><del>BBCH 25-30***</del><br>BBCH 91-92** | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | N.A.          | A<br>Use only at<br>BBCH 91-92 |
| 27.  | PL                 | <b>Strawberry</b>  | F   | Couch grass ( <i>Agropyron repens</i> )  | Broadcast<br>spraying | <del>BBCH 13-16*</del><br>BBCH 91-92**                             | a) 1<br>b) 1<br><br>OR<br><br>a) 1<br>b) 2          | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br><br>a) 0.6<br>b) 1.2                               | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br><br>a) 0.060<br>b) 0.120      | 200-300                 | N.A.>         | A<br>Use only at<br>BBCH 91-92 |
| 28.  | CEU                | <b>OSR</b>   | F   | Annual and perennial<br>grass weeds  | Spray                 | Post emergence<br>BBCH 12-39                                       | a) 1<br>b) 1  | NA   | a) 1.2<br>b) 1.2   | a) 0.12<br>b) 0.12  | 200-400                 | 90            | A                              |
| <b>Minor uses according to Article 51 (zonal uses)</b> |                    |  |   |  |                       |  |   |  |  |   |                         |               |                                |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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) | Conclusion |
|------------------|--------------------|--|---|---|-----------------------|--|---|--|--|---|-------------------------|---------------|------------|
|                  |                    |  |   |   | Method / Kind         | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |               |            |
| 29.              | PL                 | Spring<br>oilseed rape   | F   | Common banyardgrass<br>( <i>Echinochloa crus-<br/>galli</i> );<br><br>Spring wild-oat ( <i>Avena<br/>fatua</i> ) ;<br><br>Red fingergrass ( <i>Digi-<br/>taria sanguinalis</i> ) ;<br><br>Yellow bristlegrass<br>( <i>Setaria pumila</i> ) ;<br><br>Green bristlegrass<br>( <i>Setaria viridis</i> ) ;<br><br>Perennial ryegrass<br>( <i>Lolium perenne</i> ) | Broadcast<br>spraying | BBCH 13-29*<br>BBCH 12-30**                  | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | 90            | A          |
| 30.              | PL                 | Spring<br>oilseed rape   | F   | Silky bentgrass ( <i>Apera<br/>spica-venti</i> ) ;<br><br>self-seeding of cereals   | Broadcast<br>spraying | BBCH 13-21*<br>BBCH 25-30**<br>BBCH 12-30*** | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | 90            | A          |
| 31.              | PL                 | Spring<br>oilseed rape   | F   | Couch grass ( <i>Agropyron<br/>repens</i> )   | Broadcast<br>spraying | BBCH 13-16*<br>BBCH 12-30**                  | a) 1<br>b) 1<br><br>OR<br>a) 1<br>b) 2              | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br>a) 0.6<br>b) 1.2                                   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br>a) 0.060<br>b) 0.120          | 200-300                 | 90            | A          |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop)  | F,<br>Fn,<br>Fpn<br>G,<br>Gn,<br>Gpn<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)   | Conclusion   |
|------------------|--------------------|---|--|---|-----------------------|--|---|--|--|---|-------------------------|---|--|
|                  |                    |   |  |   | Method / Kind         | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |   |  |
| 32.              | PL                 | <b>Opium<br/>poppy;<br/>Common<br/>flax;<br/>Linen flax;<br/>Broccoli;<br/>Brussels<br/>sprouts;<br/>Broad<br/>beans;<br/>Faba bean;<br/>Field peas;<br/>White lu-<br/>pine;<br/>Yellow<br/>lupine;<br/>Narrow-<br/>leaved<br/>lupine</b> | F  | Common banyardgrass<br>( <i>Echinochloa crus-<br/>galli</i> );<br><br>Spring wild-oat ( <i>Avena<br/>fatua</i> );<br><br>Red fingergrass ( <i>Digi-<br/>taria sanguinalis</i> );<br><br>Yellow bristlegrass<br>( <i>Setaria pumila</i> );<br><br>Green bristlegrass<br>( <i>Setaria viridis</i> );<br><br>Perennial ryegrass<br>( <i>Lolium perenne</i> ) | Broadcast<br>spraying | BBCH 13-29*<br>BBCH 13**                     | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | Poppy,<br>common<br>flax -90.<br>Broccoli;<br>Brussels<br>sprouts-28.<br>Broad<br>beans;<br>Faba bean;<br>Field peas;<br>White<br>lupine;<br>Yellow<br>lupine;<br>Narrow-<br>leaved<br>lupine-45. | <b>A<br/>Opium poppy;<br/>Common flax;<br/>Linen flax;</b> |
| 33.              | PL                 | <b>Opium<br/>poppy;<br/>Common<br/>flax;<br/>Linen flax;<br/>Broccoli;<br/>Brussels<br/>sprouts;<br/>Broad<br/>beans;<br/>Faba bean;<br/>Field peas;<br/>White lu-<br/>pine;<br/>Yellow<br/>lupine;<br/>Narrow-<br/>leaved<br/>lupine</b> | F  | Silky bentgrass ( <i>Apera<br/>spica-venti</i> );<br><br>self-seeding of cereals  | Broadcast<br>spraying | BBCH 13-21*<br>BBCH 25-30**<br>BBCH 13***    | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | Poppy,<br>common<br>flax -90.<br>Broccoli;<br>Brussels<br>sprouts-28.<br>Broad<br>beans;<br>Faba bean;<br>Field peas;<br>White<br>lupine;<br>Yellow<br>lupine;<br>Narrow-<br>leaved<br>lupine-45. | <b>A<br/>Opium poppy;<br/>Common flax;<br/>Linen flax;</b> |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop)  | F,<br>Fn,<br>Fpn<br>G,<br>Gn,<br>Gpn<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)   | Conclusion  |
|------------------|--------------------|---|--|---|-----------------------|--|---|--|--|---|-------------------------|---|---|
|                  |                    |   |  |   | Method / Kind         | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |   |   |
|                  |                    |   |  |   |                       |  |   |  |  |   |                         |   | lupine  |
| 34.              | PL                 | <b>Opium<br/>poppy;<br/>Common<br/>flax;<br/>Linen flax;<br/>Broccoli;<br/>Brussels<br/>sprouts;<br/>Broad<br/>beans;<br/>Faba bean;<br/>Field peas;<br/>White lu-<br/>pine;<br/>Yellow<br/>lupine;<br/>Narrow-<br/>leaved<br/>lupine</b> | F  | Couch grass ( <i>Agropyron<br/>repens</i> )   | Broadcast<br>spraying | BBCH 13-16*<br>BBCH 13**                     | a) 1<br>b) 1<br><br>OR<br>a) 1<br>b) 2              | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br>a) 0.6<br>b) 1.2                                   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br>a) 0.060<br>b) 0.120          | 200-300                 | Poppy,<br>common<br>flax -90.<br>Broccoli;<br>Brussels<br>sprouts -28.<br>Broad<br>beans;<br>Faba bean;<br>Field peas;<br>White<br>lupine;<br>Yellow<br>lupine;<br>Narrow-<br>leaved<br>lupine -45. | A<br><b>Opium poppy;<br/>Common flax;<br/>Linen flax;</b> |
| 35.              | PL                 | <b>Root celery;<br/>Parsnip;<br/>Swedes</b>   | F  | Common barnyardgrass<br>( <i>Echinochloa crus-<br/>galli</i> );<br><br>Spring wild-oat ( <i>Avena<br/>fatua</i> );  | Broadcast<br>spraying | BBCH 13-29*<br>BBCH 12**                     | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | 28<br>30<br>For parsnip   | A<br>Parsnip<br>Extrapolation<br>from carrot              |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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)   | Conclusion |
|------------------|--------------------|--|---|--|-----------------------|--|---|--|--|---|----------------------------------|---|------------|
|                  |                    |  |   |  | Method / Kind         | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max          |   |            |
|                  |                    |  |   | Red fingergrass ( <i>Digi-<br/>taria sanguinalis</i> );<br><br>Yellow bristlegrass<br>( <i>Setaria pumila</i> );<br><br>Green bristlegrass<br>( <i>Setaria viridis</i> );<br><br>Perennial ryegrass<br>( <i>Lolium perenne</i> ) |                       |  |   |  |  |   | 60 for Root<br>celery;<br>Swedes | A<br>Root celery;<br>Swedes<br>Extrapolation<br>from sugar beet |            |
| 36.              | PL                 | Root celery;<br>Parsnip;<br>Swedes   | F   | Silky bentgrass ( <i>Apera<br/>spica-venti</i> );<br><br>self-seeding of cereals   | Broadcast<br>spraying | BBCH 13-21*<br>BBCH 25-30**<br>BBCH 12***    | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 28<br>30 for<br>parsnip          | A<br>Parsnip<br>Extrapolation<br>from carrot                    |            |
|                  |                    |  |   |  |                       |  |   |  |  |   | 60 for Root<br>celery;<br>Swedes | A<br>Root celery;<br>Swedes<br>Extrapolation<br>from sugar beet |            |
| 37.              | PL                 | Root celery;<br>Parsnip;<br>Swedes   | F   | Couch grass ( <i>Agropyron<br/>repens</i> )  | Broadcast<br>spraying | BBCH 13-16*<br>BBCH 12**                     | a) 1<br>b) 1<br><br>OR<br>a) 1<br>b) 2              | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br>a) 0.6<br>b) 1.2                                   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br>a) 0.060<br>b) 0.120          | 28<br>30 for<br>parsnip          | A<br>Parsnip<br>Extrapolation<br>from carrot                    |            |
|                  |                    |  |   |  |                       |  |   |  |  |   | 60 for Root<br>celery;<br>Swedes | A<br>Root celery;<br>Swedes<br>Extrapolation<br>from sugar beet |            |
| 38.              | PL                 | Garlic;<br>Shallot   | F   | Common barnyardgrass<br>( <i>Echinochloa crus-<br/>galli</i> );<br><br>Spring wild-oat ( <i>Avena</i>  | Broadcast<br>spraying | BBCH 13-29*<br>BBCH 11-12**                  | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 30                               | A   |            |



| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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)       | Conclusion |
|------------------|--------------------|--|---|--|-----------------------|--|---|--|--|---|-------------------------|---------------------|------------|
|                  |                    |  |   |  | Method / Kind         | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |                     |            |
| 39.              | PL                 | <b>Garlic;<br/>Shallot</b>   | F   | Silky bentgrass ( <i>Apera<br/>spica-venti</i> );<br><br>self-seeding of cereals   | Broadcast<br>spraying | BBCH 13-21*<br>BBCH 25-30**<br>BBCH 11-12*** | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | 30                  | A          |
| 40.              | PL                 | <b>Garlic;<br/>Shallot</b>   | F   | Couch grass ( <i>Agropyron<br/>repens</i> )  | Broadcast<br>spraying | BBCH 13-16*<br>BBCH 11-12**                  | a) 1<br>b) 1<br><br>OR<br>a) 1<br>b) 2              | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br>a) 0.6<br>b) 1.2                                   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br>a) 0.060<br>b) 0.120          | 200-300                 | 30                  | A          |
| 41.              | PL                 | <b>Fodder beet;<br/>Beetroot</b>   | F   | Common barnyardgrass<br>( <i>Echinochloa crus-<br/>galli</i> );<br><br>Spring wild-oat ( <i>Avena<br/>fatua</i> );<br><br>Red fingergrass ( <i>Digi-<br/>taria sanguinalis</i> );<br><br>Yellow bristlegrass<br>( <i>Setaria pumila</i> );<br><br>Green bristlegrass<br>( <i>Setaria viridis</i> );<br><br>Perennial ryegrass<br>( <i>Lolium perenne</i> ) | Broadcast<br>spraying | BBCH 13-29*<br>BBCH 12-35**                  | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | <del>28</del><br>60 | A          |
| 42.              | PL                 | <b>Fodder beet;<br/>Beetroot</b>   | F   | Silky bentgrass ( <i>Apera<br/>spica-venti</i> );<br><br>self-seeding of cereals   | Broadcast<br>spraying | BBCH 13-21*<br>BBCH 25-30**<br>BBCH 12-35*** | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | <del>28</del><br>60 | A          |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop)  | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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)  | Conclusion |
|------------------|--------------------|---|---|--|-----------------------|--|---|--|--|---|-------------------------|--|------------|
|                  |                    |   |   |  | Method / Kind         | Timing / Growth<br>stage of crop &<br>season   | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |  |            |
| 43.              | PL                 | <b>Fodder beet;<br/>Beetroot</b>  | F   | Couch grass ( <i>Agropyron<br/>repens</i> )  | Broadcast<br>spraying | BBCH 13-16*<br>BBCH 12-35**                    | a) 1<br>b) 1<br><br>OR<br>a) 1<br>b) 2              | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br>a) 0.6<br>b) 1.2                                   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br>a) 0.060<br>b) 0.120          | 200-300<br>min / max    | 28<br>60   | A          |
| 44.              | PL                 | <b>Jerusalem<br/>Artichokes;<br/>Horseradish;<br/>Black rad-<br/>ish;<br/>Japanese<br/>radish<br/>(daikon);<br/>Radish;<br/>Salsify;<br/>White tur-<br/>nip;<br/>Black turnip</b> | F   | Common barnyardgrass<br>( <i>Echinochloa crus-<br/>galli</i> );<br><br>Spring wild-oat ( <i>Avena<br/>fatua</i> );<br><br>Red fingergrass ( <i>Digi-<br/>taria sanguinalis</i> );<br><br>Yellow bristlegrass<br>( <i>Setaria pumila</i> );<br><br>Green bristlegrass<br>( <i>Setaria viridis</i> );<br><br>Perennial ryegrass<br>( <i>Lolium perenne</i> ) | Broadcast<br>spraying | BBCH 13-29*<br>min. BBCH 12**                  | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | 28<br>Turnips,<br>horseradish:<br>60 days<br><br>Black<br>radish;<br>Japanese<br>radish<br>(daikon);<br>Radish;<br>Salsify.<br>Jerusalem<br>Artichokes:<br>30 days | A          |
| 45.              | PL                 | <b>Jerusalem<br/>Artichokes;<br/>Horseradish;<br/>Black rad-<br/>ish;<br/>Japanese<br/>radish<br/>(daikon);<br/>Radish;<br/>Salsify;</b>  | F   | Silky bentgrass ( <i>Apera<br/>spica-venti</i> );<br><br>self-seeding of cereals   | Broadcast<br>spraying | BBCH 13-21*<br>BBCH 25-30**<br>min. BBCH 12*** | a) 1<br>b) 1  | -  | a) 0.5-0.7<br>b) 0.5-0.7   | a) 0.050-0.070<br>b) 0.050-0.070  | 200-300                 | 28<br>Turnips,<br>horseradish:<br>60 days<br><br>Black<br>radish;<br>Japanese<br>radish<br>(daikon);   | A          |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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)  | Conclusion |
|------------------|--------------------|--|---|---|---------------|--|---|--|--|---|-----------------------------|--|------------|
|                  |                    |  |   |   | Method / Kind | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br><br>min / max |  |            |
|                  |                    | White tur-<br>nip;<br>Black turnip   |   |   |               |  |   |  |  |   |                             | Radish;<br>Salsify;<br>Jerusalem<br>Artichokes;<br>30 days |            |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop)  | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<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)  | Conclusion |
|------------------|--------------------|---|---|--|-----------------------|--|---|--|--|---|-------------------------|--|------------|
|                  |                    |   |   |  | Method / Kind         | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |  |            |
| 46               | PL                 | <b>Jerusalem<br/>Artichokes;<br/>Horseradish;<br/>Black rad-<br/>ish;<br/>Daikon;<br/>Radish;<br/>Salsify;<br/>White tur-<br/>nip;<br/>Black turnip</b>   | F   | Couch grass ( <i>Agropyron<br/>repens</i> )  | Broadcast<br>spraying | BBCH 13-16*<br>min. BBCH 12**                | a) 1<br>b) 1<br><br>OR<br>a) 1<br>b) 2              | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br>a) 0.6<br>b) 1.2                                   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br>a) 0.060<br>b) 0.120          | 200-300                 | 28<br>Turnips,<br>horseradish;<br>60 days<br><br>Black<br>radish;<br>Japanese<br>radish<br>(daikon);<br>Radish;<br>Salsify,<br>Jerusalem<br>Artichokes;<br>30 days | A          |
| 47.              | PL                 | <b>Alfalfa;<br/>Yellow<br/>alfalfa;<br/>Black medic;<br/>Red clover;<br/>White clo-<br/>ver;<br/>Crimson<br/>clover;<br/>Common<br/>sainfoin;<br/>Vetch;<br/>Little white<br/>bird's-foot;<br/>Lentil;<br/>White meli-<br/>lot;<br/>Yellow<br/>melilot;<br/>Grass pea</b> | F   | Common barnyardgrass<br>( <i>Echinochloa crus-<br/>galli</i> );<br><br>Spring wild-oat ( <i>Avena<br/>fatua</i> );<br><br>Red fingergrass ( <i>Digi-<br/>taria sanguinalis</i> );<br><br>Yellow bristlegrass<br>( <i>Setaria pumila</i> );<br><br>Green bristlegrass<br>( <i>Setaria viridis</i> );<br><br>Perennial ryegrass<br>( <i>Lolium perenne</i> ) | Broadcast<br>spraying | BBCH 13-29*<br>min. BBCH 13**                | a) 1<br>b) 1  | -  | a) 0.6<br>b) 0.6   | a) 0.060<br>b) 0.060  | 200-300                 | 45   | A          |
| 48.              | PL                 | <b>Alfalfa;</b>   | F   | Silky bentgrass ( <i>Apera</i>   | Broadcast             | BBCH 13-21*                                  | a) 1  | -  | a) 0.5-0.7   | a) 0.050-0.070  | 200-300                 | 45   | A          |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop)   | F,<br>Fn,<br>Fpn<br>G,<br>Gn,<br>Gpn<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) | Conclusion |
|------------------|--------------------|--|--|---|---------------|--|---|--|--|---|-------------------------|---------------|------------|
|                  |                    |  |  |   | Method / Kind | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |               |            |
|                  |                    | <b>Yellow<br/>alfalfa;<br/>Black medic;<br/>Red clover;<br/>White clo-<br/>ver;<br/>Crimson<br/>clover;<br/>Common<br/>sainfoin;<br/>Vetch;<br/>Little white<br/>bird's-foot;<br/>Lentil;<br/>White meli-<br/>lot;<br/>Yellow<br/>melilot;<br/>Grass pea</b> |  | <i>spica-venti</i> );<br><br>self-seeding of cereals  | spraying      | BBCH 25-30**<br>min. BBCH 13***              | b) 1  |  | b) 0.5-0.7   | b) 0.050-0.070  |                         |               |            |

| Use-<br>No.<br>* | Member<br>state(s) | Crop and/<br>or situation<br>**<br><br>(crop desti-<br>nation /<br>purpose of<br>crop)  | F,<br>Fn,<br>Fpn<br>G,<br>Gn,<br>Gpn<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) | Conclusion |
|------------------|--------------------|---|--|---|-----------------------|--|---|--|--|---|-------------------------|---------------|------------|
|                  |                    |   |  |   | Method / Kind         | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | L product /<br>ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water L/ha<br>min / max |               |            |
| 49.              | PL                 | <b>Alfalfa;<br/>Yellow<br/>alfalfa;<br/>Black medic;<br/>Red clover;<br/>White clo-<br/>ver;<br/>Crimson<br/>clover;<br/>Common<br/>sainfoin;<br/>Vetch;<br/>Little white<br/>bird's-foot;<br/>Lentil;<br/>White meli-<br/>lot;<br/>Yellow<br/>melilot;<br/>Grass pea</b> | F  | Couch grass ( <i>Agropyron<br/>repens</i> )   | Broadcast<br>spraying | BBCH 13-16*<br>min. BBCH 13**                | a) 1<br>b) 1<br><br>OR<br>a) 1<br>b) 2              | 12   | a) 1.25-1.5<br>b) 1.25-1.5<br><br>OR<br>a) 0.6<br>b) 1.2                                   | a) 0.125-0.150<br>b) 0.125-0.150<br><br>OR<br>a) 0.060<br>b) 0.120          | 200-300                 | 45            | N          |
|                  |                    |   |  |   |                       |  |   |  |  |   |                         |               |            |

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

\*\* Use also code numbers according to Annex I of Regulation (EU) No 396/2005

\*\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 “Conclusion”

|   |  |
|---|--|
| A | Exposure acceptable without risk mitigation measures, safe use |
| R | Further refinement and/or risk mitigation measures required    |
| N | Exposure not acceptable, no safe use                           |

## 7.1.2 Summary of the evaluation

The preparation Propaquizafop 10% EC is composed of Propaquizafop.

**Table 7.1-2: Toxicological reference values for the dietary risk assessment of Propaquizafop**

| Reference value | Source | Year | Value              | Study relied upon     | Safety factor |
|-----------------|--------|------|--------------------|-----------------------|---------------|
| Propaquizafop   |        |      |                    |                       |               |
| ADI             | EFSA   | 2008 | 0.015 mg/kg bw/day | mouse long-term study | 100           |
| ArfD            | EFSA   | 2008 | Non applicable     | -                     | -             |

### 7.1.2.1 Summary for Propaquizafop

**Table 7.1-3: Summary for Propaquizafop**

| Use-No.* | Crop       | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance     | Chronic risk for consumers identified? | Acute risk for consumers identified? |
|----------|------------|---------------------------|----------------------------|-----------------------------|---|--------------------|--|--------------------------------------|
| 1-3      | Sugarbeet  | Yes                       | Yes                        | <del>Yes</del> -No          | Yes                                       | Yes                | No                                     | Not relevant                         |
| 4-6      | OSR        | Yes                       | Yes                        | <del>Yes</del> -No          | Yes                                       | Yes                |  |                                      |
| 7-9      | Potato     | Yes                       | Yes                        | Yes                         | Yes                                       | Yes                |  |                                      |
| 10-12    | Onion      | Yes                       | Yes                        | Yes                         | Yes                                       | Yes                |  |                                      |
| 13-15    | Beans      | Yes                       | <del>Yes</del> -No         | <del>Yes</del> -No          | <del>Yes</del> -No                        | <del>Yes</del> -No |  |                                      |
| 16-18    | Peas       | Yes                       | <del>Yes</del> -No         | <del>Yes</del> -No          | <del>Yes</del> -No                        | <del>Yes</del> -No |  |                                      |
| 19-21    | Cabbage    | Yes                       | Yes                        | <del>Yes</del> -No          | Yes                                       | Yes                |  |                                      |
| 22-24    | Carrot     | Yes                       | Yes                        | <del>Yes</del> -No          | Yes                                       | Yes                |  |                                      |
| 25-27    | Strawberry | Yes                       | <del>Yes</del> -No         | <del>Yes</del> -No          | <del>Yes</del> -No                        | <del>Yes</del> -No |  |                                      |
| 28       | OSR        | Yes                       | Yes                        | Yes                         | Yes                                       | Yes                |  |                                      |
| 29-49    | Minor uses | Yes                       | Yes/No<br>See GAP table    | Yes/No<br>See GAP table     | Yes/No<br>See 7.1                         | Yes/No<br>See 7.1  |  |                                      |

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

Intended uses 1-27 and 29-49 requested for SHA 6100A are identical to those of the reference product Agil S 100 EC (Registration R-208/2014) for more than 10 years and, therefore, not in a scope of data protection anymore.

As residues of propaquizafop do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Regarding available feeding data, there is no risk for animal MRL to be exceeded.

### 7.1.2.2 Summary for Propaquizafop 10% EC

**Table 7.1-4: Information on Propaquizafop 10% EC (KCA 6.8)**

| Crop       | PHI for Propaquizafop 10% EC | PHI/ Withholding period* sufficiently supported for | PHI for Propaquizafop 10% EC proposed by zRMS | zRMS Comments (if different PHI proposed) |
|------------|------------------------------|---|---|---|
|            | proposed by applicant        | Propaquizafop                                       |   |   |
| Sugarbeet  | 28                           | <del>Yes</del> -No                                  | Yes   | 60 days                                   |
| OSR        | 42                           | <del>Yes</del> -No                                  | Yes   | 90 days                                   |
| Potato     | 40                           | Yes   | <del>Yes</del> -No                            |   |
| Onion      | 30                           | Yes   | <del>Yes</del> -No                            |   |
| Beans      | 45                           | <del>Yes</del>                                      | <del>Yes</del>                                |   |
| Peas       | 45                           | <del>Yes</del>                                      | <del>Yes</del>                                |   |
| Cabbage    | 28                           | <del>Yes</del> -No                                  | Yes   | 30 days                                   |
| Carrot     | 28                           | <del>Yes</del> -No                                  | Yes   | 30 days                                   |
| Strawberry | —                            | <del>Yes</del>                                      | <del>Yes</del>                                | Only post-harvest use is accepted         |
| OSR        | 60                           | Yes   | <del>Yes</del> -No                            |   |
| Minor uses | 28-90                        | Yes/No  | <del>Yes</del> see GAP table                  |   |

NR: not relevant

\* Purpose of withholding period to be specified

\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

**Table 7.1-5: Waiting periods before planting succeeding crops**

| Waiting period before planting succeeding crops |                      | Overall waiting period proposed by zRMS for SHA 6100 A |
|---|----------------------|--|
| Crop group                                      | Led by Propaquizafop |  |
| All crops                                       | NR                   |  |

NR: not relevant

## Assessment

### 7.2 Propaquizafop

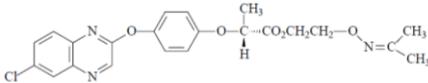
General data on Propaquizafop are summarized in the table below (last updated August 2020).

The present application is made according to the no data principle. ALIVE can be considered as equiva-

lent to AGIL S 100 EC (Reg. No. R-208/2014). For all necessary data to support this application reference is made to the unprotected data from AGIL S 100 EC authorization (in accordance with Article 34 of Regulation 1107/2009/EC).

Uses 1 to 27 and from 29 to 49 requested for ALIVE are identical to those of the reference product AGIL S 100 EC registered in Poland for more than 10 years and, therefore, not in a scope of data protection anymore. Reference is also made to new or additional Annex III data supporting this product under the re-authorization program shall not be protected, as provided in Article 43 of SANCO/12576/2012-rev.1.1 of 1 February 2013.

**Table 7.2-1: General information on Propaquizafop**

|   |   |
|---|---|
| Active substance (ISO Common Name)  | Propaquizafop   |
| IUPAC   | 2-isopropylidenamino-oxyethyl ®-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate   |
| Chemical structure  |   |
| Molecular formula   | C <sub>22</sub> H <sub>22</sub> ClN <sub>3</sub> O <sub>5</sub>   |
| Molar mass  | 443.9 g/mol   |
| Chemical group  | Aryloxyphenoxypropionate  |
| Mode of action (if available)   | Inhibition of fatty acid biosynthesis. The target site for inhibition is the enzyme Acetyl-CoA carboxylase which is located in the plastid of susceptible plants.   |
| Systemic  | Yes   |
| Company   | Makhteshim-Agan   |
| Rapporteur Member State (RMS)   | Austria (original RMS was UK)   |
| Approval status   | Approved<br>Date of 01/12/2009 (Commission Directive 2009/37 REGULATION (EU) No 540/2011)<br><a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0037&amp;from=EN">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0037&amp;from=EN</a><br><a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540&amp;from=EN">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540&amp;from=EN</a> |
| Restriction   | Only uses as herbicide may be authorised.   |
| Review Report   | SANCO/131/08 – final<br>26/05/2009  |
| Current MRL regulation  | <del>Regulation (EU) 2017/171</del> Reg. (EU) 2019/973  |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Yes   |
| EFSA Journal : Conclusion on the peer review                                | Yes (EFSA Scientific Report (2008) 204, 1-171)  |
| EFSA Journal: conclusion on article 12                                      | Yes (EFSA Journal 2017;15(12):5050)   |
| Current MRL applications on intended uses                                   | EFSA-Q-2010-00199 (EMS)<br>All commodities<br>Status: Reasoned opinion available<br>EFSA Journal 2017;15(12):5050   |

## 7.2.1 Stability of Residues (KCA 6.1)

### 7.2.1.1 Stability of residues during storage of samples

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-2: Summary of stability data achieved at  $\leq -18^{\circ}\text{C}$  (unless stated otherwise)**

| Matrix                        | Characteristics of the matrix | Acceptable Maximum Storage duration | Reference                            |
|-------------------------------|-------------------------------|-------------------------------------|--------------------------------------|
| Data relied on in EU          |                               |                                     |                                      |
| <b>Plant products</b>         |                               |                                     |                                      |
| Soya beans                    | High oil content              | > 2 years                           | EFSA,2008 (Tribolet, R., 1996)       |
| Rapeseed                      | High oil content              | > 2 years                           | EFSA,2008 (Tribolet, R., 1996)       |
| Tomato, Sugar beet (leaves)   | High water content            | > 2 years                           | EFSA,2008 (Tribolet, R., 1996)       |
| Sugar beet (leaves and roots) | High starch content           | > 2 years                           | EFSA,2008 (Tribolet, R., 1998)       |
| Carrots                       | High starch content           | > 2 years                           | EFSA,2008 (Tribolet, R., 1997)       |
| <b>Quizalofop</b>             |                               |                                     |                                      |
| Pea whole plant               | High water content            | At least 12 months                  | G. Rousseau, 2013, Report No.: 22853 |
| Pea dry seed                  | High protein content          |                                     |                                      |
| Oli seed rape grain           | High oil content              |                                     |                                      |
| Grape                         | High acid content             |                                     |                                      |

#### Conclusion on stability of residues during storage

The storage stability study showed the residue of propaquizafop and quizalofop to be stable under deep freeze storage conditions for at least 2 years in water, starch and oil plant matrices (EFSA 2008), covering the residue trials conducted to support intended uses.

In new study, storage stability of residues of Quizalofop was demonstrated for a period of 12 months at  $-18^{\circ}\text{C}$  in high water content commodities (pea whole plant), high protein content commodities (pea dry seed), high oil content commodities (oil seed rape grain) and in high acid content (grape).

Additionally, uses requested for ALIVE are identical to those of the reference product AGIL S 100 EC registered in Poland for more than 10 years and, therefore, not in a scope of data protection anymore.

### 7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

No data was submitted and required at EU level during the EU Review of Propaquizafop.

## 7.2.2 Nature of residues in plants, livestock and processed commodities

### 7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

#### Available data

**Table 7.2-3: Summary of plant metabolism studies**

| Crop Group                | Crop        | Label position  | Application and sampling details |                   |        |                |         | Reference   |
|---------------------------|-------------|---|----------------------------------|-------------------|--------|----------------|---------|---|
|                           |             |   | Method, F or G (a)               | Rate (kg a.s./ha) | No     | Sampling (DAT) | Remarks |   |
| <b>EU data</b>            |             |   |                                  |                   |        |                |         |   |
| Leafy vegetables          | lettuce     | Hydroquinone and chlorophenyl-labelled propaquizafop. | Foliar, F                        | 0.200             | 1      | 77             | -       | EFSA, 2008 (Diehl M., 2003)                         |
|                           |             | Hydroquinone-labelled propaquizafop                   | Foliar, F                        | 1                 | 1      | 77             | -       |   |
| Root and tuber vegetables | Sugar beets | Quinoxaline-labelled propaquizafop                    | Foliar, G                        | 0.200             | 2      | 98-114 DALA    | -       | EFSA, 2008 (Rümbeli, R., 1992)                      |
| Pulses and oilseeds       | Cotton      | Quinoxaline-labelled propaquizafop                    | Foliar, G                        | 0.180             | 1      | 0, 6, 12, 22   | -       | EFSA 2008 (Dieterle, P., 1988a; Dieterle, P., 1990) |
|                           |             | Hydroquinone and chlorophenyl-labelled propaquizafop. | Onto leaf                        | 0.180             | 1      | 0-51           | -       |   |
|                           |             | Hydroquinone-labelled propaquizafop                   | Foliar                           | 214 g a.s./ha     | 1      | 0, 15, 22 DALA | -       |   |
|                           | Soya beans  | Hydroquinone-labelled propaquizafop                   | Foliar                           | 0.100             | 1      | 0 to 28        | -       | EFSA 2008 (Pryde A. et al., 1987; Plüss A. 1989)    |
|                           |             |   | Onto leaf                        | 0.190             | 1      | 0, 7, 14       | -       |   |
|                           |             | Foliar  | 0.268 – 0.298                    | 2                 | 66, 70 | -              |         |   |
|                           |             | Quinoxaline-labelled propaquizafop                    | Foliar                           | 0.200             | 1      | 8, 15          | -       |   |
| Foliar                    | 0.280       |   | 2                                | 66, 100 DALA      | -      |                |         |   |

#### Summary of plant metabolism studies reported in the EU

The metabolism of propaquizafop has been investigated during first peer review in cotton, soybean, lettuce and sugar beet, representing three groups of crops; oilseed/pulse crops, leafy crops and root/tuber crops. According to OECD 501 guideline as results of these three metabolism groups studies indicate comparable metabolic route, extrapolation is also applicable to fruits, and no additional study is needed.

Studies were performed using <sup>14</sup>C-propaquizafop either labelled on the phenyl or the quinoxaline moiety

and with application rates representative of the supported uses (103 to 298 g a.s./ha). The metabolism proceeds primarily by the hydrolysis of the ester link to yield quizalofop followed by loss of the propionyl moiety leading to the quizalofop-phenol metabolite, these metabolites being also observed as conjugated in soya and cotton. Further metabolism occurs by hydroxylation of the quinoxaline moiety giving the hydroxy-quizalofop and hydroxy-quizalofop-phenol metabolites.

The metabolite pattern was dominated by quizalofop, which generally represents the major constituent of the residue, accounting for 5% to 35% of the TRR at harvest, the parent compound being mainly observed in significant proportions in immature plant samples collected within 15 days following the application. However, propaquizafop was also present in mature soybean seeds and sugar beets roots in similar amount to quizalofop accounting for c.a. 7% of the TRR (EFSA 2008).

### Conclusion on metabolism in primary crops

According to the results from all available metabolism studies in primary crops, once quizalofop is formed after hydrolysis of the ester link, the metabolic pathways of the different esters in plants are similar.

Based on the above considerations, it can be concluded that an overall residue definition for monitoring and risk assessment covering all ester variants of quizalofop can be proposed as the sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers) (EFSA 2017).

### 7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

#### Available data

**Table 7.2-4: Summary of metabolism studies in rotational crops**

| Crop group                       | Crop       | Label position                     | Application and sampling details |                   |                          |                            |         | Reference                  |
|----------------------------------|------------|------------------------------------|----------------------------------|-------------------|--------------------------|----------------------------|---------|----------------------------|
|                                  |            |                                    | Method, F or G *                 | Rate (kg a.s./ha) | Sowing intervals (DAT)** | Harvest Intervals (DAT)*** | Remarks |                            |
| <b>EU data</b>                   |            |                                    |                                  |                   |                          |                            |         |                            |
| <b>Leafy vegetables</b>          | Spinach    | Quinoxaline-labelled propaquizafop | Foliar, G                        | 0.280             | 30, 120, 270             | 85, 183, 329               | -       | EFSA, 2008 (Plüs N., 1988) |
| <b>Root and tuber vegetables</b> | Sugar beet | Quinoxaline-labelled propaquizafop | Foliar, G                        | 0.280             | 30, 120, 270             | 209, 308, 431              | -       |                            |
| <b>Cereals</b>                   | Wheat      | Quinoxaline-labelled propaquizafop | Foliar, G                        | 0.280             | 30, 120, 270             | 285, 383, 476              | -       |                            |

\* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

\*\* Days after second treatment of soya beans

\*\*\* Days after first treatment

### Summary of plant metabolism studies reported in the EU

The metabolism of propaquizafop in rotational crops was investigated in sugar beet, spinach and wheat sown at plant-back intervals (PBIs) of 30, 120 and 270 days after harvest of soybeans treated twice with

quinoxaline moiety of propaquizafop at 280 g/ha (2.8N compared to the maximum dose rate authorised for propaquizafop) (EFSA 2008). The concentrations of radioactive residues in all succeeding crops ranged from 0.004 mg eq/kg in sugar beet roots and foliage sown 270 days after the second treatment to 0.167 mg eq/kg in straw from spring wheat sown 30 days after the second treatment. The metabolic pathway in rotational crops was found to be similar to the primary crop metabolism. Parent material was extensively broken down into numerous metabolites with the majority of the residue being incorporated into the lignin fraction. At all PBIs, the radioactive residues were mainly composed of quizalofop-P (up to 25% of TRR in spinach corresponding to 0.01 mg eq/kg), CQOP and their hydroxy metabolites (up to 7.6% TRR corresponding to 0.003 mg eq/kg).

### Conclusion on metabolism in rotational crops

Propaquizafop was not observed in the plant parts investigated and the detected metabolites (quizalofop, quizalofop-phenol and their hydroxy derivatives) have also been identified in the primary crop studies, suggesting a similar metabolic pathway in both primary and rotational crops. It was concluded that no significant residues of propaquizafop or its metabolites are expected in rotational crops (EFSA 2008).

### 7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

#### Available data

No new data submitted in the framework of this application. Moreover, based on EFSA conclusions (EFSA, 2008), considering the low residue levels detected in the raw agricultural products (<0.05 mg/kg), the behaviour of the residues in processing commodities was not investigated and was considered not required.

#### Conclusion on nature of residues in processed commodities

Based on the representative uses supported in the framework of the peer review, the submission of a standard hydrolysis study was concluded to be not required (EFSA, 2008).

### 7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

**Table 7.2-5: Summary of the nature of residues in commodities of plant origin**

| <b>Endpoints</b>  |  |
|---|--|
| Plant groups covered  | Root and tuber vegetables (sugar beets...)<br>Leafy vegetables (lettuce..)<br>Pulses and oilseeds (cotton, soya beans..)<br>Fruits (citrus, olive..) |
| Rotational crops covered  | Root and tuber vegetables (sugar beets)<br>Leafy vegetables (spinach)<br>Cereals (spring wheat)  |
| Metabolism in rotational crops similar to metabolism in primary crops?          | Yes  |
| Processed commodities   | Not applicable   |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Yes  |
| Plant residue definition for monitoring   | Propaquizafop<br>Provisional:<br>Sum propaquizafop and quizalofop expressed as quizalofop (sum of  |

|  |   |
|--|---|
|  | isomers) (EFSA, 2008)<br>Sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers) (EFSA, 2017)<br>Reg. (EU) 2019/973: Quizalofop (sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers)) |
| Plant residue definition for risk assessment | Propaquizafop<br>Provisional:<br>Sum propaquizafop and quizalofop expressed as quizalofop (sum of isomers) (EFSA, 2008)<br>Sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers) (EFSA, 2017)   |
| Conversion factor from enforcement to RA     | Not applicable  |

### 7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-6: Summary of animal metabolism studies**

| Group                      | Species | Label position                                       | No of animal | Application details |                 | Sample details   |                     | Reference  |
|----------------------------|---------|--|--------------|---------------------|-----------------|------------------|---------------------|--|
|                            |         |  |              | Rate (mg/kg bw/d)   | Duration (days) | Commodity        | Time of sampling    |  |
| <b>EU data</b>             |         |  |              |                     |                 |                  |                     |  |
| <b>Lactating ruminants</b> | Goat    | Hydroquinone-labelled propaquizafop                  | 1            | 0.8                 | 10              | Milk             | Twice daily         | DAR,2005 (Ellgehausen H., 1985a,b; Dieterle P. 1988b; Cameron B.D. and Dunsire J.P., 1989) |
|                            |         |  |              |                     |                 | Urine and faeces | daily               |  |
|                            |         |  |              |                     |                 | Tissues          | 24h after last dose |  |
|                            |         | Quinoxaline-labelled propaquizafop                   | 1            | 0.9                 | 10              | Milk             | Twice daily         |  |
|                            |         |  |              |                     |                 | Urine and faeces | daily               |  |
|                            |         |  |              |                     |                 | Tissues          | 24h after last dose |  |
| <b>Laying poultry</b>      | Hens    | hydroquinone- and quinoxaline-labelled propaquizafop | 10           | 50                  | 6               | Eggs             | daily               |  |
|                            |         |  |              |                     |                 | Excreta          | daily               |  |
|                            |         |  |              |                     |                 | Tissues          | At sacrifice        |  |

#### Summary of animal metabolism studies reported in the EU

During the peer review, the metabolism of propaquizafop in livestock has been investigated with hydroquinone- and quinoxaline-labelled propaquizafop in lactating goats and in laying hens (DAR, 2005). In the goat study, the animals were dosed during 10 consecutive days with an exaggerate dose of 0.8–0.9 mg/kg bw per day (7N compared to maximum dietary burden for sheep). In the hens study, the animals

were dosed during six consecutive days with an exaggerate dose of 50 mg/kg bw per day (1389N compared to maximum dietary burden for poultry).

These metabolism studies show that propaquizafop is rapidly metabolised and excreted by livestock. Radioactivity in milk reached a plateau level (0.95 mg/kg) at 3–4 days. Residues in ruminant tissues were generally low, with the highest being in the kidney (0.84 mg/kg) and in fat (0.275 mg/kg). The major component of the residues in liver, kidney and muscle was quizalofop-P. Further metabolism of quizalofop-P by hydroxylation to hydroxy-quizalofop-P and dealkylation to the metabolite CQOP was evident but these metabolites did not comprise significant portions of the total residue.

In hens, the highest residues were observed in liver and kidney (76 mg/kg and 75 mg/kg, respectively). Quizalofop-P was the only radioactive product found in tissues and eggs, with the exception of the metabolite CQOPOH that was found in one of the two liver samples analysed (25 mg/kg).

### Conclusion on metabolism in livestock

On the basis on these studies on propaquizafop, it is concluded that, since these studies demonstrate that propaquizafop is rapidly metabolised to quizalofop, the results from the metabolism studies performed with the other ester variants may be considered representative of the metabolism of propaquizafop as well (DAR, 2005).

Based on the results of all metabolism studies available for the three ester variants, the residue definition for enforcement and risk assessment in all animal commodities, is proposed as the sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers) (EFSA 2017).

### 7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

**Table 7.2-7: Summary on the nature of residues in commodities of animal origin**

|   | <b>Endpoints</b>  |
|---|---|
| Animals covered                               | Lactating goats   |
|   | Laying hens   |
| Time needed to reach a plateau concentration  | Plateau level (0.46 – 0.95 mg/kg) at 3–4 days in milk (Study No. 047880, H. Ellgehausen, 1985a from DAR)  |
|   | Plateau level (0.42 – 0.71 mg/kg) at 3-4 days in milk (Study No. 047891, H. Ellgehausen, 1985b from DAR)  |
| Animal residue definition for monitoring      | Propaquizafop<br>Provisional EFSA, 2017):<br>For poultry liver and kidney: sum of quizalofop, its salts, its esters (including propaquizafop), its conjugates, its pentanoic acid metabolite and its conjugates, expressed as quizalofop (any ratio of constituent isomers)<br>For all other commodities of animal origin including milks and eggs: sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers) |
| Animal residue definition for risk assessment | Propaquizafop<br>Provisional (EFSA, 2017):<br>For poultry liver and kidney: sum of quizalofop, its salts, its esters (including propaquizafop), its conjugates, its pentanoic acid metabolite and its conjugates, expressed as quizalofop (any ratio of constituent isomers)<br>For all other commodities of animal origin including milks and eggs: sum of quizalofop, its salts, its esters (including propaquizafop) and its   |

|  |  |
|--|--|
|  | conjugates, expressed as quizalofop (any ratio of constituent isomers) |
| Conversion factor                      | Not applicable   |
| Metabolism in rat and ruminant similar | Yes  |
| Fat soluble residue                    | No   |

### 7.2.3 Magnitude of residues in plants (KCA 6.3)

#### 7.2.3.1 Summary of European data and new data supporting the intended uses

No new data are submitted in the framework of this application.

**Table 7.2-8: Summary of EU reported and new data supporting the intended uses of Propaquizafop 10% EC and conformity to existing MRL**

| Commodity    | Source   | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation<br>GAP<br>Residue levels (mg/kg)<br>E = according to enforcement residue definition<br>RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg) * | MRL compliance |
|--------------|--|---|--|--------------|------------|---------------------------------------|--------------------------|----------------|
| Strawberries | EFSA 2017  | NEU                                       | GAP on which EU a.s. assessment is based: 1x 0.15 kg as/ha, BBCH 39, PHI 35<br><br>3<0.01, 1x<0.02   | 0.01         | 0.02       |                                       | 0.02                     |                |
|              | Unprotected data RR Agil 100 EC (Registration No. R-208/2014)                  | NEU                                       | Trials GAP: 1 x 0.2 kg a.s./ha, PHI: 49-171d<br><br>3<0.01, 1x<0.02  | 0.01         | 0.02       | 0.02                                  | 0.02                     | Yes            |
| Potato       | EFSA 2017<br><br>Unprotected data RR Agil 100 EC (Registration No. R-208/2014) | NEU                                       | GAP on which EU a.s. assessment is based: 1x 0.15 kg as/ha, PHI 30<br><br>2x<0.02, 4x<0.01   |              |            |                                       |                          |                |

|  |   |     |  |               |      |       |     |     |
|--|---|-----|--|---------------|------|-------|-----|-----|
|  |   |     |  |               |      |       |     |     |
|  | EFSA 2017   | SEU | 6x<0.02, 4x<0.01   |               |      |       |     |     |
|  | Unprotected data RR Agil 100 EC (Registration No. R-208/2014) | NEU | Trials GAP: 1 x 0.2 kg a.s./ha, PHI: 49-171d<br>2<0.01, 2x<0.02  |               |      |       |     |     |
|  | Overall supporting data for cGAP                              |     | 8x<0.02, 8x<0.01<br>6<0.01, 4x<0.02  | 0.01          | 0.02 | 0.02  | 0.1 | Yes |
| Carrot → extrapolated to parsley, parsnip, swede, Jerusalem artichokes, horseradish, black radish, Japanese radish, radish, salsify, turnips | EFSA 2017   | NEU | GAP on which EU a.s. assessment is based: 1x 0.15 kg as/ha, BBCH 29, PHI 30<br>3 x < 0.01; 0.012; 0.016; 0.017; 2 x < 0.02; 0.025; 0.061   |               |      |       |     |     |
|  | Unprotected data RR Agil 100 EC (Registration No. R-208/2014) |     |  |               |      |       |     |     |
|  | EFSA 2017   | SEU | <0.01; <0.01; 0.017; 0.017; <0.02; <0.02; <0.02; <0.02   |               |      |       |     |     |
|  | Overall supporting data for cGAP                              |     | 3 x < 0.01; 0.012; 0.016; 0.017; 2 x < 0.02; 0.025; 0.061, < 0.01; < 0.01; 0.017; 0.017; < 0.02; < 0.02; < 0.02; < 0.02<br>3 x < 0.01; 0.012; 0.016; 0.017; 2 x < 0.02; 0.025; 0.061 | 0.02<br>0.017 | 0.06 | 0.081 | 0.2 | Yes |
| Onion → extrapolated to garlic, shallot  | EFSA 2017   | NEU | GAP on which EU a.s. assessment is based: 1x 0.2 kg as/ha, PHI 30<br>7 x < 0.01; 2 x < 0.02;   |               |      |       |     |     |
|  | Unprotected data RR Agil 100 EC (Registration                 |     |  |               |      |       |     |     |

|   |  |     |  |      |               |       |      |     |
|---|--|-----|--|------|---------------|-------|------|-----|
|   | No. R-208/2014)  |     | 0.025<br><br>8 x <0.01, 1 x <0.02, 0.025   |      |               |       |      |     |
|   | EFSA 2017  | SEU | Onions: 4 x <0.01<br>Garlic: 1x<0.02   |      |               |       |      |     |
|   | Overall supporting data for cGAP   |     | 7 x <0.01; 2 x <0.02; 0.025, 4 x <0.01, 1x<0.02<br><br>8 x <0.01, 1 x <0.02, 0.025                             | 0.01 | 0.03<br>0.025 | 0.034 | 0.04 | Yes |
| Sugar beet → extrapolated to fodder beet, beet-root, root celery, swede | EFSA 2017 / DAR 2005 (Mostert, 1992a,b,c; Schwager, 1991; Adams, 1996a,b, 1997a; Freeman 1991a; Hänni 1987a, 1989a,b)<br><br>Unprotected data RR Agil 100 EC (Registration No. R-208/2014) | NEU | GAP on which EU a.s. assessment is based: 1x 0.15-0.2 kg as/ha, BBCH 37, PHI 91<br><br>15 x < 0.02; 7 x < 0.05 |      |               |       |      |     |
|   | EFSA 2017  | SEU | 2 x <0.02  |      |               |       |      |     |
|   | Overall supporting data for cGAP   |     | 15 x < 0.02; 7 x < 0.05, 2 x <0.02   | 0.02 | 0.05          | 0.05  | 0.06 | Yes |
| Beans, Peas → extrapolated to   | EFSA 2017  | NEU | GAP on which EU a.s. assessment is based: 1x 0.15-0.2 kg as/ha, BBCH 39, PHI 40-45                             |      |               |       |      |     |

|   |   |     |  |               |               |       |     |     |
|---|---|-----|--|---------------|---------------|-------|-----|-----|
| lupines, field<br>peas, field<br>beans  |   |     | 4 x < 0.01   |               |               |       |     |     |
|   | EFSA 2017   | SEU | <0.006; 4 x < 0.01   |               |               |       |     |     |
|   | Unprotected data RR Agil 100 EC (Registration No. R-208/2014)           | NEU | Peas<br>Trials GAP: 1 x 0.2 kg a.s./ha, Phi 38 d<br><br>2 x < 0.01<br><br>Beans<br>3 x < 0.02, < 0.05  |               |               |       |     |     |
|   | Overall supporting data for cGAP  |     | 4 x < 0.01, 3 x < 0.02, < 0.05 < 0.006; 4 x < 0.01   | 0.01          | 0.05          | 0.05  | 0.2 | Yes |
| Head cabbages → extrapolated to broccoli, brussels sprout extrapolated to brussels sprout | EFSA 2017 Unprotected data RR Agil 100 EC (Registration No. R-208/2014) | NEU | GAP on which EU a.s. assessment is based: 1x 0.15 kg as/ha, BBCH 29, PHI 30<br><br>4 x < 0.01; 0.012; 0.013; 0.014; 0.017; 0.018; 0.020; 0.023; 0.039; 0.081<br><br>0.01, 0.016, 0.018, 0.023, 0.024, 0.027, 0.03, 0.052, 0.108            |               |               |       |     |     |
|   | EFSA 2017   | SEU | 0.018; 2 x 0.027; 0.112  |               |               |       |     |     |
|   | Overall supporting data for cGAP  |     | 4 x < 0.01; 0.012; 0.013; 0.014; 0.017; 0.018; 0.020; 0.023; 0.039; 0.081, 0.018; 2 x 0.027; 0.112<br><br>4 x < 0.01, 0.01, 0.012, 0.013, 0.014, 0.016, 0.017, 2 x 0.018, 0.020, 2 x 0.023, 0.024, 0.027, 0.03, 0.039, 0.052, 0.081, 0.108 | 0.03<br>0.018 | 0.11<br>0.108 | 0.125 | 0.6 | Yes |
| Rapeseeds → extrapolated to poppy seed, flax,   | EFSA 2017 / DAR 2005 (Adams 1997b,c;                                    | NEU | GAP on which EU a.s. assessment is based: 1x 0.2 kg as/ha, BBH 31, PHI 90<br><br>5 x < 0.01; 0.01; 0.02;   |               |               |       |     |     |

|          |   |     |   |      |      |       |     |     |
|----------|---|-----|---|------|------|-------|-----|-----|
| linseeds | Freeman<br>1990)<br>Unprotected<br>data RR Agil<br>100 EC<br>(Registration<br>No. R-<br>208/2014) |     | 0.014; 0.015; 0.017; 0.019;<br>< 0.02; 0.022; 0.03; < 0.05;<br>0.062 0.03, 0.02, 6x<0.05                                |      |      |       |     |     |
|          | EFSA 2017   | SEU | 4 x < 0.01  |      |      |       |     |     |
|          | Overall<br>supporting<br>data for cGAP  |     | 5 < 0.01; 0.01; 0.02; 0.014; 0.015; 0.017; 0.019; < 0.02;<br>0.022; 0.03; < 0.05; 0.062 0.03, 0.02, 6x<0.05, 4 x < 0.01 | 0.02 | 0.06 | 0.099 | 2.0 | Yes |

\* Source of EU MRL: Reg. (EU) 2019/973

### 7.2.3.2 Conclusion on the magnitude of residues in plants

For all necessary data to support this application reference is made to the unprotected data from AGIL S 100 EC authorization (Reg. No. R-208/2014).

Uses 1 to 27 and from 29 to 49 requested for ALIVE are identical to those of the reference product AGIL S 100 EC registered in Poland for more than 10 years and, therefore, not in a scope of data protection anymore. Reference is also made to new or additional Annex III data supporting this product under the re-authorization program shall not be protected, as provided in Article 43 of SANC0/12576/2012-rev.1.1 of 1 February 2013.

~~According to the available data, the intended uses are considered acceptable.~~

~~The data submitted in Table 7.2-9 show that no exceedance of the MRL will occur.~~

### 7.2.4 Magnitude of residues in livestock

#### 7.2.4.1 Dietary burden calculation

Animal metabolism studies presented during the Annex I inclusion process of Propaquizafop demonstrate that Propaquizafop is rapidly metabolised and excreted from the body and therefore it is unlikely that there will be significant accumulation of residues in animal tissues and animal products. Moreover, on the basis of the calculations performed in the DAR, dietary burden calculations show that total Propaquizafop residues in the total diet as received by cattle do not exceed 0.1 mg/kg using either diet, which was confirmed by EFSA conclusions (EFSA Scientific Report (2008) 204, 1-171).

However, EFSA proposed a new residue definition for animal commodities defined as “sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers)”. Therefore, EFSA performed new calculations taking into account the following assumptions: “Quizalofop variants and propaquizafop are authorised for use on several crops that might be fed to livestock. For each feed item, risk assessment values were compared and the most critical values selected for the exposure calculation. This approach is based on the assumption that the three ester variants are not used together on the same crop.”

These calculations are presented below for intended uses for ALIVE.

**Table 7.2-9: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)**

| Feed Commodity  | Median dietary burden |   | Maximum dietary burden |   |
|---|-----------------------|---|------------------------|---|
|   | Input value (mg/kg)   | Comment                                 | Input value (mg/kg)    | Comment                                 |
| Risk assessment residue definition: sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers) |                       |   |                        |   |
| Beet, mangel (roots)  | 0.04                  | STMR (quizalofop-P-tefuryl) (tentative) | 0.05                   | STMR (quizalofop-P-tefuryl) (tentative) |
| Beet, mangel (tops)   | 0.18                  | STMR (quizalofop-P-tefuryl) (tentative) | 0.25                   | STMR (quizalofop-P-tefuryl) (tentative) |

| Feed Commodity                          | Median dietary burden |   | Maximum dietary burden |   |
|---|-----------------------|---|------------------------|---|
|   | Input value (mg/kg)   | Comment   | Input value (mg/kg)    | Comment   |
| Beet, sugar (tops)                      | 0.18                  | STMR<br>(quizalofop-P-tefuryl)<br>(tentative)                     | 0.25                   | STMR<br>(quizalofop-P-tefuryl)<br>(tentative)                     |
| Cabbage, heads                          | 0.05                  | STMR<br>(quizalofop-P-ethyl)<br>(tentative)                       | 0.20                   | HR<br>(quizalofop-P-ethyl)<br>(tentative)                         |
| Carrot, culls                           | 0.06                  | STMR<br>(quizalofop-P-tefuryl)<br>(tentative)                     | 0.10                   | HR<br>(quizalofop-P-tefuryl)<br>(tentative)                       |
| Potato, culls                           | 0.04                  | STMR<br>(quizalofop-P-tefuryl)<br>(tentative)                     | 0.08                   | HR<br>(quizalofop-P-tefuryl)<br>(tentative)                       |
| Beans, dry<br>Cowpeas, dry<br>Peas, dry | 0.07                  | STMR<br>(quizalofop-P-ethyl)<br>(tentative)                       | 0.07                   | HR<br>(quizalofop-P-tefuryl)<br>(tentative)                       |
| Sugar beet, dried pulp                  | 0.72                  | STMR x 18 <sup>(a)</sup><br>(quizalofop-P-tefuryl)<br>(tentative) | 0.72                   | STMR x 18 <sup>(a)</sup><br>(quizalofop-P-tefuryl)<br>(tentative) |
| Sugar beet, ensiled pulp                | 0.12                  | STMR x 3 <sup>(a)</sup><br>(quizalofop-P-tefuryl)<br>(tentative)  | 0.12                   | STMR x 3 <sup>(a)</sup><br>(quizalofop-P-tefuryl)<br>(tentative)  |
| Sugar beet, molasses                    | 1.12                  | STMR x 28 <sup>(a)</sup><br>(quizalofop-P-tefuryl)<br>(tentative) | 1.12                   | STMR x 28 <sup>(a)</sup><br>(quizalofop-P-tefuryl)<br>(tentative) |
| Rapeseed (canola), meal                 | 0.42                  | STMR x PF (1.81)<br>(quizalofop-P-tefuryl)<br>(tentative)         | 0.42                   | STMR x PF (1.81)<br>(quizalofop-P-tefuryl)<br>(tentative)         |
| Flaxseed/Linseed, meal                  | 0.2                   | STMR x 2 <sup>(a)</sup><br>(quizalofop-P-ethyl)<br>(tentative)    | 0.2                    | STMR x 2 <sup>(a)</sup><br>(quizalofop-P-ethyl)<br>(tentative)    |
| Potato process waste                    | 0.80                  | STMR x 20 <sup>(a)</sup><br>(quizalofop-P-tefuryl)<br>(tentative) | 0.80                   | STMR x 20 <sup>(a)</sup><br>(quizalofop-P-tefuryl)<br>(tentative) |
| Potato dried pulp                       | 1.52                  | STMR x 38 <sup>(a)</sup><br>(quizalofop-P-tefuryl)<br>(tentative) | 1.52                   | STMR x 38 <sup>(a)</sup><br>(quizalofop-P-tefuryl)<br>(tentative) |
| Rape meal                               | 0.42                  | STMR x PF (1.81)<br>(quizalofop-P-tefuryl)<br>(tentative)         | 0.42                   | STMR x PF (1.81)<br>(quizalofop-P-tefuryl)<br>(tentative)         |

**Table 7.2-10: Results of the dietary burden calculation**

| Animal species  | Median dietary burden (mg/kg bw/d) | Maximum dietary burden (mg/kg bw/d) | Highest contributing commodity | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
|---|------------------------------------|-------------------------------------|--------------------------------|-------------------------------|------------------------|
| Sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers) |                                    |                                     |                                |                               |                        |
| Beef cattle (all diets)*  | 0.092                              | 0.109                               | Potato, process waste          | 3.55                          | Y                      |
| Dairy cattle*   | 0.092                              | 0.109                               | Potato, process waste          | 1.14                          | Y                      |
| Ram/ewe   | 0.103                              | 0.124                               | Potato, process waste          | 3.71                          | Y                      |
| Finishing swine (all diets)*  | 0.039                              | 0.044                               | Potato, process waste          | 1.90                          | Y                      |
| Poultry (all diets)   | 0.029                              | 0.036                               | Potato, dried pulp             | 0.53                          | Y                      |

\* These categories correspond to those (formerly) assessed at EU level.

Applicants provides updated results of dietary burden calculation according to the current EU requirements.

**Table 7.2-11: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)**

| Feed Commodity  | Median dietary burden |                                     | Maximum dietary burden |                                   |
|---|-----------------------|-------------------------------------|------------------------|-----------------------------------|
|   | Input value (mg/kg)   | Comment                             | Input value (mg/kg)    | Comment                           |
| Risk assessment residue definition: sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers) |                       |                                     |                        |                                   |
| Alfalfa, forage   | 0.02                  | STMR (EFSA, 2017)                   | 0.51                   | HR (EFSA, 2017)                   |
| Alfalfa, hay  | 0.05                  | STMR (0.02) * PF (2.5) (EFSA, 2017) | 1.28                   | HR (0.51) * PF (2.5) (EFSA, 2017) |
| Alfalfa, meal   | 0.05                  | STMR (0.02) * PF (2.5) (EFSA, 2017) | 1.28                   | HR (0.51) * PF (2.5) (EFSA, 2017) |
| Alfalfa, silage   | 0.02                  | STMR (0.02) * PF (1.1) (EFSA, 2017) | 0.56                   | HR (0.51) * PF (1.1) (EFSA, 2017) |
| Beet, sugar tops  | 0.18                  | STMR (EFSA, 2017)                   | 0.25                   | HR (EFSA, 2017)                   |
| Cabbage, heads leaves   | 0.05                  | STMR (EFSA, 2017)                   | 0.20                   | HR (EFSA, 2017)                   |
| Clover forage   | 0.02                  | STMR (EFSA, 2017)                   | 0.51                   | HR (EFSA, 2017)                   |
| Clover hay  | 0.06                  | STMR (0.02) * PF (3) (EFSA, 2017)   | 1.53                   | HR (0.51) * PF (3) (EFSA, 2017)   |

| Feed Commodity           | Median dietary burden |                                     | Maximum dietary burden |                                     |
|--------------------------|-----------------------|-------------------------------------|------------------------|-------------------------------------|
|                          | Input value (mg/kg)   | Comment                             | Input value (mg/kg)    | Comment                             |
| Clover silage            | 0.02                  | STMR (EFSA, 2017)                   | 0.51                   | HR (EFSA, 2017)                     |
| Rice straw               | 0.02                  | STMR (EFSA, 2017)                   | 0.02                   | HR (EFSA, 2017)                     |
| Turnip tops              | 0.03                  | STMR (EFSA, 2017)                   | 0.40                   | HR (EFSA, 2017)                     |
| Vetch forage             | 0.02                  | STMR (EFSA, 2017)                   | 0.26                   | HR (EFSA, 2017)                     |
| Vetch hay                | 0.06                  | STMR (0.02) * PF (2.8) (EFSA, 2017) | 0.73                   | HR (0.26) * PF (2.8) (EFSA, 2017)   |
| Carrot culls             | 0.06                  | STMR (EFSA, 2017)                   | 0.10                   | HR (EFSA, 2017)                     |
| Potato culls             | 0.04                  | STMR (EFSA, 2017)                   | 0.08                   | HR (EFSA, 2017)                     |
| Swede roots              | 0.04                  | STMR (EFSA, 2017)                   | 0.05                   | HR (EFSA, 2017)                     |
| Turnip roots             | 0.04                  | STMR (EFSA, 2017)                   | 0.05                   | HR (EFSA, 2017)                     |
| Bean seed dry            | 0.07                  | STMR (EFSA, 2017)                   | 0.07                   | STMR (EFSA, 2017)                   |
| Cotton undelinted seed   | 0.04                  | STMR (EFSA, 2017)                   | 0.04                   | STMR (EFSA, 2017)                   |
| Cowpea seed              | 0.07                  | STMR (EFSA, 2017)                   | 0.07                   | STMR (EFSA, 2017)                   |
| Pea seed                 | 0.07                  | STMR (EFSA, 2017)                   | 0.07                   | STMR (EFSA, 2017)                   |
| Soybean seed             | 0.04                  | STMR (EFSA, 2017)                   | 0.04                   | STMR (EFSA, 2017)                   |
| Apple pomace wet         | 0.10                  | STMR (0.02) * PF (5) (EFSA, 2017)   | 0.10                   | STMR (0.02) * PF (5) (EFSA, 2017)   |
| Beet, sugar dried pulp   | 0.72                  | STMR (0.04) * PF (18) (EFSA, 2017)  | 0.72                   | STMR (0.04) * PF (18) (EFSA, 2017)  |
| Beet, sugar ensiled pulp | 0.12                  | STMR (0.04) * PF (3) (EFSA, 2017)   | 0.12                   | STMR (0.04) * PF (3) (EFSA, 2017)   |
| Canola meal              | 0.46                  | STMR (0.23) * PF (2) (EFSA, 2017)   | 0.46                   | STMR (0.23) * PF (2) (EFSA, 2017)   |
| Cotton meal              | 0.05                  | STMR (0.04) * PF (1.3) (EFSA, 2017) | 0.05                   | STMR (0.04) * PF (1.3) (EFSA, 2017) |
| Flaxseed/Linseed meal    | 0.20                  | STMR (0.10) * PF (2) (EFSA, 2017)   | 0.20                   | STMR (0.10) * PF (2) (EFSA, 2017)   |

| Feed Commodity       | Median dietary burden |  | Maximum dietary burden |  |
|----------------------|-----------------------|--|------------------------|--|
|                      | Input value (mg/kg)   | Comment                                | Input value (mg/kg)    | Comment                                |
| Potato process waste | 0.80                  | STMR (0.04) * PF (20)<br>(EFSA, 2017)  | 0.80                   | STMR (0.04) * PF (20)<br>(EFSA, 2017)  |
| Potato dried pulp    | 1.52                  | STMR (0.04) * PF (38)<br>(EFSA, 2017)  | 1.52                   | STMR (0.04) * PF (38)<br>(EFSA, 2017)  |
| Rape meal            | 0.46                  | STMR (0.23) * PF (2)<br>(EFSA, 2017)   | 0.46                   | STMR (0.23) * PF (2)<br>(EFSA, 2017)   |
| Rice bran/pollard    | 0.50                  | STMR (0.05) * PF (10)<br>(EFSA, 2017)  | 0.50                   | STMR (0.05) * PF (10)<br>(EFSA, 2017)  |
| Soybean meal         | 0.05                  | STMR (0.05) * PF (1.3)<br>(EFSA, 2017) | 0.05                   | STMR (0.05) * PF (1.3)<br>(EFSA, 2017) |
| Soybean hulls        | 0.52                  | STMR (0.05) * PF (13)<br>(EFSA, 2017)  | 0.52                   | STMR (0.05) * PF (13)<br>(EFSA, 2017)  |
| Sunflower meal       | 0.23                  | STMR (0.12) * PF (2)<br>(EFSA, 2017)   | 0.23                   | STMR (0.12) * PF (2)<br>(EFSA, 2017)   |

**Table 7.2-12: Results of the dietary burden calculation**

| Animal species  | Median dietary burden (mg/kg bw/d) | Maximum dietary burden (mg/kg bw/d) | Highest contributing commodity | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
|---|------------------------------------|-------------------------------------|--------------------------------|-------------------------------|------------------------|
| Sum of quizalofop, its salts, its esters (including propaquizafop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers) |                                    |                                     |                                |                               |                        |
| Cattle (all diets)  | 0.090                              | 0.109                               | Potato, process waste          | 3.54                          | Y                      |
| Cattle (dairy only)   | 0.090                              | 0.109                               | Potato, process waste          | 2.82                          | Y                      |
| Sheep (all diets)   | 0.098                              | 0.123                               | Potato, process waste          | 3.70                          | Y                      |
| Sheep (ewe only)  | 0.098                              | 0.123                               | Potato, process waste          | 3.70                          | Y                      |
| Swine (all diets)   | 0.037                              | 0.044                               | Potato, process waste          | 1.90                          | Y                      |
| Poultry (all diets)   | 0.029                              | 0.036                               | Potato, dried pulp             | 0.53                          | Y                      |
| Poultry (layer only)  | 0.025                              | 0.036                               | Potato, dried pulp             | 0.53                          | Y                      |

\* These categories correspond to those (formerly) assessed at EU level.

#### 7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

##### Available data

No new data were submitted in the framework of this application.



**Table 7.2-13: Overview of the values derived from livestock feeding studies**

| Commodity   | Dietary burden    |                   | Results of the livestock feeding study |    |                        |              |               |              | Median residue (mg/kg) <sup>(b)</sup> | Highest residue (mg/kg) <sup>(c)</sup> | Calculated MRL (mg/kg)           | CF for RA <sup>(d)</sup> |
|---|-------------------|-------------------|--|----|------------------------|--------------|---------------|--------------|---------------------------------------|--|----------------------------------|--------------------------|
|   | Med. (mg/kg bw/d) | Max. (mg/kg bw/d) | Dose Level (mg/kg bw/d) <sup>(a)</sup> | No | Result for enforcement |              | Result for RA |              |                                       |  |                                  |                          |
|   |                   |                   |  |    | Mean (mg/kg)           | Max. (mg/kg) | Mean (mg/kg)  | Max. (mg/kg) |                                       |  |                                  |                          |
| <b>EU data (EFSA, 2017)</b>   |                   |                   |  |    |                        |              |               |              |                                       |  |                                  |                          |
| Enforcement residue definition: Sum of quizalofop, its salts, its esters (including propaquizalofop) and its conjugates, expressed as quizalofop (any ratio of constituent isomers) |                   |                   |  |    |                        |              |               |              |                                       |  |                                  |                          |
| <b>Pig meat<sup>(g)</sup></b>   | 0.039             | 0.044             | 0.025 (0.6N) <sup>(d)</sup>            |    | n.r.                   | n.r.         | <0.02         | <0.02        | <0.02                                 | <0.02                                  | 0.02* (tentative) <sup>(e)</sup> | -                        |
| <b>Pig fat<sup>(g)</sup></b>  |                   |                   |  |    | n.r.                   | n.r.         | <0.02         | <0.02        | <0.02                                 | <0.02                                  | 0.02* (tentative) <sup>(e)</sup> | -                        |
| <b>Pig liver<sup>(g)</sup></b>  |                   |                   |  |    | n.r.                   | n.r.         | <0.02         | <0.02        | <0.02                                 | <0.02                                  | 0.02* (tentative) <sup>(e)</sup> | -                        |
| <b>Pig kidney<sup>(g)</sup></b>   |                   |                   |  |    | n.r.                   | n.r.         | 0.04          | 0.04         | 0.07                                  | 0.10                                   | 0.10 (tentative) <sup>(e)</sup>  | -                        |
| <b>Ruminant meat<sup>(g)</sup></b>  | 0.092             | 0.109             | 0.08 (0.7N) <sup>(d)</sup>             |    | n.r.                   | n.r.         | <0.02         | <0.02        | <0.02                                 | <0.02                                  | 0.02* (tentative) <sup>(e)</sup> | -                        |
| <b>Ruminant fat<sup>(g)</sup></b>   |                   |                   |  |    | n.r.                   | n.r.         | <0.02         | <0.02        | <0.02                                 | <0.02                                  | 0.02* (tentative) <sup>(e)</sup> | -                        |
| <b>Ruminant liver<sup>(g)</sup></b>   |                   |                   |  |    | n.r.                   | n.r.         | <0.02         | <0.02        | <0.02                                 | <0.02                                  | 0.03 (tentative) <sup>(e)</sup>  | -                        |
| <b>Ruminant kidney<sup>(g)</sup></b>  |                   |                   |  |    | n.r.                   | n.r.         | 0.15          | 0.19         | 0.16                                  | 0.22                                   | 0.3 (tentative) <sup>(e)</sup>   | -                        |
| <b>Poultry meat</b>   | 0.029             | 0.036             | 0.04 (1.1N) <sup>(d)</sup>             |    | n.r.                   | n.r.         | <0.02         | <0.02        | <0.02                                 | <0.02                                  | 0.02* (tentative) <sup>(e)</sup> | -                        |
| <b>Poultry fat</b>  |                   |                   |  |    | n.r.                   | n.r.         | 0.03          | 0.03         | 0.03                                  | 0.03                                   | 0.04 (tentative) <sup>(e)</sup>  | -                        |
| <b>Poultry liver</b>  |                   |                   |  |    | n.r.                   | n.r.         | 0.04          | 0.04         | 0.04                                  | 0.04                                   | 0.04 (tentative) <sup>(e)</sup>  | -                        |
| <b>Milk<sup>(f)</sup></b>   | 0.092             | 0.109             | 0.08 (0.7N) <sup>(d)</sup>             |    | n.r.                   | n.r.         | <0.01         | n.a          | 0.1                                   | 0.1                                    | 0.015 (tentative) <sup>(e)</sup> | -                        |
| <b>Eggs</b>   | 0.025             | 0.036             | 0.04 (1.1N) <sup>(d)</sup>             |    | n.r.                   | n.r.         | <0.01         | <0.01        | <0.01                                 | <0.01                                  | 0.01* (tentative) <sup>(e)</sup> | -                        |

n.r.: Not reported

(\*): Indicates that the MRL is set at the limit of analytical quantification.

(a): Livestock feeding studies performed with quizalofop-P-tefuryl variant.

(b): The mean residue level for milk, eggs and tissues were recalculated at the 1N rate for the median dietary burden.

(c): The mean residue level in milk and the highest residue levels in eggs and tissues were recalculated at the 1N rate for the maximum dietary burden.

(d): Closest feeding level and N dose rate related to the maximum dietary burden.

- (e): MRL proposal is tentative because efficiency of extraction and hydrolysis steps of the analytical method used in the livestock feeding studies and proposed for enforcement needs to be demonstrated.
- (f): Highest residue level from day 1 to day 28 (daily mean of 3 cows).
- (g): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

### **Conclusion on feeding studies**

Regarding available feeding data, there is no risk for animal MRL to be exceeded.

## **7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)**

### **7.2.5.1 Available data for all crops under consideration**

No new data were submitted in the framework of this application.

### **Conclusion on processing studies**

Conclusions drawn from EFSA Scientific Report (2008) 204, 1-171 are reported below:  
Considering the low residue levels detected in the raw agricultural products (<0.1 mg/kg), the behaviour of the residues in processing commodities was not investigated and was considered not required.

## **7.2.6 Magnitude of residues in representative succeeding crops**

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

### **7.2.6.1 Field rotational crop studies (KCA 6.6.2)**

#### **Available data**

No new data submitted in the framework of this application.

#### **Conclusion on rotational crops studies**

It is concluded that significant residues of propaquizafop are not expected to be present in rotational crops (EFSA 2008).

## **7.2.7 Other / special studies (KCA6.10, 6.10.1)**

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of Propaquizafop 10% EC. Therefore, other special studies are not needed.

## **7.2.8 Estimation of exposure through diet and other means (KCA 6.9)**

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

### 7.2.8.1 Input values for the consumer risk assessment

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

Current MRL are considered for all crops for consumer risk assessment.

### 7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

**Table 7.2-14: Consumer risk assessment**

|  |  |
|--|--|
| TMDI (% ADI) according to EFSA PRIMo 3.1   | 40 % (based on NL toddler)   |
| IESTI (% ARfD) according to EFSA PRIMo 3.1 | Not applicable as no ARfD was considered applicable during active ingredient inclusion (EFSA 2008) |

\* include raw and processed commodities if both values are required for PRIMo

\*\* if national model is available

The calculation of the TMDI was performed taking into account all the crops to which propaquizafop may be applied. The summary of the calculation using the EFSA model rev 3.1 is presented in Appendix 3. With the current EFSA model the chronic risk assessment reaches a maximum of 40% of ADI. The diet with the highest TMDI is “NL toddler”. For this diet, the highest contributor is OSR with 13% of ADI.

Based on the above calculation, it can be concluded that the proposed uses of propaquizafop in the formulation SHA 6100A do not represent unacceptable chronic or acute risk for the consumer.

## 7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

## 7.4 References

Italy, 2006. Draft Assessment Report (DAR). Initial risk assessment provided by the rapporteur Member State Italy for the existing active substance Propaquizafop of the third stage (Part A) of the Council Directive 91/414/EEC; Volume 3, Annex B, B.7. June 2006.

DAR 2005. Draft assessment report on the active substance on the active substance propaquizafop prepared by the rapporteur Member State Italy in the framework of Council Directive 91/414/EEC, September 2005.

Italy, 2008. Final addendum to the draft assessment report on the active substance propaquizafop, compiled by EFSA, September 2008.

EFSA (European Food Safety Authority), 2017. Review of the existing maximum residue levels for quizalofop-P-ethyl, quizalofop-P-tefuryl and Propaquizafop according to Article 12 of Regulation (EC) No 396/2005. 13 October 2017.

EFSA (European Food Safety Authority), 2008. Conclusion regarding the peer review of the pesticide risk assessment of propaquizafop (an ester variant of quizalofop-P). EFSA Scientific Report (2008) 204, 1-171.

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

Tables considered not relevant can be deleted as appropriate.  
 MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study<br>Y/N | Owner |
|------------|-----------|------|---|-------------------------|-------|
|            |           |      |   |                         |       |
|            |           |      |   |                         |       |

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

| Data point        | Author(s)    | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Owner                           |
|-------------------|--------------|------|--|-------------------------|---------------------------------|
| III A<br>8.3.7/01 | E. Chevalier | 2011 | Magnitude of residue of quizalofop-P- ethyl, propaquizafop and metabolites in open-field strawberry Raw Agricultural Commodity after one application of AG-Q2-50 EC or AG- P6-100 EC - 4 trials (2 DCS + 2 HS) . Northern Europe . 2011<br>BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL 11/341/CL.<br>Report No.: 90014452<br>GLP, Published | N                       | Quena Plant Protection N.<br>V. |

| 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 study<br>Y/N | Owner                           |
|-------------------|---------------|------|---|-------------------------|---------------------------------|
| IIIA<br>8.3.7/02  | R. Tribolet   | 1994 | Determination of total residue of parent compound CGA233380 and metabolites CGA 129674 and CGA 287422 in strawberries - 1 trials . Northern Europe . 1994<br>Quena Plant Protection<br>Report No.: 90003977<br>Unpublished  | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.9/02  | C. Bousquet   | 2010 | Magnitude of residue of Propaquizafop and metabolites in potato Raw Agricultural Commodity after one application of AG-P6-100 EC . 2 trials (1 HS + 1 DCS) . Northern Europe (Northern France and Poland) - 2009, BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL09/182/CL<br>Report No.: 90012474<br>GLP, Published   | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.9/03  | C. H. Roussel | 2007 | Magnitude of the Residues of Propaquizafop In Potatoes (RAC Tubers) Following One Application of AGIL, France, 2006 STAPHYT<br>Quena Plant Protection<br>Study No: ChR-06-2018<br>Report No.: 90011990<br>GLP, Published  | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.10/01 | C. Bastiani   | 2010 | Magnitude of residue of propaquizafop and quinalofop-P-ethyl and metabolites in carrot Raw Agricultural Commodity after one or two application of AG-P6-100 EC or one application of AG-Q2-50 EC . 3 trials (1 HS & 2 DCS) . Northern Europe (Northern France), 2009<br>BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL09/194/CL<br>Report No.: 90012486<br>GLP, Published | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.10/02 | C. H. Rouseel | 2007 | Magnitude of the Residues of Propaquizafop In Carrots (RAC Roots) Following One Application of AGIL, France, 2006<br>STAPHYT<br>Quena Plant Protection  | N                       | Quena Plant Protection N.<br>V. |

| 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 study<br>Y/N | Owner                           |
|-------------------|--------------|------|--|-------------------------|---------------------------------|
|                   |              |      | Study No.: ChR-06-2014.<br>Report No.: 90011987<br>GLP, Published  |                         |                                 |
| IIIA<br>8.3.10/03 | J. M. Hualme | 2011 | Magnitude of residue of quizalofop-P- ethyl, propaquizafop and and metabolites in carrot Raw Agricultural Commodity after one or two application of AG-Q2-50 EC or two applications of AG-P6-100 EC . 6 trials (2 DCS & 4 HS) . Northern Europe (France, Poland and Hungary), 2010<br>BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL10/254/CL.<br>Report No.: 90013517<br>GLP, Published | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.17/02 | C. Bousquet  | 2010 | Magnitude of residue of propaquizafop and quizalofop-P-ethyl and metabolites in bulb onion Raw Agricultural Commodity after one application of AG-P6-100 EC or AG- Q2-50 EC . 2 trials (2 DCS) . Northern Europe (Poland), 2009<br>BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL09/178/CL.<br>Report No.: 90012472<br>GLP, Published  | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.17/03 | C. Bousquet  | 2011 | Magnitude of residue of propaquizafop and quizalofop-P-ethyl and metabolites in bulb onion Raw Agricultural Commodity after one application of AG-P6-100 EC or AG- Q2-50 EC . 2 trials (2 HS) . Northern Europe (France), 2010<br>BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL10/249/CL.<br>Report No.: 90013516<br>GLP, Published   | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.17/05 | L. Schwager  | 1991 | Propaquizafop, Onion DR. R. MAAG Ltd.<br>Report No.: 6163-90068.<br>Quena Plant Protection<br>Report No.: 90003878   | N                       | Quena Plant Protection N.<br>V. |

| 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 study<br>Y/N | Owner                           |
|-------------------|--------------|------|--|-------------------------|---------------------------------|
|                   |              |      | GLP, Published   |                         |                                 |
| IIIA<br>8.3.17/06 | E. Chevalier | 2011 | Magnitude of residue of propaquizafop and metabolites in bulb onion agricultural commodity after one foliar application of AG-P6-100 EC (100 g/L propaquizafop) . 5 trials (3 harvest trials and 2 decline trials) . Northern Europe (France, United Kingdom) -2011<br>BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL11/385/CL,<br>Report No.: 90014477<br>GLP, Published                              | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.24/01 | L. Schwager  | 1991 | Propaquizafop, Cabbage R. R. MAAG Ltd.<br>Quena Plant Protection<br>Report No.: 6163-90018,<br>Report No.: 90003827<br>GLP, Published  | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.24/03 | C. Bastiani  | 2010 | Magnitude of residue of Propaquizafop and quizalofop-P-ethyl and metabolites in head cabbage Raw Agricultural Commodity after one or two applications of AG-P6-100 EC or after one application of AG-Q2-50- EC . 2 DCS . Northern Europe (Northern France and Germany), 2009<br>BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL 09/176/CL,<br>Report No.: 90012470<br>GLP, Published                    | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.24/04 | C. Bousquet  | 2011 | Magnitude of residue of Propaquizafop and quizalofop-P-ethyl and metabolites in head cabbage Raw Agricultural Commodity after one or two applications of AG-P6-100 EC or one application of AG-Q2-50-EC . 6 trials (2 DCS + 4 HS) . Northern Europe (Northern France, Germany and Poland), 2010<br>BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL 10/247/CL,<br>Report No.: 90013515<br>GLP, Published | N                       | Quena Plant Protection N.<br>V. |

| 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 study<br>Y/N | Owner                           |
|-------------------|--------------------------|--------------|---|-------------------------|---------------------------------|
| IIIA<br>8.3.28/01 | C. Bastiani              | 2010         | Magnitude of residue of Propaquizafop and metabolites in fresh peas with pods Raw Agricultural Commodity after one application of AG-P6-100 EC . 2 trials (1 HS + 1 DCS) . Northern Europe (The Netherlands & Germany), 2009<br>BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL 09/186/CL,<br>Report No.: 90012478<br>GLP, Published                                       | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.28/02 | C. Bousquet              | 2011         | Magnitude of residue of Propaquizafop and quizalofop-P-ethyl and metabolites in fresh peas with pods Raw Agricultural Commodity after one application of AG-P6-100 EC or AG-Q2-50 EC . 2 trials (1 DCS + 1 HS) . Southern Europe (Spain and Southern France), 2010<br>BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL 10/263/CL,<br>Report No.: 90013523<br>GLP, Published | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.32/01 | L. Schwager              | 1991         | Propaquizafop, Green beans DR. R. MAAG Ltd.<br>Report No.: 6163-90023,<br>Quena Plant Protection<br>Report No.: 90003816<br>GLP, Unpublishe   | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.32/02 | A. Perny                 | 2004         | Determination of Propaquizafop Residues In Spring Horse Bean Following Treatment with the Preparation AGIL, Under Field Conditions in France in 2003<br>ANADIAG Report No.: RA3112,<br>Quena Plant Protection<br>Report No.: 90011533<br>GLP, Published   | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.32/03 | R Heyer<br>B. Lauterbach | 1995<br>1994 | Determination of Propaquizafop, Formulated as CGD 10280H (A- 8726D), AGIL, In/On Field Beans (Plant and Seed) RCC Ltd. Report 498003,<br>Quena Plant Protection   | N                       | Quena Plant Protection N.<br>V. |

| 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 study<br>Y/N | Owner                           |
|-------------------|-------------|------|---|-------------------------|---------------------------------|
|                   |             |      | Report No.: 9003810A<br>GLP, Published<br><br>Field Trial for Determination of Residue Levels in Broad Beans<br>BIOCHEM Report 94 10 47 022,<br>Quena Plant Protection<br>Report No.: 9003810B<br>GLP, Published  |                         |                                 |
| IIIA<br>8.3.37/01 | C. Bousquet | 2010 | Magnitude of residue of Propaquizafop and its metabolite in spring oil seed rape Raw Agricultural Commodity after one application of AG-P6-100 EC . 2 decline curve + 2 harvest trials . Northern Europe (Germany and The Netherlands) . 2009<br>BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL09/195/GC,<br>Report No.: 90012487<br>GLP, Published | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.37/02 | C. Bastiani | 2010 | Magnitude of residue of Propaquizafop and its metabolites in winter oil seed rape Raw Agricultural Commodity after one application of AG-P6-100 EC . 2 Decline curve trials - Northern Europe (Northern France) . 2009.<br>BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL09/192/GC,<br>Report No.: 90012484<br>GLP, Published                       | N                       | Quena Plant Protection N.<br>V. |
| IIIA<br>8.3.37/03 | C. Bousquet | 2011 | Magnitude of residue of Propaquizafop and its metabolite in spring oil seed rape Raw Agricultural Commodity after one application of AG-P6-100 EC . 4 trials (2 DCS + 2 HS) . Northern Europe (Germany and The Netherlands) . 2010. BIOTEK Agriculture<br>Quena Plant Protection<br>Study No.: BPL10/238/GC,<br>Report No.: 90013511<br>GLP, Published              | N                       | Quena Plant Protection N.<br>V. |

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title</b><br><b>Company Report No.</b><br><b>Source (where different from company)</b><br><b>GLP or GEP status</b><br><b>Published or not</b>   | <b>Vertebrate study</b><br><b>Y/N</b> | <b>Owner</b>            |
|-------------------|------------------|-------------|--|---------------------------------------|-------------------------|
| KCP<br>8.3.1.1    | G. Rousseau      | 2013        | Freezing storage stability study of residues of quizalofop in pea whole plant, pea dry seed, oil seed rape grain and grape (0, 6 and 12 months)<br>Walloon Agricultural Research Centre, CRA-W<br>GLP<br>Unpublished | N                                     | Sharda Cropchem Limited |

The following tables are to be completed by MS.

**List of data submitted by the applicant and not relied on**

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title</b><br><b>Company Report No.</b><br><b>Source (where different from company)</b><br><b>GLP or GEP status</b><br><b>Published or not</b> | <b>Vertebrate study</b><br><b>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--|---------------------------------------|--------------|
|                   |                  |             |  |                                       |              |
|                   |                  |             |  |                                       |              |

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

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title</b><br><b>Company Report No.</b><br><b>Source (where different from company)</b><br><b>GLP or GEP status</b><br><b>Published or not</b> | <b>Vertebrate study</b><br><b>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--|---------------------------------------|--------------|
|                   |                  |             |  |                                       |              |

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title</b><br><b>Company Report No.</b><br><b>Source (where different from company)</b><br><b>GLP or GEP status</b><br><b>Published or not</b> | <b>Vertebrate study</b><br><b>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--|---------------------------------------|--------------|
|                   |                  |             |  |                                       |              |

## Appendix 2 Detailed evaluation of the additional studies relied upon

### A 2.1 Propaquizafop

#### A 2.1.1 Stability of residues

##### A 2.1.1.1 Stability of residues during storage of samples

##### A 2.1.1.1.1 Storage stability of residues in plant products

###### A 2.1.1.1.1.1 Study 1

Comments of zRMS: Study is accepted

Reference: KCP 8.3.1.1

Report Freezing storage stability study of residues of quizalofop in pea whole plant, pea dry seed, oil seed rape grain and grape (0, 6 and 12 months), Gilles Rousseau, 2013, Report No.: 22853 (Project No.: SHARDA/RE22853/2013)

Guideline(s): Yes  
Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000. Guidance document on residue analytical methods. Document SANCO 825/00, 2010

Deviations: No

GLP: Yes

Acceptability: Yes

### Materials and methods

#### Specificity

The analysis of untreated samples in comparison with the analysis of standard solutions and spiked samples showed the absence of compound interfering with the determination of quizalofop-ethyl and quizalofop (< 30 % LOQ). Moreover the relative intensities of the detected m/z ions in the spiked samples of pea whole plant, pea dry seed, oil seed rape grain and grape corresponds to those of the standard solutions at comparable concentrations.

#### Quizalofop-P-ethyl:

Parent ion = 373.08 amu

Cone voltage : 34 v

Quantification on ion m/z = 298.98 amu

Collision energy : 18 v

Confirmation on ion m/z = 90.96 amu

Collision energy : 32 v

### **Quizalofop-P:**

Parent ion = 345.10 amu  
Cone voltage : 36 v  
Quantification on ion m/z = 298.94 amu  
Collision energy : 20 v  
Confirmation on ion m/z = 162.90 amu (T0) or 163.50 amu  
Collision energy : 36 v

With these conditions the retention time of quizalofop-P-ethyl is about 1.52 minutes and the retention time of quizalofop-P is about 1.09 minutes.

### **Recovery**

Recovery values were calculated by fortifying untreated samples (level I – 0.02 mg/kg, level II – 1.0 mg/kg) of pea whole plant, pea dry seed, oil seed rape grain and grape with known amounts of quizalofop-ethyl and quizalofop. The untreated specimens of pea whole plant, pea dry seed, oil seed rape grain, and grape were analysed prior to spiking and showed the absence of compound interfering with the determination of quizalofop-ethyl and quizalofop (< 30 % LOQ).

The results are expressed as total quizalofop [sum of quizalofop-ethyl, quizalofop and quizalofop conjugates, expressed as quizalofop (sum of isomers)]. The results for quizalofop-ethyl and quizalofop acid alone are only given for information.

### **Limit of Quantification**

Limit of quantification for quizalofop-ethyl was LOQ = 0.01 mg/kg  
Limit of quantification for quizalofop was LOQ = 0.01 mg/kg

### **Sample preparation**

Chop the specimen of pea whole plant, pea dry seed and grape in a food cutter in order to obtain a reduced homogenised sample representative of the original specimen. Take analytical portions of 20 g and analyse immediately.

### **Extraction**

- Weigh (to the nearest 0.01 g) 20 g of sample into a 100 mL extraction flask.
- For recoveries, spike the untreated sample with the appropriate standard solution.
- Add 60 mL acetone / water (80/20, v/v) solution.
- Extract at high speed in an Ultra Turrax blender for about 2 minutes.
- Hydrolyse with 1 mL or 5 mL (for grape) hydrochloric acid (pH < 1) to extract the quizalofop conjugates. Wait for 30 minutes with regular manual shaking and neutralise to pH 4-5 with ammonium hydroxide (5 N).
- Filter the extract by suction through a Büchner funnel containing a filter paper.
- Collect the filtrate into a 100 mL volumetric flask.
- Rinse the Ultra Turrax blender, the extraction flask and the filter cake with acetone / water (80/20, v/v) solution. Collect into the same 100 mL volumetric flask and fill up to volume with acetone / water (80/20, v/v) solution.

### **Cleanup by Solid Supported Liquid / Liquid Extraction (SSLLE) on a diatomaceous earth cartridge**

- Apply 25 mL of the extract from 3.3.5.2 onto the cartridge.
- Let the extract penetrate into the cartridge for about 5 minutes.
- Elute quizalofop-P-ethyl with 7 x 20 mL dichloromethane or 8 x 20 mL hexane (for oil seed rape grain) and quizalofop-P with 8 x 20 mL ethyl acetate in two 300 mL conical flask.
- Combine the eluates and evaporate the solvent to nearly dryness using a rotary vacuum evaporator (bath temperature at about 40°C).

### **Standard solution preparation**

About 25 mg of quizalofop-P-ethyl analytical standard are accurately weighed (to the nearest 0.1 mg) into a 50 mL volumetric flask. The flask is filled up to volume with methanol (= stock solution A).  
 About 25 mg of quizalofop-P analytical standard are accurately weighed (to the nearest 0.1 mg) into a 50 mL volumetric flask. The flask is filled up to volume with methanol (= stock solution B).

Standard solutions of mixed quizalofop-P-ethyl and quizalofop-P in methanol are prepared by serial dilution of the stock solutions to obtain the following concentrations: 50, 10, 5, 2, 1, 0.5, 0.2, 0.1, 0.05, 0.02 and 0.01 µg/mL. Several pea whole plant, pea dry seed, oil seed rape grain and grape matrices are prepared using untreated samples. Each of them is prepared according to the sample preparation described above excepted that the dry residue is re-dissolved in 2 mL of each of the standard solutions of quizalofop-ethyl and quizalofop in methanol. The mixed standard solutions from 0.01 µg/mL to 5 µg/mL in pea whole plant, pea dry seed, oil seed rape grain and grape matrix are used to form the calibration curves (matrix-matched calibration).

The standard solutions in methanol are stored in a fridge at a temperature below at 4°C. Under these conditions they are stable for at least 121 days.

## Results and discussions

**Table A 1: Summary of concurrent recoveries of Quizalofop**

| Matrix   | Spike level (mg/kg) | Storage Interval (days) | Sample size (n) | Individual procedural recoveries (%) | Mean ± std dev |    |
|--|---------------------|-------------------------|-----------------|--------------------------------------|----------------|----|
| total quizalofop [sum of quizalofop-ethyl, quizalofop and quizalofop conjugates, expressed as quizalofop (sum of isomers)] |                     |                         |                 |                                      |                |    |
| Pea whole plant  | 0.9158              | 0                       | 20 g            | 85                                   | 79             |    |
|  | 0.8983              |                         |                 | 80                                   |                |    |
|  | 0.9109              |                         |                 | 72                                   |                |    |
|  | 0.9336              |                         |                 | 80                                   |                |    |
|  | 0.9061              | 174                     |                 | 77                                   | 76 - 3.8       |    |
|  | 0.9158              |                         |                 | 78                                   |                |    |
|  | 0.9335              |                         |                 | 70                                   |                |    |
|  | 0.9253              |                         |                 | 78                                   |                |    |
|  | 0.9308              | 370                     | 20 g            | 68                                   | 70 - 11.4      |    |
|  | 0.9354              |                         |                 | 67                                   |                |    |
|  | 0.8987              |                         |                 | 72                                   |                |    |
|  | 0.9158              |                         |                 | 72                                   |                |    |
|  | Pea dry seed        | 0.9327                  | 0               |                                      | 76             | 79 |
|  |                     | 0.9114                  |                 |                                      | 87             |    |
| 0.9109   |                     | 77                      |                 |                                      |                |    |
| 0.9336   |                     | 75                      |                 |                                      |                |    |
| 0.9235   |                     | 174                     |                 | 80                                   | 81 + 2.5       |    |
| 0.9267   |                     |                         |                 | 79                                   |                |    |
| 0.9026   |                     |                         |                 | 84                                   |                |    |
| 0.9066   |                     |                         |                 | 80                                   |                |    |
| 0.9327   |                     | 371                     |                 | 66                                   | 70 – 11.4      |    |

| Matrix              | Spike level (mg/kg) | Storage Interval (days) | Sample size (n) | Individual procedural recoveries (%) | Mean ± std dev |
|---------------------|---------------------|-------------------------|-----------------|--------------------------------------|----------------|
|                     | 0.9158              |                         |                 | 67                                   |                |
|                     | 0.9244              |                         |                 | 73                                   |                |
|                     | 0.9267              |                         |                 | 76                                   |                |
| Oli seed rape grain | 0.9313              | 0                       |                 | 74                                   | 88             |
|                     | 0.9364              |                         |                 | 92                                   |                |
|                     | 0.9350              |                         |                 | 93                                   |                |
|                     | 0.9281              |                         |                 | 91                                   |                |
|                     | 0.9313              | 174                     |                 | 62                                   | 62 – 29.5      |
|                     | 0.9244              |                         |                 | 60                                   |                |
|                     | 0.9336              |                         |                 | 62                                   |                |
|                     | 0.9373              |                         |                 | 64                                   |                |
|                     | 0.9368              | 380                     |                 | 63                                   | 70 – 20.5      |
|                     | 0.9378              |                         |                 | 78                                   |                |
|                     | 0.9217              |                         |                 | 76                                   |                |
|                     | 0.9267              |                         |                 | 61                                   |                |
| Grape               | 0.9341              | 0                       |                 | 108                                  | 100            |
|                     | 0.9378              |                         |                 | 98                                   |                |
|                     | 0.9359              |                         |                 | 104                                  |                |
|                     | 0.9373              |                         |                 | 91                                   |                |
|                     | 0.9368              | 174                     |                 | 119                                  | 112 + 12.0     |
|                     | 0.9290              |                         |                 | 112                                  |                |
|                     | 0.9239              |                         |                 | 92                                   |                |
|                     | 0.9387              |                         |                 | 126                                  |                |
|                     | 0.9235              | 378                     |                 | 79                                   | 92 – 8.0       |
|                     | 0.9285              |                         |                 | 88                                   |                |
|                     | 0.8987              |                         |                 | 97                                   |                |
|                     | 0.9364              |                         |                 | 105                                  |                |

### Conclusion

Regarding the residues of total quizalofop before and during the storage period, no degradation higher than 30 % of total quizalofop residues was observed in pea whole plant (-11.4%), pea dry seed (-11.4%), oil seed rape grain (-20.5%) and grape (-8.0%) after storage for 12 months at -18°C ( $\leq -15^{\circ}\text{C}$ ,  $\geq -30^{\circ}\text{C}$ ). Total quizalofop residues are therefore stable in pea whole plant, pea dry seed, oil seed rape grain and grape for at least 12 months at -18°C ( $\leq -15^{\circ}\text{C}$ ,  $\geq -30^{\circ}\text{C}$ ).

#### A 2.1.1.1.2 Storage stability of residues in animal products

#### A 2.1.2 Nature of residues in plants, livestock and processed commodities

- A 2.1.2.1 Nature of residue in plants**
- A 2.1.2.1.1 Nature of residue in primary crops**
- A 2.1.2.1.2 Nature of residue in rotational crops**
- A 2.1.2.1.3 Nature of residues in processed commodities**
- A 2.1.2.2 Nature of residues in livestock**
- A 2.1.3 Magnitude of residues in plants**
- A 2.1.4 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)**
- A 2.1.4.1 Distribution of the residue in peel/pulp**
- A 2.1.4.2 Processing studies on a core set of representative processes**
- A 2.1.5 Magnitude of residues in representative succeeding crops**

## Appendix 3 Pesticide Residue Intake Model (PRIMO)

### A 3.1 TMDI calculations



| PROPAQUIZAFOP                  |                                      |
|--------------------------------|--------------------------------------|
| LOQs (mg/kg) range from:       | 0,01 to 0,05                         |
| Toxicological reference values |                                      |
| ADI (mg/kg bw/day):            | 0,015 ARID (mg/kg bw): not necessary |
| Source of ADI:                 | EFSA 2008                            |
| Year of evaluation:            | 2008                                 |

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

| Calculated exposure (% of ADI) | MS Diet           | Exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) |                                  | 2nd contributor to MS diet (in % of ADI) |                                  | 3rd contributor to MS diet (in % of ADI) |                                  | Exposure resulting from MRLs set at the LOQ (in % of ADI) |  |
|--------------------------------|-------------------|-----------------------------|--|----------------------------------|--|----------------------------------|--|----------------------------------|---|--|
|                                |                   |                             | Commodity / group of commodities             | Commodity / group of commodities | Commodity / group of commodities         | Commodity / group of commodities | Commodity / group of commodities         | Commodity / group of commodities |   |  |
| 40%                            | NL toddler        | 5,99                        | 13%  | Rapeseeds/canola seeds           | 6%                                       | Milk: Cattle                     | 3%                                       | Potatoes                         | 4%  |  |
| 23%                            | NL child          | 3,40                        | 6%   | Rapeseeds/canola seeds           | 3%                                       | Sugar beet roots                 | 2%                                       | Milk: Cattle                     | 3%  |  |
| 21%                            | GEMS/Food G07     | 3,09                        | 7%   | Rapeseeds/canola seeds           | 3%                                       | Potatoes                         | 2%                                       | Soyabeans                        | 2%  |  |
| 19%                            | GEMS/Food G08     | 2,92                        | 4%   | Rapeseeds/canola seeds           | 3%                                       | Soyabeans                        | 3%                                       | Sunflower seeds                  | 2%  |  |
| 19%                            | GEMS/Food G15     | 2,90                        | 3%   | Head cabbages                    | 3%                                       | Sunflower seeds                  | 3%                                       | Rapeseeds/canola seeds           | 2%  |  |
| 18%                            | GEMS/Food G10     | 2,77                        | 4%   | Soyabeans                        | 3%                                       | Rapeseeds/canola seeds           | 2%                                       | Potatoes                         | 2%  |  |
| 17%                            | RO general        | 2,57                        | 6%   | Head cabbages                    | 4%                                       | Sunflower seeds                  | 2%                                       | Potatoes                         | 1%  |  |
| 15%                            | GEMS/Food G11     | 2,22                        | 5%   | Soyabeans                        | 3%                                       | Potatoes                         | 1,0%                                     | Carrots                          | 2%  |  |
| 13%                            | UK infant         | 1,98                        | 4%   | Milk: Cattle                     | 2%                                       | Potatoes                         | 2%                                       | Carrots                          | 1%  |  |
| 13%                            | FR toddler 2-3 yr | 1,93                        | 3%   | Milk: Cattle                     | 2%                                       | Beans (with pods)                | 1%                                       | Potatoes                         | 2%  |  |
| 13%                            | NL general        | 1,93                        | 4%   | Rapeseeds/canola seeds           | 2%                                       | Potatoes                         | 1%                                       | Sugar beet roots                 | 1%  |  |
| 13%                            | FR child 3-15 yr  | 1,93                        | 2%   | Milk: Cattle                     | 1%                                       | Sugar beet roots                 | 1%                                       | Sunflower seeds                  | 2%  |  |
| 13%                            | DE child          | 1,89                        | 2%   | Milk: Cattle                     | 2%                                       | Potatoes                         | 2%                                       | Apples                           | 4%  |  |
| 12%                            | GEMS/Food G06     | 1,78                        | 2%   | Soyabeans                        | 1%                                       | Potatoes                         | 1%                                       | Sunflower seeds                  | 2%  |  |
| 12%                            | SE general        | 1,75                        | 3%   | Potatoes                         | 3%                                       | Head cabbages                    | 1%                                       | Milk: Cattle                     | 2%  |  |
| 11%                            | UK toddler        | 1,62                        | 2%   | Potatoes                         | 2%                                       | Milk: Cattle                     | 1%                                       | Sugar beet roots                 | 2%  |  |
| 10%                            | IE adult          | 1,56                        | 2%   | Potatoes                         | 1%                                       | Sunflower seeds                  | 0,5%                                     | Broccoli                         | 1%  |  |
| 9%                             | FI general        | 1,39                        | 4%   | Potatoes                         | 2%                                       | Sunflower seeds                  | 0,9%                                     | Carrots                          | 1%  |  |
| 9%                             | FR infant         | 1,29                        | 2%   | Milk: Cattle                     | 1%                                       | Carrots                          | 1%                                       | Potatoes                         | 0,7%  |  |
| 9%                             | DE women 14-50 yr | 1,29                        | 2%   | Sugar beet roots                 | 1%                                       | Milk: Cattle                     | 0,7%                                     | Potatoes                         | 2%  |  |
| 8%                             | DE general        | 1,26                        | 2%   | Sugar beet roots                 | 1%                                       | Milk: Cattle                     | 0,8%                                     | Potatoes                         | 2%  |  |
| 8%                             | ES child          | 1,23                        | 1%   | Milk: Cattle                     | 1%                                       | Potatoes                         | 0,8%                                     | Sunflower seeds                  | 2%  |  |
| 8%                             | FI 3 yr           | 1,19                        | 3%   | Potatoes                         | 1%                                       | Carrots                          | 1%                                       | Rapeseeds/canola seeds           | 1%  |  |
| 8%                             | DK child          | 1,18                        | 2%   | Carrots                          | 2%                                       | Potatoes                         | 1%                                       | Milk: Cattle                     | 2%  |  |
| 6%                             | FI 6 yr           | 0,94                        | 3%   | Potatoes                         | 0,8%                                     | Carrots                          | 0,7%                                     | Rapeseeds/canola seeds           | 0,8%  |  |
| 6%                             | LT adult          | 0,87                        | 2%   | Potatoes                         | 2%                                       | Head cabbages                    | 0,4%                                     | Milk: Cattle                     | 0,8%  |  |
| 6%                             | PL general        | 0,86                        | 2%   | Potatoes                         | 1%                                       | Head cabbages                    | 0,4%                                     | Carrots                          | 0,5%  |  |
| 6%                             | FR adult          | 0,85                        | 0,6%   | Sunflower seeds                  | 0,5%                                     | Potatoes                         | 0,5%                                     | Beans (with pods)                | 1%  |  |
| 6%                             | ES adult          | 0,83                        | 0,7%   | Lettuces                         | 0,6%                                     | Potatoes                         | 0,5%                                     | Sunflower seeds                  | 1%  |  |
| 5%                             | UK vegetarian     | 0,73                        | 0,9%   | Potatoes                         | 0,5%                                     | Beans                            | 0,4%                                     | Head cabbages                    | 0,8%  |  |
| 5%                             | FI adult          | 0,72                        | 2%   | Coffee beans                     | 0,8%                                     | Potatoes                         | 0,4%                                     | Carrots                          | 2%  |  |
| 4%                             | UK adult          | 0,62                        | 0,9%   | Potatoes                         | 0,3%                                     | Milk: Cattle                     | 0,3%                                     | Beans                            | 0,8%  |  |
| 4%                             | DK adult          | 0,61                        | 0,8%   | Potatoes                         | 0,7%                                     | Carrots                          | 0,5%                                     | Milk: Cattle                     | 0,9%  |  |
| 4%                             | IT toddler        | 0,59                        | 0,6%   | Potatoes                         | 0,5%                                     | Tomatoes                         | 0,4%                                     | Wheat                            | 1%  |  |
| 4%                             | IT adult          | 0,55                        | 0,5%   | Lettuces                         | 0,4%                                     | Potatoes                         | 0,4%                                     | Tomatoes                         | 0,8%  |  |
| 2%                             | IE child          | 0,29                        | 0,4%   | Potatoes                         | 0,4%                                     | Milk: Cattle                     | 0,2%                                     | Carrots                          | 0,4%  |  |

**Conclusion:**  
 The estimated long-term dietary intake (TMDI/IEDI) was below the ADI.  
 The long-term intake of residues of PROPAQUIZAFOP is unlikely to present a public health concern.

## Appendix 4 Additional information provided by the applicant