

REGISTRATION REPORT  
**Part B**  
**Section 3**  
**Efficacy Data and Information**  
Concise summary

Product name(s): **Lieto 66 WG**

Chemical active substances:

Zoxamide, 330 g/L

Cymoxanil, 330 g/L

Central Zone

Zonal Rapporteur Member State: Poland

ZONAL ASSESSMENT  
(Article 43 Re-registration)

Applicant: Sipcam Oxon S.p.A.

Submission date: 30 December 2020

MS Finalisation date: August 2021

Revision date: December 2021

## Version history

| When                           | What  |
|--------------------------------|---|
| 30 <sup>th</sup> December 2020 | Submission of initial Version 0 by the applicant. |
| August 2021                    | Version evaluated by zRMS                         |
| December 2021                  | Corrected by zRMS                                 |
|                                |   |

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

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

|                   |   |
|-------------------|---|
| Comments of zRMS: | This is the version of dRR from December 2021, submitted by the applicant in the framework of Article 43 of Regulation (EC) 1107/2009. The original text provided by the applicant has been retained for transparency. The applicant's text is commented by the zRMS and the comments and conclusions are placed in commenting boxes shaded in grey at the end of each chapter. Amendments in the text are highlighted in yellow. |
|-------------------|---|

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

##### Abstract

This draft registration report concerns the field uses of GWN-9823 fungicide, containing the two active substances: zoxamide (330 g/L) and cymoxanil, (330 g/L). Zoxamide and cymoxanil are both included into Annex I of Council Directive 91/414/EEC and approved in accordance with Regulation (EC) No. 1107/2009 by Commission Implementing Regulation (EC) no. 540/2011. Zoxamide as an AIR 3 substance, was re-evaluated at an EU level and was successfully re-approved by Commission Implementing Regulation (EU) no. 2018/692) that applies from 1st July 2018. For cymoxanil (AIR 4 substance) the original expiry date has been extended to 31st August 2021 by Commission Implementing Regulation (EU) no. 2017/195.

GWN-9823 is a water dispersible granules (WG) formulation intended for the use as fungicide for control of Late blight (*Phytophthora infestans*) in potato and tomato and Downy mildew (*Plasmopara viticola*) in grapevine. The tested fungicide is approved for the use in the countries where re-registration is envisaged. Since the previous submissions supporting current national authorisations of GWN-9823, there are no changes to any of the relevant national labels, with the exception of reductions in the maximum numbers of applications. For re-registration, the number of applications has been restricted to maximum 3 per crop and per season for the purpose of resistance management. Data supporting current registrations of GWN-9823, with higher maximum numbers of applications, fully support the efficacy and crop safety of fewer applications and there are no new data requirements relating to the efficacy since the previous authorisations.

ZRMS agrees with the applicant and accept do not providing the efficacy data.

The only data for the current status of GWN-9823 registration regarding resistance and the absence of adverse effects on grape transformation processes were needed. The sensitivity of PHYTIN to zoxamide has been tested on a total of 426 isolates, either laboratory strains or from commercial crops and field trials across countries in Europe in 1 study carried out between 1993 and 2014.

A total of 5 trials have been carried out in 2015 and 2017 in grapevine to produce samples of fruit for processing and taint testing following multiple application of GWN-9823. Of these trials, 2 were carried out within the Maritime climatic zone (both in Austria) and 3 were carried out within the Mediterranean climatic zone (all in Greece). Vinification and taint testing of wine was carried out on fruit sampled from 2 trials, processing and taint testing of raisins was carried out on fruit sampled from 1 trial and taint testing of fresh grapes was carried out on fruit sampled from the other 2 trials.

Overall, multiple applications of GWN-9823 at 0.4 kg/ha had no consistent effects on wine or raisin production processes and caused no significant taints of wine, raisins or fresh table grapes, compared to the untreated control or approved standard reference products applied according to label recommendations, on fruit sampled from any of these trials.

Based on the presented data, it is therefore reasonable to conclude that GWN-9823 applied at maximum label rates and according to other label recommendations on grapevine has no adverse impact on any relevant processing procedures and causes no taints of processed or fresh commodities. For the supported uses, the maximum label rates of GWN-9823 are 0.4 kg or 0.45 kg/ha, with a maximum of 3 applications per season, made within the crop growth stage range of BBCH 13-89 and with minimum intervals between applications of 7-10 days and applications made in water volumes of 200-1000 L/ha.

Re-registration is recommended in the Central zone according to the label claims proposed by applicant, at the range of current registration. This assessment has been performed according to the uniform principles.

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-1:Acceptability of intended uses**

**PPP (product name/code)** Lieto 66 WG  
**active substances** zoxamide + cymoxanil  
**Applicant:** Sipcarn Oxon S.p.A.  
**Zone(s):** Central  
**Verified by MS:**

**Formulation type:** WG  
**Conc. of as:** 330 + 330 g/L  
**Professional use**   
**Non professional use**

**Field of use:** fungicide

| 1                               | 2                  | 3  | 4   | 5  | 6                  | 7   | 8  | 9   | 10  | 11  | 12                            | 13            | 14  |
|---------------------------------|--------------------|--|---|--|--------------------|---|--|---|---|---|-------------------------------|---------------|---|
| Use-<br>No.<br>(e)              | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop<br>destination /<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:<br>developmental stages<br>of the pest or pest<br>group) | Application        |   |  |   | Application rate  |   |                               | PHI<br>(days) | Remarks:<br><br>e.g. g safener/synergist per ha <sup>(6)</sup>  |
|                                 |                    |  |   |  | Method /<br>Kind   | Timing /<br>Growth stage<br>of crop &<br>season | Max. number<br>a) per use<br>b) per crop/ season | Min.<br>interval<br>between<br>applications<br>(days) | kg or L product /<br>ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | g or kg as/ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | Water<br>L/ha<br>min /<br>max |               |   |
| <b>Details of existing uses</b> |                    |  |   |  |                    |   |  |   |   |   |                               |               |   |
| 1                               | PL                 | Potatoes<br><i>Solanum<br/>tuberosum</i><br>(L.)<br>SOLTU                      | F   | potato late blight<br><i>Phytophthora<br/>infestans</i> (Mont. De<br>Bary)<br>PHYTIN                                 | Foliar<br>spraying | BBCH 21-<br>89                                  | a) 3<br>b) 3                                     | 7   | a) 0.45 kg/ha<br>b) 1.35 kg/ha  | a) 0.1485 kg/ha<br>b) 0.4455 kg/ha  | 200-400                       | 7             | <b>Registration holder: Gowan<br/>and Sipcarn Oxon</b><br><br>Due to resistance management<br>reasons the maximum number<br>of applications will be<br>restricted to 3. |
| 2                               | CZ                 | Potatoes<br><i>Solanum<br/>tuberosum</i><br>(L.)<br>SOLTU                      | F   | potato late blight<br><i>Phytophthora<br/>infestans</i> (Mont. De<br>Bary)<br>PHYTIN                                 | Foliar<br>spraying | BBCH 21-<br>89                                  | a) 3<br>b) 3                                     | 7   | a) 0.45 kg/ha<br>b) 1.35 kg/ha  | a) 0.1485 kg/ha<br>b) 0.4455 kg/ha  | 200-<br>1000                  | 7             | <b>Registration holder: Sipcarn<br/>Oxon</b><br><br>Due to resistance management<br>reasons the maximum number<br>of applications will be<br>restricted to 3.           |
| 3                               | IE                 | Potatoes<br><i>Solanum<br/>tuberosum</i><br>(L.)<br>SOLTU                      | F   | potato late blight<br><i>Phytophthora<br/>infestans</i> (Mont. De<br>Bary)<br>PHYTIN                                 | Foliar<br>spraying | BBCH 21-<br>89                                  | a) 3<br>b) 3                                     | 7   | a) 0.45 kg/ha<br>b) 1.35 kg/ha  | a) 0.1485 kg/ha<br>b) 0.4455 kg/ha  | 200-<br>1000                  | 7             | <b>Registration holder: Sipcarn<br/>Oxon</b><br><br>Due to resistance management<br>reasons the maximum number<br>of applications will be<br>restricted to 3.           |

| 1                  | 2                  | 3  | 4   | 5  | 6                  | 7   | 8  | 9   | 10  | 11  | 12                                | 13            | 14   |
|--------------------|--------------------|--|---|--|--------------------|---|--|---|---|---|-----------------------------------|---------------|--|
| Use-<br>No.<br>(e) | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop<br>destination /<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:<br>developmental stages<br>of the pest or pest<br>group) | Application        |   |  |   | Application rate  |   |                                   | PHI<br>(days) | Remarks:<br><br>e.g. g safener/synergist per ha <sup>(f)</sup>   |
|                    |                    |  |   |  | Method /<br>Kind   | Timing /<br>Growth stage<br>of crop &<br>season | Max. number<br>a) per use<br>b) per crop/ season | Min.<br>interval<br>between<br>applications<br>(days) | kg or L product /<br>ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | g or kg as/ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | Water<br>L/ha<br><br>min /<br>max |               |  |
| 4                  | NL                 | Potatoes<br><i>Solanum<br/>tuberosum</i><br>(L.)<br>SOLTU                      | F   | potato late blight<br><i>Phytophthora<br/>infestans</i> (Mont. De<br>Bary)<br>PHYTIN                                 | Foliar<br>spraying | BBCH 21-<br>89                                  | a) 3<br>b) 3                                     | 7   | a) 0.45 kg/ha<br>b) 1.35 kg/ha  | a) 0.1485 kg/ha<br>b) 0.4455 kg/ha  | 200-<br>1000                      | 7             | <b>Registration holders:<br/>Sipcam Oxon and Gowan<br/>(back-to-back approval from<br/>Sipcam-Oxon)</b><br><br>Due to resistance management<br>reasons the maximum number<br>of applications will be<br>restricted to 3.     |
| 5                  | HU                 | Potatoes<br><i>Solanum<br/>tuberosum</i><br>(L.)<br>SOLTU                      | F   | potato late blight<br><i>Phytophthora<br/>infestans</i> (Mont. De<br>Bary)<br>PHYTIN                                 | Foliar<br>spraying | BBCH 21-<br>91                                  | a) 3<br>b) 3                                     | 7   | a) 0.45 kg/ha<br>b) 1.35 kg/ha  | a) 0.1485 kg/ha<br>b) 0.4455 kg/ha  | 300-600                           | 7             | <b>Registration holder: Sipcam<br/>Oxon</b><br><br>Due to resistance management<br>reasons the maximum number<br>of applications will be<br>restricted to 3.   |
| 6                  | DE                 | Potatoes<br><i>Solanum<br/>tuberosum</i><br>(L.)<br>SOLTU                      | F   | potato late blight<br><i>Phytophthora<br/>infestans</i> (Mont. De<br>Bary)<br>PHYTIN                                 | Foliar<br>spraying | BBCH 21-<br>89                                  | a) 3<br>b) 3                                     | 7   | a) 0.45 kg/ha<br>b) 1.35 kg/ha  | a) 0.1485 kg/ha<br>b) 0.4455 kg/ha  | 200-<br>1000                      | 7             | <b>Registration holder: Gowan</b><br>Application in case of risk of<br>infection and/or after warning<br>alert.<br>Due to resistance management<br>reasons the maximum number<br>of applications will be<br>restricted to 3. |
| 7                  | AT                 | Potatoes<br><i>Solanum<br/>tuberosum</i><br>(L.)<br>SOLTU                      | F   | potato late blight<br><i>Phytophthora<br/>infestans</i> (Mont. De<br>Bary)<br>PHYTIN                                 | Foliar<br>spraying | BBCH 21-<br>89                                  | a) 3<br>b) 3                                     | 7   | a) 0.45 kg/ha<br>b) 1.35 kg/ha  | a) 0.1485 kg/ha<br>b) 0.4455 kg/ha  | 200-<br>1000                      | 7             | <b>Registration holder: Gowan</b><br>Application in case of risk of<br>infection and/or after warning<br>alert.  |

| 1                  | 2                  | 3  | 4   | 5  | 6                  | 7   | 8  | 9   | 10  | 11  | 12                                | 13            | 14   |
|--------------------|--------------------|--|---|--|--------------------|---|--|---|---|---|-----------------------------------|---------------|--|
| Use-<br>No.<br>(e) | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop<br>destination /<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:<br>developmental stages<br>of the pest or pest<br>group) | Application        |   |  |   | Application rate  |   |                                   | PHI<br>(days) | Remarks:<br><br>e.g. g safener/synergist per ha <sup>(f)</sup>   |
|                    |                    |  |   |  | Method /<br>Kind   | Timing /<br>Growth stage<br>of crop &<br>season | Max. number<br>a) per use<br>b) per crop/ season | Min.<br>interval<br>between<br>applications<br>(days) | kg or L product /<br>ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | g or kg as/ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | Water<br>L/ha<br><br>min /<br>max |               |  |
|                    |                    |  |   |  |                    |   |  |   |   |   |                                   |               | Due to resistance management reasons the maximum number of applications will be restricted to 3.   |
| 8                  | BE                 | Potatoes<br><i>Solanum tuberosum</i><br>(L.)<br>SOLTU                          | F   | potato late blight<br><i>Phytophthora infestans</i> (Mont. De Bary)<br>PHYTIN  | Foliar<br>spraying | BBCH 21-<br>89                                  | a) 3<br>b) 3                                     | 7   | a) 0.45 kg/ha<br>b) 1.35 kg/ha  | a) 0.1485 kg/ha<br>b) 0.4455 kg/ha  | 200-<br>1000                      | 7             | <b>Registration holder: Gowan</b><br>Application in case of danger of infection and/or after warning service appeal.<br>Due to resistance management reasons the maximum number of applications will be restricted to 3. |
| 9                  | RO                 | Potatoes<br><i>Solanum tuberosum</i><br>(L.)<br>SOLTU                          | F   | potato late blight<br><i>Phytophthora infestans</i> (Mont. De Bary)<br>PHYTIN  | Foliar<br>spraying | BBCH 21-<br>89                                  | a) 3<br>b) 3                                     | 10  | a) 0.45 kg/ha<br>b) 1.35 kg/ha  | a) 0.1485 kg/ha<br>b) 0.4455 kg/ha  | 200-<br>1000                      | 7             | <b>Registration holder: Sipcarn Oxon</b>   |
| 10                 | SI                 | Potatoes<br><i>Solanum tuberosum</i><br>(L.)<br>SOLTU                          | F   | potato late blight<br><i>Phytophthora infestans</i> (Mont. De Bary)<br>PHYTIN  | Foliar<br>spraying | BBCH 21-<br>89                                  | a) 3<br>b) 3                                     | 7-10  | a) 0.45 kg/ha<br>b) 1.35 kg/ha  | a) 0.1485 kg/ha<br>b) 0.4455 kg/ha  | 200-600                           | 7             | <b>Registration holder: Gowan</b><br>Application in case of risk of infection and/or after warning alert.<br>Due to resistance management reasons the maximum number of applications will be restricted to 3.            |
| 11                 | UK                 | Potatoes<br><i>Solanum tuberosum</i>   | F   | potato late blight<br><i>Phytophthora infestans</i> (Mont. De  | Foliar<br>spraying | BBCH 21-<br>89                                  | a) 3<br>b) 3                                     | 7   | a) 0.45 kg/ha<br>b) 1.35 kg/ha  | a) 0.1485 kg/ha<br>b) 0.4455 kg/ha  | 200-<br>1000                      | 7             | <b>Registration holders: Gowan and Sipcarn Oxon</b><br>Due to resistance management  |

| 1                  | 2                  | 3  | 4   | 5  | 6                  | 7   | 8  | 9   | 10  | 11  | 12                                  | 13            | 14  |
|--------------------|--------------------|--|---|--|--------------------|---|--|---|---|---|-------------------------------------|---------------|---|
| Use-<br>No.<br>(e) | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop<br>destination /<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:<br>developmental stages<br>of the pest or pest<br>group) | Application        |   |  |   | Application rate  |   |                                     | PHI<br>(days) | Remarks:<br><br>e.g. g safener/synergist per ha <sup>(f)</sup>  |
|                    |                    |  |   |  | Method /<br>Kind   | Timing /<br>Growth stage<br>of crop &<br>season | Max. number<br>a) per use<br>b) per crop/ season | Min.<br>interval<br>between<br>applications<br>(days) | kg or L product /<br>ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | g or kg as/ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | Water<br>L/ha<br><br>min /<br>max   |               |   |
|                    |                    | (L.)<br>SOLTU  |   | Bary)<br>PHYTIN  |                    |   |  |   |   |   |                                     |               | reasons the maximum number<br>of applications will be<br>restricted to 3.   |
| 12                 | RO                 | Wine grapes<br><i>Vitis vinifera</i><br>(L.) ssp.<br><i>sativa</i><br>VITVI              | F   | grape downy mildew<br><i>Plasmopara viticola</i><br>PLASVI   | Foliar<br>spraying | BBCH 14-<br>89                                  | a) 3<br>b) 3                                     | 10  | a) 0.40 kg/ha<br>b) 1.2 kg/ha   | a) 0.132 kg/ha<br>b) 0.396 kg/ha  | 200-<br>1000                        | 28            | <b>Registration holder: Sipcam<br/>Oxon</b><br><br>Due to resistance management<br>reasons the maximum number<br>of applications will be<br>restricted to 3.  |
| 13                 | AT                 | Wine and<br>table grapes<br><i>Vitis vinifera</i><br>(L.) ssp.<br><i>sativa</i><br>VITVI | F   | grape downy mildew<br><i>Plasmopara viticola</i><br>PLASVI   | Foliar<br>spraying | BBCH 15-<br>89                                  | a) 3<br>b) 3                                     | 7   | a) 0.40 kg/ha<br>b) 1.2 kg/ha   | a) 0.132 kg/ha<br>b) 0.396 kg/ha  | 1000<br>(calcula-<br>tion<br>basis) | 28            | <b>Registration holder: Gowan</b><br><br>Application rates depending<br>on the crop density and the<br>crop development stages:<br>till BBCH 61: 0.08-0.2 kg/ha<br>till BBCH 71: 0.13-0.3 kg/ha<br>from BBCH 71: 0.2-0.4 kg/ha<br>Due to resistance management<br>reasons the maximum number<br>of applications will be<br>restricted to 3. |
| 14                 | HU                 | Wine grapes<br><i>Vitis vinifera</i><br>(L.) ssp.<br><i>sativa</i><br>VITVI              | F   | grape downy mildew<br><i>Plasmopara viticola</i><br>PLASVI   | Foliar<br>spraying | BBCH 57-<br>79                                  | a) 3<br>b) 3                                     | 7   | a) 0.45 kg/ha<br>b) 1.35 kg/ha  | a) 0.1485 kg/ha<br>b) 0.4455 kg/ha  | 300-800                             | 30            | <b>Registration holder: Sipcam<br/>Oxon</b><br><br>Due to resistance management<br>reasons the maximum number<br>of applications will be<br>restricted to 3.  |

| 1   | 2   | 3  | 4   | 5  | 6                  | 7   | 8  | 9   | 10  | 11  | 12                                | 13            | 14   |
|---|---|--|---|--|--------------------|---|--|---|---|---|-----------------------------------|---------------|--|
| Use-<br>No.<br>(e)  | Member<br>state(s)  | Crop and/<br>or situation<br><br>(crop<br>destination /<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:<br>developmental stages<br>of the pest or pest<br>group) | Application        |   |  |   | Application rate  |   |                                   | PHI<br>(days) | Remarks:<br><br>e.g. g safener/synergist per ha <sup>(f)</sup>   |
|   |   |  |   |  | Method /<br>Kind   | Timing /<br>Growth stage<br>of crop &<br>season | Max. number<br>a) per use<br>b) per crop/ season | Min.<br>interval<br>between<br>applications<br>(days) | kg or L product /<br>ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | g or kg as/ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | Water<br>L/ha<br><br>min /<br>max |               |  |
| 15  | SI  | Wine and<br>table grapes<br><i>Vitis vinifera</i><br>(L.) ssp.<br><i>sativa</i><br>VITVI | F   | grape downy mildew<br><i>Plasmopara viticola</i><br>PLASVI   | Foliar<br>spraying | BBCH 15-<br>89                                  | a) 3<br>b) 3                                     | 7-10  | a) 0.40 kg/ha<br>b) 1.2 kg/ha   | a) 0.132 kg/ha<br>b) 0.396 kg/ha  | up to<br>1000                     | 28            | <b>Registration holder: Gowan</b><br>Application in case of risk of<br>infection and/or after warning<br>alert.<br>Due to resistance management<br>reasons the maximum number<br>of applications will be<br>restricted to 3. |
| 47  | RO  | Tomatoes<br><i>Solanum</i><br><i>lycopersicum</i><br>(L.)<br>LYPES                       | F   | tomato late blight<br>Phytophthora<br>infestans (Mont. De<br>Bary)<br>PHYTIN   | Foliar<br>spraying | BBCH 13-<br>89                                  | a) 3<br>b) 3                                     | 7   | a) 0.4 kg/ha<br>b) 1.2 kg/ha  | a) 0.132 kg/ha<br>b) 0.396 kg/ha  | 500-800                           | 3             |  |
| <b>Zonal uses (field or outdoor uses, certain types of protected crops)</b> |   |  |   |  |                    |   |  |   |   |   |                                   |               |  |
| 1-<br>11  | PL, NL,<br>HU, DE,<br>AT, BE,<br>RO, SI,<br>CZ, IE,<br>UK | Potatoes   | F   | potato late blight<br>Phytophthora<br>infestans (Mont. De<br>Bary)<br>PHYTIN   | Foliar<br>spraying | BBCH 21-<br>89                                  | a) 3<br>b) 3                                     | 7-10  | a) 0.45 kg/ha<br>b) 1.35 kg/ha  | a) 0.1485 kg/ha<br>b) 0.4455 kg/ha  | 200-<br>1000                      | 7             | Due to resistance management<br>reasons the maximum number<br>of applications will be<br>restricted to 3.  |
| 12-<br>15   | RO, AT,<br>HU, SI   | Wine and<br>table grapes   | F   | grape downy mildew<br><i>Plasmopara viticola</i><br>PLASVI   | Foliar<br>spraying | BBCH 14-<br>89                                  | a) 3<br>b) 3                                     | 7-10  | a) 0.40-0.45<br>kg/ha<br>b) 1.35 kg/ha  | a) 0.132-0.1485<br>kg/ha<br>b) 0.4455 kg/ha   | 200-<br>1000                      | 28            | Due to resistance management<br>reasons the maximum number<br>of applications will be<br>restricted to 3.  |
| 47  | RO*   | Tomatoes<br><i>Solanum</i><br><i>lycopersicum</i><br>(L.)<br>LYPES                       | F   | tomato late blight<br>Phytophthora<br>infestans (Mont. De<br>Bary)<br>PHYTIN   | Foliar<br>spraying | BBCH 13-<br>89                                  | c) 3<br>d) 3                                     | 7   | a) 0.4 kg/ha<br>b) 1.2 kg/ha  | a) 0.132 kg/ha<br>b) 0.396 kg/ha  | 500-800                           | 3             |  |

| 1  | 2                  | 3  | 4   | 5  | 6                | 7   | 8  | 9   | 10  | 11  | 12                                | 13            | 14   |
|--|--------------------|--|---|--|------------------|---|--|---|---|---|-----------------------------------|---------------|--|
| Use-<br>No.<br>(e)   | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop<br>destination /<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:<br>developmental stages<br>of the pest or pest<br>group) | Application      |   |  |   | Application rate  |   |                                   | PHI<br>(days) | Remarks:<br><br>e.g. g safener/synergist per ha <sup>(f)</sup> |
|  |                    |  |   |  | Method /<br>Kind | Timing /<br>Growth stage<br>of crop &<br>season | Max. number<br>a) per use<br>b) per crop/ season | Min.<br>interval<br>between<br>applications<br>(days) | kg or L product /<br>ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | g or kg as/ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | Water<br>L/ha<br><br>min /<br>max |               |  |
| <b>Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)</b> |                    |  |   |  |                  |   |  |   |   |   |                                   |               |  |
|  |                    |  |   |  |                  |   |  |   |   |   |                                   |               |  |
| <b>Minor uses according to Article 51 (zonal uses)</b>   |                    |  |   |  |                  |   |  |   |   |   |                                   |               |  |
|  |                    |  |   |  |                  |   |  |   |   |   |                                   |               |  |
| <b>Minor uses according to Article 51 (interzonal uses)</b>  |                    |  |   |  |                  |   |  |   |   |   |                                   |               |  |
|  |                    |  |   |  |                  |   |  |   |   |   |                                   |               |  |

**Remarks table:**

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>(1) Numeration necessary to allow references</li> <li>(2) Use official codes/nomenclatures of EU</li> <li>(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)</li> <li>(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)</li> <li>(5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named</li> <li>(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench<br/>Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated</li> <li>(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</li> </ul> | <ul style="list-style-type: none"> <li>(8) The minimum and maximum number of application possible under practical conditions of use must be provided</li> <li>(9) Minimum interval (in days) between applications of the same product.</li> <li>(10) For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products</li> <li>(11) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".</li> <li>(12) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</li> <li>(13) PHI - minimum pre-harvest interval</li> <li>(14) Remarks may include: Extent of use/economic importance/restrictions</li> </ul> |
|--|--|

## 3.2 Efficacy data (KCP 6)

### Introduction

This document summarises the information related to the efficacy of the plant protection product GWN-9823 containing zoxamide and cymoxanil. Zoxamide was included into Annex I of Council Directive 91/414/EEC (Directive 2003/119/EC, 05<sup>th</sup> December 2003) and approved in accordance with Regulation (EC) No. 1107/2009 by Commission Implementing Regulation (EC) no. 540/2011 (25<sup>th</sup> May 2011). As an AIR 3 substance, zoxamide was re-evaluated at an EU level and was successfully re-approved by Commission Implementing Regulation (EU) no. 2018/692 (07<sup>th</sup> May 2018) that applies from 01<sup>st</sup> July 2018. Cymoxanil was included into Annex I of Council Directive 91/414/EEC (Directive 2008/125/EC, 19<sup>th</sup> December 2008) and approved in accordance with Regulation (EC) No. 1107/2009 by Commission Implementing Regulation (EC) no. 540/2011 (25<sup>th</sup> May 2011). As an AIR 4 substance, the original expiry date of cymoxanil has been extended to the 31<sup>st</sup> August 2021 by Commission Implementing Regulation (EU) no. 2017/195 (03<sup>rd</sup> February 2017).

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) no. 1107/2009, the conclusions of the renewal report on zoxamide (SANTE/10052/2018 Rev 2), as finalised in the Standing Committee on the Food Chain and Animal Health on 23<sup>rd</sup> March 2018, shall be taken into account.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on cymoxanil and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28<sup>th</sup> October 2008, with note taken of a revision in the review report on 09<sup>th</sup> July 2010, shall be taken into account.

There are no specific additional points that Member States need to pay particular attention to with regard to granting of authorisations of plant protection products containing zoxamide or cymoxanil relating to efficacy or other Section 3 data requirements.

Following the renewal of zoxamide, the objective of this Biological Assessment Dossier is to support the re-registration of GWN-9823 in the relevant EU Central Registration zone countries (Austria, Belgium, Germany, Hungary, Netherlands, Poland, Romania, Slovenia, United Kingdom) for use as a fungicide for control of Late blight (*Phytophthora infestans*) in potato and tomato and Downy mildew (*Plasmopara viticola*) in grapevine.

Since the previous submissions supporting current national authorisations of GWN-9823, there are no changes to any of the relevant national labels, with the exception of reductions in the maximum numbers of applications. For re-registration, the number of applications has been restricted to maximum 3 per crop and season for the purpose of resistance management. Data supporting current registrations of GWN-9823, with higher maximum numbers of applications, are fully supportive of demonstrating efficacy and crop safety of fewer applications and there are no new data requirements relating to efficacy or other Section 3 requirements since the previous authorisations. Therefore no further information is required or submitted and reference should be made to the existing labels and previously submitted efficacy and crop safety data supporting current authorisations. The only exceptions to this are requirements for a new evaluation of the current status regarding resistance (KCP 6.3) and for additional data to demonstrate the absence of adverse effects on transformation processes (KCP 6.4.4) for use on grapevine. For resistance, information on the current status regarding resistance risk relating to zoxamide and cymoxanil and the uses of GWN-9823, including summaries of new sensitivity data and updated resistance risk assessments, which is presented in this dossier.

Data from new processing and taint studies are summarised and submitted in support of further demonstrating the absence of adverse effects on transformation processes for grapevine.

The GAP table for all uses supported for the re-registration of GWN-9823 is included in **Błąd! Nie można odnaleźć źródła odwołania.** of this document.

### Description of the active substance

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-1:Details of the active substance**

| Active substances                       | zoxamide  | cymoxanil   |
|---|---|---|
| Concentration<br>(Unit: g/Kg or g/L...) | 330 g/L   | 330 g/L   |
| Chemical group                          | benzamide   | cianoacetamide-oxime                              |
| Mode of action                          | Arrests nuclear division through irreversible covalent interaction with $\beta$ -subunit of tubulin | Inhibits nucleic acid synthesis                   |
| Biological action                       | Non-systemic, residual preventive fungicide   | Local systemic, protective and curative fungicide |

### Description of the plant protection product

GWN-9823 is a Water Dispersible Granules (WG) formulation containing 330 g/Kg cymoxanil and 330 g/Kg zoxamide currently registered in EU Central registration zone countries (Austria, Belgium, Germany, Hungary, Netherlands, Poland, Romania, Slovenia, United Kingdom) under various trade names and approved for control of various fungal pathogens in a range a different crop types.

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-2** gives a summary of currently approved uses of GWN-9823 in EU Central Registration zone countries.

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-2: Currently approved uses of GWN-9823**

| Country     | Product name    | a.i. content                            | Formul'n type | National registration no. | Crops     | Targets | Max. no. appl'ns | Appl'n rate (product/ha) |
|-------------|-----------------|---|---------------|---------------------------|-----------|---------|------------------|--------------------------|
| Austria     | Reboot          | 330 zoxamide +<br>330 cymoxanil<br>g/Kg | WG            | 3640-0                    | Potato    | PHYTIN  | 4                | 0.45 Kg                  |
|             |                 |   |               |                           | Grapevine | PLASVI  | 4                | 0.4 Kg                   |
| Belgium     | Reboot          | 330 zoxamide +<br>330 cymoxanil<br>g/Kg | WG            | 10484P/B                  | Potato    | PHYTIN  | 6                | 0.45 Kg                  |
| Germany     | Reboot          | 330 zoxamide +<br>330 cymoxanil<br>g/Kg | WG            | 007692-00                 | Potato    | PHYTIN  | 6                | 0.45 Kg                  |
| Hungary     | Lieto           | 330 zoxamide +<br>330 cymoxanil<br>g/Kg | WG            | 04.2/762-1/2018           | Potato    | PHYTIN  | 4                | 0.45 Kg                  |
|             |                 |   |               |                           | Grapevine | PLASVI  | 4                | 0.45 Kg                  |
| Netherlands | Lieto           | 330 zoxamide +<br>330 cymoxanil<br>g/Kg | WG            | 15041                     | Potato    | PHYTIN  | 6                | 0.45 Kg                  |
|             | Reboot          |   |               | 15624                     |           |         |                  |                          |
| Poland      | Lieto 66<br>WG  | 330 zoxamide +<br>330 cymoxanil<br>g/Kg | WG            | R-163/2015                | Potato    | PHYTIN  | 6                | 0.45 Kg                  |
|             | Reboot 66<br>WG |   |               | R-164/2015                |           |         |                  |                          |
| Romania     | Lieto           | 330 zoxamide +<br>330 cymoxanil<br>g/Kg | WG            | 205PC/<br>20.10.2016      | Potato    | PHYTIN  | 5                | 0.45 Kg                  |
|             |                 |   |               |                           | Grapevine | PLASVI  | 5                | 0.4 Kg                   |
|             |                 |   |               |                           | Tomato    | PHYTIN  | 5                | 0.4 Kg                   |
| Slovenia    | Reboot          | 330 zoxamide +                          | WG            | U34330-                   | Potato    | PHYTIN  | 4                | 0.45 Kg                  |

| Country        | Product name | a.i. content                      | Formul'n type | National registration no. | Crops     | Targets | Max. no. appl'ns | Appl'n rate (product/ha) |
|----------------|--------------|-----------------------------------|---------------|---------------------------|-----------|---------|------------------|--------------------------|
|                |              | 330 cymoxanil g/Kg                |               | 90/2017/5                 | Grapevine | PLASVI  | 4                | 0.4 Kg                   |
| United Kingdom | Lieto        | 330 zoxamide + 330 cymoxanil g/Kg | WG            | 16703                     | Potato    | PHYTIN  | 6                | 0.45 Kg                  |
|                | Reboot       |                                   |               | 18202                     | Potato    | PHYTIN  | 6                | 0.45 Kg                  |

### Description of the target diseases

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-3:  
**Glossary of diseases mentioned in the dossier**

| EPPO code | Scientific name | Common name                   |
|-----------|-----------------|-------------------------------|
| PHYTIN    | Late blight     | <i>Phytophthora infestans</i> |
| PLASVI    | Downy mildew    | <i>Plasmopara viticola</i>    |

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-4: **Major / minor status of uses**

| Crop and/or situation | Crop status                        |       | Pests or group of pests controlled | Pest status                        |       |
|-----------------------|------------------------------------|-------|------------------------------------|------------------------------------|-------|
|                       | Major                              | minor |                                    | Major                              | minor |
| Grapevine             | AT, HU, RO, SI                     | -     | PLASVI                             | AT, HU, RO, SI                     | -     |
| Potato                | AT, BE, DE, HU, NL, PL, RO, SI, UK | -     | PHYTIN                             | AT, BE, DE, HU, NL, PL, RO, SI, UK | -     |
| Tomato                | RO                                 | -     | PHYTIN                             | RO                                 | -     |

### Compliance with the Uniform Principles

This overall assessment has been performed according to the uniform principles.

#### 3.2.1 Preliminary tests (KCP 6.1)

No new data are required or submitted.

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

No new data are required or submitted.

#### 3.2.3 Efficacy tests (KCP 6.2)

No new efficacy data are required or submitted.

|                   |   |
|-------------------|---|
| Comments of zRMS: | GWN-9823 (Reboot, Lieto) is a Water Dispersible Granules (WG) formulation containing the two active substances: zoxamide (330 g/L) and cymoxanil, (330 g/L). Zoxamide and cymoxanil are both included into Annex I of Council Directive 91/414/EEC and approved in accordance with Regulation (EC) No. 1107/2009 by Commission Implementing Regulation (EC) no. 540/2011. Zoxamide as an AIR 3 substance, was re-evaluated at an EU level and was successfully re-approved by Commission Implementing Regulation (EU) no. 2018/692 that applies from 1st July 2018. For cymoxanil (AIR 4 substance) the original expiry date has been extended to the 31st August 2021 by Commission Implementing Regulation (EU) no. 2017/195. |
|-------------------|---|

|  |   |
|--|---|
|  | <p>GWN-9823 is intended for the use as fungicide for control of Late blight (<i>Phytophthora infestans</i> – PHYTIN) in potato and tomato and Downy mildew (<i>Plasmopara viticola</i> – PLASVI) in grapevine. For the supported uses, the maximum label rates of GWN-9823 are 0.4 kg or 0.45 kg/ha, with a maximum of 3 applications per season, made within the crop growth stage range of BBCH 13-89 and with minimum intervals between applications of 7-10 days and applications made in water volumes of 200-1000 L/ha.</p> <p>The tested fungicide is approved for the use in the countries where re-registration is envisaged. The applicant have presented the current uses of the products containing the active substances cymoxanil (330 g/L) + zoxamide (330 g/L) in WG formulation (e.g. Reboot) in the Central Zone countries as well as the intended re-registration of those products. The intended re-registration is in the line with the current uses. Since the previous submissions supporting current national authorisations of GWN-9823, there are no changes to any of the relevant national labels, with the exception of reductions in the maximum numbers of applications. For re-registration, the number of applications has been restricted to maximum 3 per crop and per season for the purpose of resistance management. Data supporting current registrations of GWN-9823, with higher maximum numbers of applications, fully support the efficacy and crop safety of fewer applications and there are no new data requirements relating to the efficacy since the previous authorisations. As the intended re-registration remained the same as the previous one the applicant did not provided additional efficacy data for supporting GWN-9823 (Reboot 66 WG) registration.</p> <p>ZRMS agrees with the applicant and accept do not providing the efficacy data. The only data for the current status regarding resistance and the absence of adverse effects on transformation processes for use on grapevine were needed.</p> |
|--|---|

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

| EPPO guideline number       | Title                    |
|-----------------------------|--------------------------|
| EPPO guideline PP 1/213 (2) | Resistance Risk Analysis |

GWN-9823, a Water dispersible Granules (WG) formulation, containing 330 g/Kg of cymoxanil and 330 g/Kg of zoxamide, is intended for use as a fungicide for control of Late blight (*Phytophthora infestans*) in potato and tomato and Downy mildew (*Plasmopara viticola*) in grapevine.

For the supported uses, the maximum label rates of GWN-9823 are 0.4 Kg or 0.45 Kg product/ha, with a maximum of 3 applications per season, made within the crop growth stage range of 13-89 (BBCH) and with minimum intervals between applications of 7-10 days and applications made in water volumes of 200-1000 L/ha.

#### Mode of action

##### **Cymoxanil**

Cymoxanil is a cyanoacetamide-oxime fungicide with an unknown mode of action (MoA Group U; FRAC code 27). Whilst the primary mode of action and target site of cymoxanil is unknown, it has been proposed to inhibit nucleic acid synthesis, reduce membrane permeability and mycelial respiration and disrupt cysteine, glycine and serine synthesis. This leads to inhibition of mycelial and germ tube growth and reduced sporulation. Cymoxanil is rapidly taken up by the leaves and has local systemic activity, giving

preventative and curative control during the incubation period and prevents the appearance of disease symptoms on the crop.

### **Zoxamide**

Zoxamide belongs to the benzamide group of chemistry (toluamides) that inhibit mitosis and cell division by targeting  $\beta$ -tubulin assembly in mitosis (MoA Group B3; FRAC code 22), thereby preventing proper functioning of the cytoskeleton through direct interactions with  $\beta$ -tubulin polymerisation. By binding to and penetrating the cuticle, zoxamide inhibits the formation of zoospores within the sporangia, preventing fungal penetration of the host plant cells to give preventive control. Additionally, there is some evidence that zoxamide can reduce the number of viable motile zoospores<sup>1</sup>.

### **Mechanism of resistance**

#### **Cymoxanil**

Despite widespread use to control the disease in potatoes over a number of years, there are no recorded cases of Late blight (*Phytophthora infestans*) resistance to cymoxanil to date. Sensitivity testing of isolates of *Phytophthora infestans* for different fungicides by Gui-ning ZHU *et al.*, 2008 and P. Leroux *et al.*, 1987, found none to be resistant to cymoxanil.

Shifts in the sensitivity of downy mildew (*Plasmopara viticola*) of grapevine to cymoxanil has been reported in Italy and France (Guillino *et al.*, 1997). As the mode of action of cymoxanil is as yet unknown, the mechanism of this resistance has not been established.

#### **Zoxamide**

Laboratory studies conducted by Young *et al.*, 2001 unsuccessfully attempted to generate mutants of *Phytophthora capsici* and *Phytophthora infestans* with resistance to zoxamide by mycelial adaptation on fungicide-amended medium. The authors concluded that failure to isolate mutants resistant to zoxamide results from the diploid nature of the Oomycetes and the possibility that target-site mutations would produce a recessive phenotype. This indicates that the risk of a highly resistant pathogen population developing rapidly in the field is much lower for zoxamide compared to different mode of action single site inhibitors. In a more recent study, a laboratory generated zoxamide resistant strain of *Phytophthora capsici* was found to be controlled by two recessive, non-target site genes, and resistance required at least one pair of alleles to be homozygous<sup>2</sup>.

In the absence of any known cases of resistance to zoxamide, potential mechanisms of resistance have therefore not been identified.

### **Evidence of resistance**

#### **Cymoxanil**

According to the FRAC list of first confirmed cases of plant pathogenic organisms resistant to disease control agents (revised May 2020), there is no evidence of resistance against *Phytophthora infestans* in potato and to cymoxanil despite widespread use of this active substance in products approved and widely used for the control of this disease in EU countries and other parts of the world for a number of years.

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<sup>1</sup> Edmonds J, Young D (2004) Studies on the Mechanism of Tuber Blight Control by Zoxamide: Investigations into Effects on Sporangia and Zoospores of *Phytophthora*. PPO-Special Report no 10: 165

<sup>2</sup> Yang B, Chen L, Cai, M *et al.* (2014) Two Non-target Recessive Genes Confer Resistance to the Anti-Oomycete Microtubule Inhibitor Zoxamide in *Phytophthora capsici*. PLoS ONE 9(2):e89336  
doi:10.1371/journal.pone.0089336

Evidence of resistance to cymoxanil in *Plasmopara viticola* in grapevine was first reported in vineyards in Italy in 1997<sup>3</sup> and cases of reduced sensitivity to cymoxanil have been found to occur in other countries, including France and Portugal. However, with management of the resistance risk by use in mixtures and programs with active substances with other modes of action, products that include cymoxanil in co-formulation with other active substances continue to give good performance against *Plasmopara viticola* in the field even on populations shown to be less sensitive to cymoxanil in leaf disc assays and cymoxanil continues to effectively contribute to control of this disease despite shifts in sensitivity that may have occurred in some areas.

### **Zoxamide**

According to the FRAC list of first confirmed cases of plant pathogenic organisms resistant to disease control agents (revised May 2020), there is no evidence of resistance having developed in the field in any target diseases in potato, grapevine, tomato, Cucurbit crops (both edible and non-edible peel) or Allium crops to zoxamide MoA despite widespread use of this active substance in products approved and widely used for the control of these diseases in EU countries and other parts of the world for a number of years.

### **Cross resistance**

#### **Cymoxanil**

To date, there is no evidence of isolates of PLASVI with reduced sensitivity to cymoxanil having multiple resistance to other modes of action. There are no recorded cases of resistance of *Phytophthora infestans* to the MoA of cymoxanil and isolates of these pathogens with resistance to other modes of action do not exhibit reduced sensitivity to cymoxanil.

#### **Zoxamide**

With no recorded cases of resistance of fungal pathogens to zoxamide in the field, there is no cross resistance between zoxamide and ethaboxam, the only other fungicide within the same mode of action group (MoA code B3, FRAC Group 22), or with any other fungicidal mode of action groups, where resistance exists.

### **Sensitivity data**

#### **Cymoxanil**

Whilst no new data are summarised on sensitivity of target diseases to cymoxanil, products containing this active substance have been used over a number of years and continue to give consistent efficacy in the field. There is no evidence of a significant shift in sensitivity of PHYTIN to cymoxanil in the field and despite some evidence of reduced sensitivity to cymoxanil in populations of PLASVI in certain parts of southern Europe, products containing cymoxanil still provide effective control of this disease in grapevine.

#### **Zoxamide**

##### ***Phytophthora infestans* (PHYTIN)**

The sensitivity of *Phytophthora infestans* isolates to zoxamide has been continuously monitored across Europe before and following the testing in trials and subsequent approval of products containing this active substance.

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<sup>3</sup> Sensitivity to cymoxanil in populations of *Plasmopara viticola* in northern Italy. M. L. Gullino *et al*, 1997

The sensitivity of PHYTIN to zoxamide has been tested on a total of 426 isolates, either laboratory strains or from commercial crops and field trials across countries in Europe in 1 study carried out between 1993 and 2014.

Initially, sensitivity tests conducted between 1997 and 2003 were carried out using an *in vivo* potato leaf disc method, with the *in vivo* leaf disc method then tested alongside a more reliable *in vitro* poisoned agar technique from 2000-2004, with the latter then being the sole method used to test isolates from 2004 onwards and also 1 isolate tested in 1997.

A total of 33 laboratory isolates, 20 isolates from commercial crops and 326 isolates from field trials carried out across 13 European countries (Belgium, France, Germany, Greece, Republic of Ireland, Italy, the Netherlands, Poland, Portugal, Romania, Spain and the British Isles, including the United Kingdom and Jersey) were tested for sensitivity to zoxamide.

Data on zoxamide sensitivity of PHYTIN isolates across all monitoring studies carried out between 1993 and 2014 are summarised in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-1.

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-1: Summary of zoxamide sensitivity data for PHYTIN isolates treated with zoxamide compared to those from untreated plots in field trials or laboratory isolates never previously exposed to zoxamide**

| PHYTIN isolate type                          | Total no. of isolates | <i>In vivo</i> test method |                          | <i>In vitro</i> test method |                                       |
|--|-----------------------|----------------------------|--------------------------|-----------------------------|---------------------------------------|
|  |                       | No. of isolates            | Mean MIC (mg zoxamide/L) | No. of isolates             | Mean EC <sub>50</sub> (µg zoxamide/L) |
| Non-zoxamide treated (baseline lab isolates) | 33                    | 33                         | 3.4                      | 0                           | -                                     |
| Non-zoxamide treated                         | 187                   | 100                        | 8.2                      | 109                         | 19.3                                  |
| zoxamide treated                             | 112                   | 55                         | 9.4                      | 75                          | 18.3                                  |
| Not known                                    | 47                    | 17                         | 13.6                     | 37                          | 18.7                                  |

Across 33 isolates that had never previously been exposed to zoxamide and 172 isolates collected from field trials that were tested between 1997 and 2003 using the *in vivo* method, MIC values ranged from 0.5 to >40 mg zoxamide/L.

Across 221 isolates tested using the *in vitro* method, one in 1997 and all others between 2000 and 2014, EC<sub>50</sub> values ranged from 1 to 88 µg/L.

Between tests, the overall sensitivity of PHYTIN isolates from crops treated with zoxamide was no different to that of laboratory isolates and those from crops in untreated plots of field trials that had never been previously exposed to zoxamide.

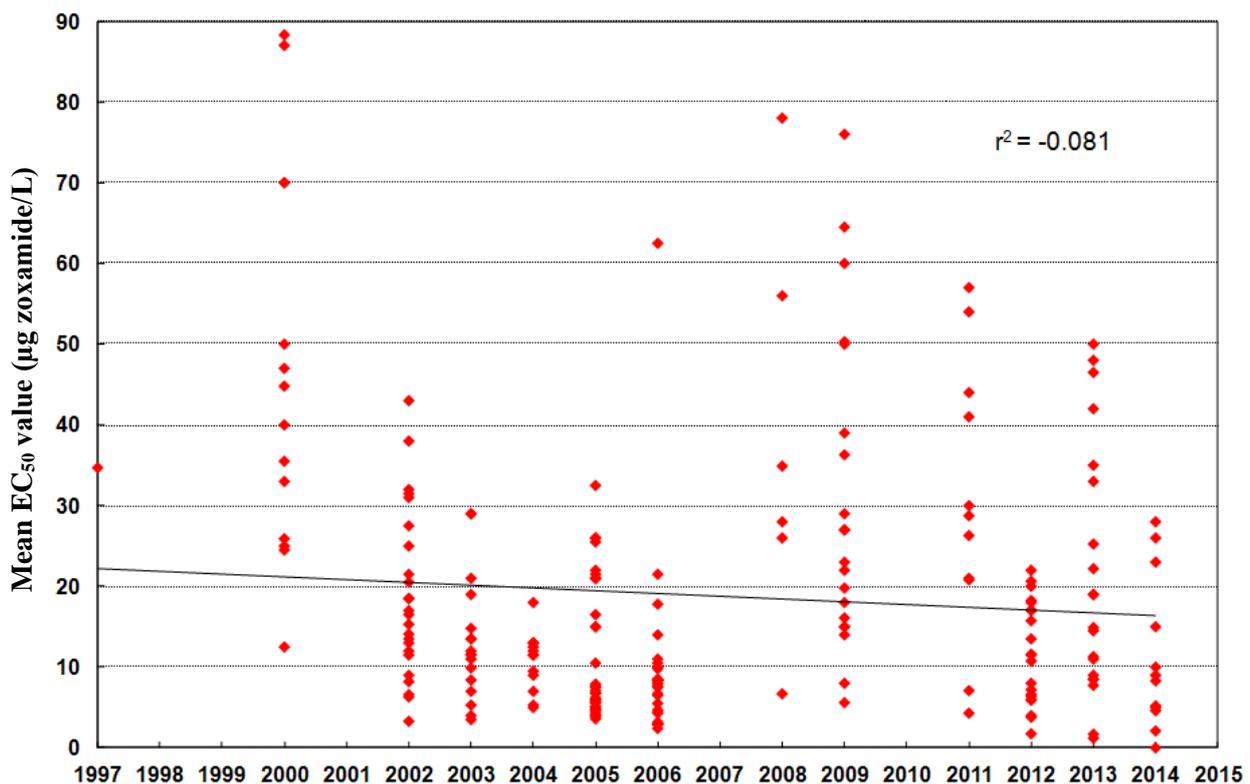
Zoxamide sensitivity data for PHYTIN isolates from screening carried out across Europe in 1997 (1 isolate) and between 2000 and 2014 using the more reliable *in vitro* test method are summarised by country in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-2, with data by year presented in graphical form in Figure Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-1.

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-2: Summary of zoxamide sensitivity data generated using the *in vitro* method for isolates collected across 12 European countries in 1997 (1 isolate) and between 2000 and 2014**

| Country of origin – PHYTIN isolates | Years collected  | No. of isolates tested ( <i>in vitro</i> method) | EC <sub>50</sub> values (µg zoxamide/L) |          |       |
|-------------------------------------|--|--|---|----------|-------|
|                                     |  |  | Mean                                    | Min-max  | S.D.  |
| Belgium                             | 2013   | 1  | 33.0                                    | -        | -     |
| France                              | 1997, 2000, 2002, 2003, 2004, 2005, 2006, 2009, 2011, 2012, 2013, 2014 | 62   | 19.6                                    | 4.3-87   | 13.84 |
| Germany                             | 2002, 2003, 2004, 2005, 2012   | 11   | 10.7                                    | 3.3-31.5 | 9.00  |

|                       |  |    |             |           |       |
|-----------------------|--|----|-------------|-----------|-------|
| Greece                | 2003, 2004, 2005                         | 12 | <b>8.9</b>  | 4-19      | 4.81  |
| Republic of Ireland   | 2009                                     | 6  | <b>43.3</b> | 15-64.5   | 20.86 |
| Netherlands           | 2000, 2004, 2006, 2009, 2014             | 9  | <b>32.4</b> | 4.4-70    | 26.06 |
| Poland                | 2003                                     | 4  | <b>6.5</b>  | 3.5-11.5  | 3.67  |
| Portugal              | 2000                                     | 3  | <b>25.1</b> | 24.5-25.9 | 0.71  |
| Romania               | 2004, 2005                               | 4  | <b>9.1</b>  | 5.8-13    | 3.72  |
| Spain                 | 2000                                     | 1  | <b>12.5</b> | -         | -     |
| UK – England          | 2000, 2003, 2005, 2006, 2012, 2013, 2014 | 50 | <b>14.2</b> | 1.2-88.3  | 14.89 |
| UK – Scotland         | 2005, 2006, 2013                         | 18 | <b>22.9</b> | 1.7-62.5  | 13.41 |
| UK - Wales            | 2000, 2006, 2009, 2011, 2013, 2014       | 24 | <b>20.9</b> | 0.98-76   | 21.64 |
| UK – Northern Ireland | 2003, 2008, 2009                         | 11 | <b>30.5</b> | 6.7-78    | 21.05 |
| Jersey                | 2005                                     | 5  | <b>5.9</b>  | 3.6-7.1   | 1.38  |

**Figure Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-1:**



**Zoxamide sensitivity (EC<sub>50</sub>, µg zoxamide/L) of *Phytophthora infestans* isolates over time**

Data shows that the variation in mean sensitivity levels between individual countries are within the normal sensitivity range for zoxamide and clearly demonstrate that there has been no consistent trend or shift in the sensitivity of PHYTIN isolates to zoxamide in the field over time across Europe.

Based on all presented sensitivity monitoring data and with no evidence of reduced efficacy of products containing zoxamide in the field, it can therefore be concluded that there have been no consistent changes in zoxamide sensitivity amongst field populations of PHYTIN since products containing this active substance were first introduced in Europe.

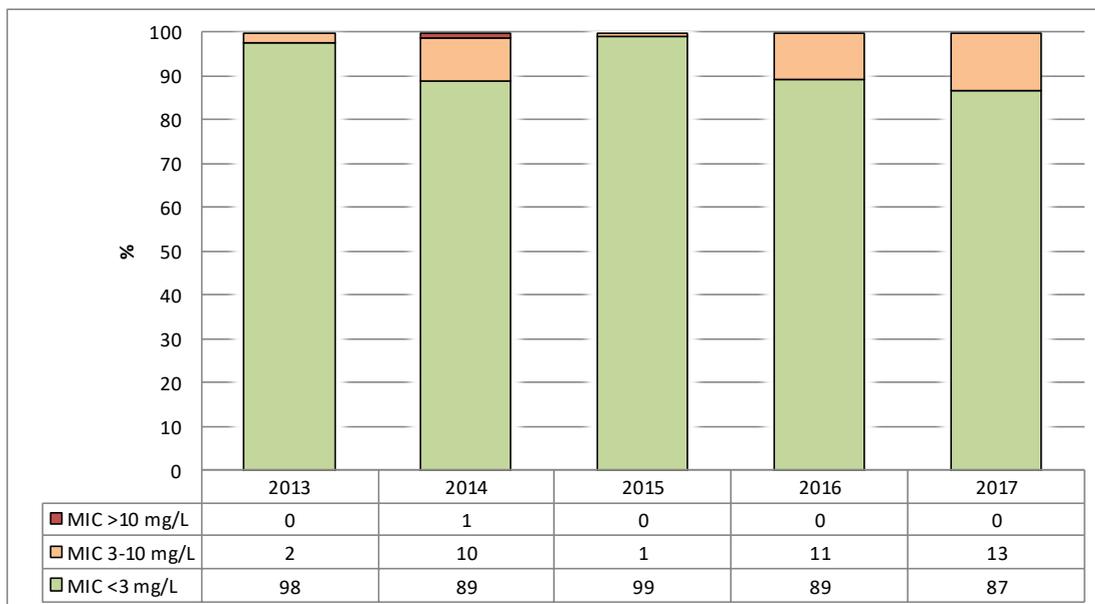
*Plasmopara viticola* (PLASVI)

The sensitivity of PLASVI to zoxamide has been tested on a total of 406 isolates from commercial crops and field trials across countries in Europe (343 from France, 13 from Italy, 16 from Portugal, 34 from Spain) in 7 studies carried out between 2013 and 2017.

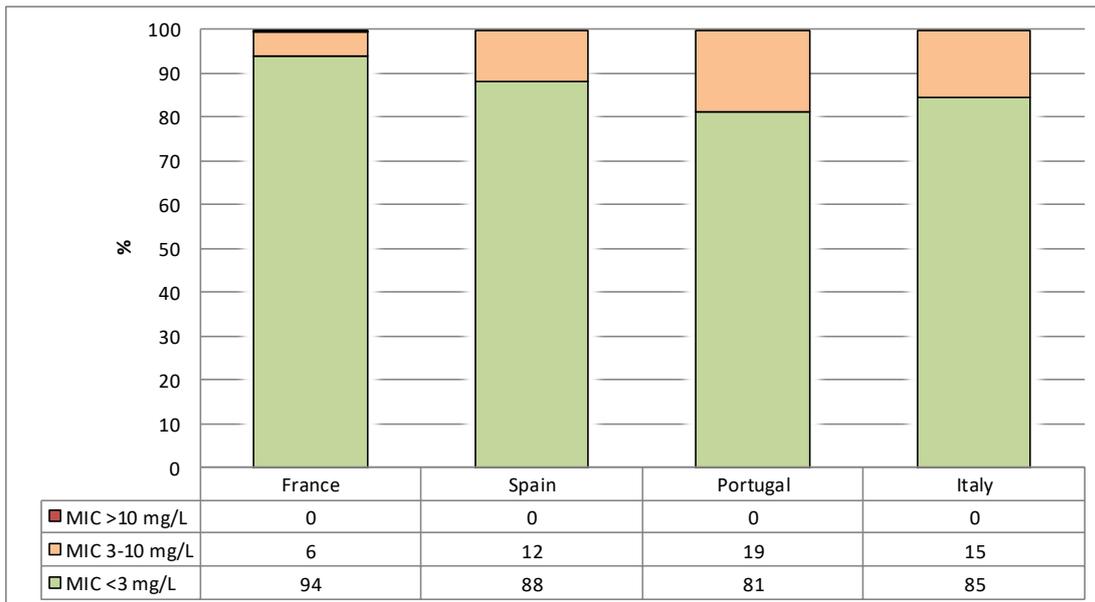
Fresh sporulations were produced from sampled leaves and sporangia collected into solution which were then inoculated onto Petri dishes and the sensitivity of each isolate tested at rates 1 and 3 mg zoxamide/L, with those that were not sensitive to 3 mg/L then tested at a 3 mg/L rate.

Percentage distributions of the isolates between those for which minimum inhibitory concentrations were <3, 3-10 and >10 mg zoxamide/L for the 406 isolates tested between 2013 and 2017 are presented in graphical form by year in Figure **Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.**-2 and by country in Figure **Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.**-3.

**Figure Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-2: Percentage distribution of PLASVI isolates between those with MIC values of <3, 3-10 and >10 mg zoxamide/L) by year based on data on 406 isolates tested in sensitivity monitoring studies carried out between 2013 and 2017 across 4 main grapevine growing countries in Europe (France, Italy, Portugal, Spain)**



**Figure Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-3: Percentage distribution of PLASVI isolates between those with MIC values of <3, 3-10 and >10 mg zoxamide/L) by country based on data on 406 isolates tested in sensitivity monitoring studies carried out between 2013 and**



2017 across 4 main grapevine growing countries in Europe



Of the total of 406 isolates tested across these studies carried out between 2013 and 2017, 377 (92.9%) were highly sensitive (MIC of <3 mg/L) to zoxamide and 28 (6.9%) were slightly less sensitive (MIC of 3-10 mg/L). Only 1 of the 406 isolates (0.2%) was indicated to more tolerant (MIC of >10 mg/L) and potentially exhibiting a level of resistance to zoxamide. This isolate was one of those sampled in 2014 from a vineyard in the Charentes region of France. The other 16 isolates from vineyards in the same region in 2014 and also those in the previous year (6 isolates) and following year (8 isolates) were all sensitive. It is therefore considered unlikely that the apparent higher tolerance to zoxamide of the single isolate with was attributable to developed resistance.

There was no consistent trend of the sensitivity of PLASVI isolates to zoxamide changing between 2013 and 2017, with the majority (87-99%) being highly sensitive (MIC of <3 mg/L) in each of the 5 years.

Although the numbers of isolates tested in each of the 4 countries was disproportionate, with far higher numbers tested in France than the other countries, the data shows no consistent differences in sensitivity between countries.

All sensitivity monitoring for PLASVI to zoxamide has been on isolates from across Southern EU Registration zone countries. However, it is considered that with grapevine being more widely grown in Southern countries and with no cases of reduced sensitivity to products containing zoxamide in Central EU Registration zone countries that sensitivity of isolates of PLASVI to zoxamide in relevant Central EU Registration zone countries (Austria, Hungary, Romania) will be similar or higher to that in Southern EU Registration zone countries

Based on all presented sensitivity monitoring data and with no evidence of reduced efficacy of products containing zoxamide in the field, it can therefore be concluded that there have been no consistent changes in zoxamide sensitivity amongst field populations of PLASVI between 2013 and 2017.

#### **Resistance risk assessment of unrestricted use pattern**

According to FRAC Pathogen Risk List<sup>©</sup> 2014, the risk of resistance developing to fungicides for the target diseases can be considered as **medium (2)** for PHYTIN and **high (3)** for PLASVI.

There is no evidence of resistance of any fungal pathogens to cymoxanil MoA, with the exception of evidence of a shift in sensitivity of PLASVI in some regions of southern Europe. The resistance risk relating to the MoA of cymoxanil is therefore considered to be **medium (4)**.

With the exception of resistance of PHYTCP to zoxamide that was characterised in a laboratory study and from which it was surmised that the potential for resistance occurring to this pathogen in the field was low to medium, there is no evidence of resistance to zoxamide MoA in any other fungal diseases despite widespread use of this active substance against a range of different pathogens in in EU countries and other parts of the world for a number of years. The risk of resistance relating to zoxamide is therefore considered to be **low-medium (1-4)**.

As GWN-9823 is a co-formulated mixture containing two active ingredients with two different modes of action and therefore, the overall risk arising from the use of such a co-formulation is considered to be **low-medium (2)** as they reduce the exposure and hence selection pressure on disease pathogens.

A more complex scheme of risk interactions, involving agronomic risk is determined by the geographical area in which the crop is grown, the crop variety, the expected disease pressure in that area and the disease control practices used, for example, application number and timing. The disease control practices are particularly important because these factors can be modified by growers and advisors and are also influenced by precautionary statements on fungicide labels. Thus use of resistant varieties, crop-rotation, following good agronomic practice and maintaining plant hygiene, reduces the risk of resistance arising. Season-long spray programs are used for control of target diseases of GWN-9823, in which fungicides with

different modes of action are used in sequences and mixtures in commercial practice. The risk of resistance relating to agronomic practices is therefore considered as **medium (0.5)**.

Based on available criteria, the overall risk of resistance arising from an 'unrestricted use pattern' of GWN-9823 is therefore **low or medium (2-3)** with respect to target diseases (PHYTIN, PLASVI).

### **Management strategy**

The risk management strategy to reduce the risk of resistance developing to zoxamide from the use of GWN-9823 is based on Good Agricultural Practices (GAP) and current measures advocated by FRAC.

The risk management strategy to reduce the risk of resistance developing to directly from the use of GWN-9823 is specifically based on:

- The combination of 2 active substances with different modes of action in the co-formulation
- Application at the label rates for each use, as those giving effective control
- Maximum numbers of applications per season of 3 in all crops
- Use in tank mixture with other fungicides with different modes of action and as part of spray programs in sequences with other fungicides

This should ensure there is no adverse shift in the sensitivity of the target fungal pathogens to the active ingredient included in the product and the overall risk of resistance developing to zoxamide is therefore considered to be low and acceptable for all uses when GWN-9823 is applied according to label recommendations.

In addition to the preventive management of risk of resistance, the applicant is committed to maintaining its monitoring (investigation of claims of reduced efficacy and suspected resistance, followed by sensitivity testing) and to reporting any developments related to the efficacy of GWN-9823 based on resistance arising to cymoxanil or zoxamide to the relevant organisations.

|                   |   |
|-------------------|---|
| Comments of zRMS: | <p><b><u>RESISTANCE</u></b></p> <p>Fungicides containing the active substances cymoxanil and zoxamide (both 330 g/kg) are registered in some countries of EU Central registration zone under various trade names (Reboot, Lieto) and approved for control of various fungal pathogens in a range of different crop types. In dRR applicant described the mode of action (MoA), mechanism of resistance, evidence of resistance and cross resistance of both active substances, included in a tested product (GWN-9823). According to FRAC Pathogen Risk List 2019, the risk of resistance developing to fungicides for the target diseases can be considered as medium for PHYTIN and high for PLASVI.</p> <p><b><u>Cymoxanil</u></b></p> <p>There is no evidence for resistance or a significant change in sensitivity of <i>Phytophthora infestans</i> (PHYTIN) to cymoxanil in potato. The some cases of reduced sensitivity of <i>Plasmopara viticola</i> (PLASVI) to cymoxanil in certain parts of southern Europe were noted. The evidence of PLASVI resistance to cymoxanil in grapevine was first reported in vineyards in Italy in 1997 and another cases of reduced sensitivity to cymoxanil have been found in other countries, including France and Portugal. However, the use of this substance in mixtures and in programs with another active substances having different modes of action, allows to effectively control of this disease, despite reduced sensitivity in some areas.</p> <p><b><u>Zoxamide</u></b></p> <p><i>Phytophthora infestans</i>. According to the FRAC list there is no evidence of resistance having developed in the field in any diseases in potato, grapevine, tomato, <i>Cucurbit</i> crops</p> |
|-------------------|---|

|  |
|--|
| <p>(edible and non-edible peel) or <i>Allium</i> crops to zoxamide MoA despite widespread use of this active substance in products approved and widely used for the control of these diseases in EU countries and other parts of the world for a number of years.</p> <p>The sensitivity of <i>Phytophthora infestans</i> isolates to zoxamide has been continuously monitored across the Europe. Besides the continuous monitoring the sensitivity of PHYTIN to zoxamide on a total of 426 isolates: 33 laboratory isolates, 20 isolates from commercial crops and 326 isolates from field trials has been tested across 13 European countries, between 1993 and 2014. The sensitivity of isolates that were not exposed to zoxamide (33) and isolates collected from field trials treated with the tested product (172) were also determined by in vivo method, in 1997-2003. It was shown that the overall sensitivity of PHYTIN isolates from the crops treated with zoxamide did not differ from those from laboratory isolates and from untreated field crops.</p> <p>Based on all presented sensitivity monitoring data and with no evidence of reduced efficacy of products containing zoxamide in the field, it can be concluded that there have been no changes in zoxamide sensitivity among field populations of PHYTIN since products containing this active substance were first introduced in the Europe.</p> <p><b><i>Plasmopara viticola</i></b>. The sensitivity of PLASVI to zoxamide has been tested between 2013 and 2017 on a total of 406 isolates from commercial crops and field trials across countries in Europe. Based on all presented sensitivity monitoring data and with no evidence of reduced efficacy of products containing zoxamide in the field, it can therefore be concluded that there have been no consistent changes in zoxamide sensitivity among field populations of PLASVI.</p> <p>The ZRMS have concluded that resistance of pathogens to zoxamide and cymoxanil has been properly described, as well as accepted the data of tests with pathogen isolates and also the applicant's explanation of the lack or little risk of resistance developing in tested pathogens. ZRMS recommends re-registration of the GWN-9823 product in accordance with the proposal presented by the applicant. However, the resistance management strategy should be included into the product label, regardless the occurrence and the pathogens sensitivity to the active substances of the GWN-9823. All users of this product should follow this strategy.</p> |
|--|

### **3.4 Adverse effects (KCP 6.4)**

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

No new data on safety on treated crops are required or submitted.

#### **3.4.2 Effects on yield of treated plants or plant products (KCP 6.4.2)**

No new data on effects on yield are required or submitted.

#### **3.4.3 Effects on quality of plants and plant products (KCP 6.4.3)**

No new data on quality of plants and plant products are required or submitted.

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

The absence of adverse effects on processing procedures and taints, relevant to grapevine, potato and tomato, following applications of GWN-9823 according to label recommendations have been demonstrated by previously submitted data and proven through commercial use over a number of years.

Furthermore, new processing (vinification, raisins) and subsequent taint tests have been carried out on fruit sampled at commercial harvest following 3 or 4 applications of GWN-9823 at a rate of 0.4 Kg product/ha on 5 trials carried out in 2015 and 2017 in grapevine for the specific purpose of generating samples for processing and taint tests.

Of these trials, 2 were carried out in the Maritime climatic zone (Austria) and 3 were carried out in the Mediterranean climatic zone (Greece).

The 0.4 Kg product/ha rate tested in these trials is the maximum label rate for use on grapevine in some countries and sufficiently close to the higher maximum label rate of 0.45 Kg product/ha in other countries for the data generated in these trials to be fully supportive of demonstrating the absence of adverse effects on processing and taints when GWN-9823 is applied at label rates in all relevant countries.

All trials were carried out by organisations that are officially recognised as competent to carry out efficacy testing in accordance with Regulation (EU) 284/2013 by the authorities in the relevant countries.

Processing and taint testing phases of the studies were carried out by organisations with relevant accreditation.

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 3 do tekstu, który ma się tutaj pojawić.-1:Details on trial methodology (trials generating samples for processing and/or taint testing)**

|                            |   |   |
|----------------------------|---|---|
| <b>Guidelines</b>          | General guidelines                            | EPPO PP1/152 (4), EPPO PP1/181 (3/4), EPPO PP1/135 (4)                      |
|                            | Specific guidelines                           | EPPO PP1/242 (1/2), EPPO PP 1/268 (1), ISO 4120:2004, AFNOR V 09-013        |
| <b>Experimental design</b> | Plot design                                   | RCBD (5)  |
|                            | Plot size                                     | 17.5-107.8 m <sup>2</sup>   |
|                            | Number of replications                        | 4   |
| <b>Crop</b>                | Trials per crop                               | Grapevine (5)   |
|                            | Varieties                                     | Zweigelt (1), Blauer Portugieser (1), Soultanina (2), Corinthian raisin (1) |
| <b>Applications</b>        | Number  | 3 (3), 4 (2)  |
|                            | Application intervals                         | 7-10 days   |
|                            | Pre-harvest intervals                         | 27-28 days  |
|                            | Crop stage (BBCH) <sup>§</sup> at application | 72-89 (BBCH)  |
|                            | Spray volumes                                 | 500 L/ha (2), 700 L/ha (1), 1000 L/ha (2)                                   |
| <b>Testing</b>             | Processing                                    | Vinification (2), raisin production (1)                                     |
|                            | Taints  | Red wine (2), raisin (1), fresh table grape (2)                             |

For potential effects on processing and taint testing, grapes sampled from GWN-9823 treated plots were compared to either grapes from untreated control plots (vinification and wine taint tests) or grapes sampled from plots treated with standard reference products applied at label rates (raisin production and taint tests, fresh table grape taint tests).

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 3 do tekstu, który ma się tutaj pojawić.-2: Presentation of reference standards used in trials in grapevine (trials to produce samples for processing and taint testing)**

| Reference standard | Country where the product is registered <sup>(1)</sup> | Authorization number | Active substances      | Formulation         |                       | Registered application Rate (/ha) <sup>(3)</sup> | Application rate in trials (per treatment) | Remark <sup>(4)</sup> |
|--------------------|--|----------------------|------------------------|---------------------|-----------------------|--|--|-----------------------|
|                    |  |                      |                        | Type <sup>(2)</sup> | Concentration of a.s. |  |  |                       |
| Equation Pro       | EL   | 60522                | cymoxanil + famoxadone | WG                  | 300 + 225 g/Kg        | 0.4 Kg   | 0.4 Kg                                     |                       |

| Reference standard | Country where the product is registered <sup>(1)</sup> | Authorization number | Active substances                        | Formulation         |                       | Registered application Rate (/ha) <sup>(3)</sup> | Application rate in trials (per treatment) | Remark <sup>(4)</sup> |
|--------------------|--|----------------------|--|---------------------|-----------------------|--|--|-----------------------|
|                    |  |                      |  | Type <sup>(2)</sup> | Concentration of a.s. |  |  |                       |
| Valbon             | EL   | 60219                | benthiavali carb<br>isopropyl + mancozeb | WG                  | 17.5 +<br>700 g/Kg    | 2.0 Kg   | 2.0 Kg                                     |                       |

It is reasonable to consider that the potential for a product to have impact on processing procedures or to cause taints of the harvested commodity is sufficiently similar under different climatic conditions for the data generated in trials carried out in both the Maritime and Mediterranean climatic zones to be supportive of demonstrating that GWN-9823 has no adverse impact on processing and causes no taints under conditions in all climatic zones relevant to the Central Registration zone.

On all trials, multiple (3 or 4) applications of the treatments were made when crops were within the growth stage range of 72-89 (BBCH) and therefore representative of the label growth stage range of 14-89 (BBCH) for the application of GWN-9823. Intervals between applications were within the range of 7-10 days and therefore representative of the minimum label interval of 7-10 days and commercial practice for multiple applications spray programs for control of Downy mildew (*Plasmopara viticola*) in grapevine.

Across trials, treatments were applied in water volumes within the range of 500-1000 L/ha and therefore fully representative of the proposed 200-1000 L/ha range for the application of GWN-9823.

Sampling of the bunches was carried out 27-28 days after the final application of the treatments on all trials, which corresponded with normal commercial harvest when the crop growth stage was at 89 (BBCH).

Fermentation/vinification – red wine was produced from a minimum 130-140 Kg sample of grapes per treatment. Grapes were weighed, crushed and stemmed and the must then placed in fermentation tanks and Instantenzyme added. Chaptalization (addition of sugar) was carried out for each sample to start the alcoholic fermentation process, with vinification carried out both with and without yeast added for the treatment and the untreated control. This was followed by addition of the bacteria to the malolactic fermentation in 34 litres glass-balloons. Once the fermentation was finished the wine was filtered and sulfited, then after approximately two months the wine was bottled and free SO<sub>2</sub> was adjusted.

Raisin production – raisins were produced from minimum 2 Kg samples of grapes per treatment. Raisins were produced from the fruit following standard production methods, including stemming, pre-treatment with hot lye and drying.

Fresh table grapes – 2 Kg of grapes were sampled per treatment for taint testing

Raisin and fresh table grape samples were subjected to triangle taint tests carried out in accordance with EPPO standard 1/242(1/2) and ISO 4120:2004 and wine samples were subjected to 'unstructured tasting diagram'.

### **Quality assessments on fresh grapes**

Evaluations of quality parameters of the fruit were carried out on a total of 3 trials conducted in 2015 specifically to generate samples of grapes for processing and/or taint tests following multiple (3) applications of GWN-9823 at a rate of 0.4 Kg product/ha in the absence of disease at levels likely to affect crop yield and quality in grapevine. All three trials were carried out within the Mediterranean climatic zone in Greece.

Across these trials, GWN-9823 was applied at multiple (3) timings when crop growth stages were within the range of 72-85 (BBCH). Intervals between applications were within the range of 7-10 days.

A summary of mean fruit quality data across these 3 trials is given in Table **Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 3 do tekstu, który ma się tutaj pojawić.-3**.

Multiple (3) applications of GWN-9823 at 0.4 Kg product/ha, caused no consistent differences in quality of the fruit at commercial harvest in terms of BRIX content (all 3 trials) and acid content (2 of the trials), compared to standard reference products applied at label rates, on any of these trials.

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 3 do tekstu, który ma się tutaj pojawić.-3: Overall summary of mean fruit quality data following multiple applications of GWN-9823 at 0.4 Kg product/ha across 3 trials on grapevine, Mediterranean climatic zone**

|  | No. of trials |                   | Mean              |                             |             |
|--|---------------|-------------------|-------------------|-----------------------------|-------------|
|  |               |                   | GWN-9823          | Standard reference products |             |
|  |               |                   |                   | Equation Pro                | Valbon      |
|  |               | 0.4 Kg product/ha | 0.4 Kg product/ha | 2.0 Kg product/ha           |             |
| <b>BRIX content – processing trials</b>          |               |                   |                   |                             |             |
| <b>GWN-9823</b><br>- all trials                  | 3             | <b>Mean</b>       | <b>17.7</b>       | -                           | -           |
|  |               | Min-Max           | 15.7-19.3         | -                           | -           |
| Direct comparison to<br><b>Equation Pro</b>      | 1             | <b>Mean</b>       | <b>18.2</b>       | <b>15.5</b>                 | -           |
| Direct comparison to<br><b>Valbon</b>            | 2             | <b>Mean</b>       | <b>17.5</b>       | -                           | <b>18.2</b> |
|  |               | Min-Max           | 15.7-19.3         | -                           | 15.6-20.8   |
| <b>Acidity content (g/L) – processing trials</b> |               |                   |                   |                             |             |
| <b>GWN-9823</b><br>- all trials                  | 3             | <b>Mean</b>       | <b>6.4</b>        | -                           | -           |
|  |               | Min-Max           | 5.9-7.0           | -                           | -           |
| Direct comparison to<br><b>Equation Pro</b>      | 1             | <b>Mean</b>       | <b>5.9</b>        | <b>8.0</b>                  | -           |
| Direct comparison to<br><b>Valbon</b>            | 1             | <b>Mean</b>       | <b>7.0</b>        | -                           | <b>6.6</b>  |

### **Vinification and wine quality**

Processing (vinification) and subsequent taint testing of the wine has been carried out on fruit sampled from a total of 2 trials carried out in 2017 on grapevine. Both trials were carried out in the Maritime climatic zone (Austria). The cultivar type and wine production was for red wine from the fruit on both trials.

On these 2 trials, multiple applications (4) were made of GWN-9823 at 0.4 Kg product/ha. Intervals between applications were within the range of 7-9 days and crop growth stages at the final application timings were within the range of 85-89 (BBCH). Intervals between the final application and sampling were 27 days on 1 trial and 28 days on the other trial.

### **Measurements of the processing procedures**

A summary of key processing and wine quality parameters from these 2 trials is given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 3 do tekstu, który ma się tutaj pojawić.-4.

Multiple applications of GWN-9823 at a label rate of 0.4 Kg product/ha had no consistent or marked effects on quality parameters of the fruit following sampling, key measurements of the vinification processes or quality parameters of the wine produced from fruit sampled 27-28 days after the last application, compared to processing and wine quality parameters with fruit sampled from the untreated control plots on either trial.

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 3 do tekstu, który ma się tutaj pojawić.-4: Key processing and wine quality parameter data following the production of red wine from grapes sampled following multiple applications of GWN-9823 at 0.4 Kg product/ha on grapevine**

| Trial No. (Variety)   | GOW17-VITVI-F01 (Zweigelt)      |                              |                        |                     | GOW17-VITVI-F02 (Blauer Portugieser) |                              |                        |                     |
|---|---------------------------------|------------------------------|------------------------|---------------------|--------------------------------------|------------------------------|------------------------|---------------------|
| Final application – sampling interval (days)                | 27                              |                              |                        |                     | 28                                   |                              |                        |                     |
| Measured parameter (unit)                                   | Untreated control without yeast | Untreated control with yeast | GWN-9823 without yeast | GWN-9823 with yeast | Untreated control without yeast      | Untreated control with yeast | GWN-9823 without yeast | GWN-9823 with yeast |
| <b>Analytical composition of fresh musts</b>                |                                 |                              |                        |                     |                                      |                              |                        |                     |
| °KMW  | 18.0                            | 18.0                         | 18.2                   | 18.2                | 15.2                                 | 15.2                         | 15.3                   | 15.3                |
| % acid  | 6.6                             | 6.6                          | 6.5                    | 6.5                 | 6.0                                  | 6.0                          | 6.0                    | 6.0                 |
| pH value  | 3.45                            | 3.45                         | 3.45                   | 3.45                | 3.37                                 | 3.37                         | 3.40                   | 3.40                |
| Tartaric acid   | 6.2                             | 6.2                          | 6.1                    | 6.1                 | 5.1                                  | 5.1                          | 5.0                    | 5.0                 |
| Malic acid  | 3.5                             | 3.5                          | 3.2                    | 3.2                 | 2.8                                  | 2.8                          | 2.8                    | 2.8                 |
| Nitrogen (mg/L)   | 220                             | 220                          | 190                    | 190                 | 150                                  | 150                          | 175                    | 175                 |
| g yeast   | 0                               | 30                           | 0                      | 30                  | 0                                    | 30                           | 0                      | 30                  |
| Chaptalisation to °KMW                                      | +1.5                            | +1.5                         | +1.5                   | +1.5                | +3.5                                 | +3.5                         | +3.5                   | +3.5                |
| <b>Malolactic fermentation</b>                              |                                 |                              |                        |                     |                                      |                              |                        |                     |
| Latent period of spontaneous malolactic fermentation (days) | 7                               | 7                            | 7                      | 7                   | 6                                    | 6                            | 6                      | 6                   |
| Malolactic fermentation duration after inoculation (days)   | 74                              | 74                           | 74                     | 74                  | 81                                   | 81                           | 81                     | 81                  |
| <b>Analysis of wine following bottling</b>                  |                                 |                              |                        |                     |                                      |                              |                        |                     |
| Density   | 0.9930                          | 0.9929                       | 0.9932                 | 0.9927              | 0.9932                               | 0.9930                       | 0.9934                 | 0.9929              |
| Alcohol content (% vol.)                                    | 12.8                            | 12.8                         | 12.5                   | 12.9                | 12.6                                 | 12.4                         | 12.7                   | 12.6                |
| Reduced sugar (g/L)   | 0.9                             | 0.7                          | 0.9                    | 0.7                 | 0.9                                  | 0.8                          | 1.0                    | 0.8                 |
| Titrateable acid  | 4.8                             | 4.9                          | 4.9                    | 5.0                 | 5.6                                  | 5.6                          | 5.5                    | 5.4                 |
| pH  | 3.5                             | 3.5                          | 3.5                    | 3.5                 | 3.4                                  | 3.3                          | 3.4                    | 3.4                 |
| Volatile acid   | 0.4                             | 0.4                          | 0.5                    | 0.5                 | 0.3                                  | 0.3                          | 0.4                    | 0.3                 |
| Tartaric acid   | 1.9                             | 2.0                          | 1.9                    | 2.0                 | 2.4                                  | 2.5                          | 2.4                    | 2.5                 |
| Malic acid  | 0.2                             | 0.1                          | 0.1                    | 0.1                 | 0.3                                  | 0.3                          | 0.3                    | 0.3                 |
| Lactic acid   | 1.5                             | 1.5                          | 1.5                    | 1.4                 | 1.1                                  | 1.2                          | 1.2                    | 1.2                 |
| Glucose   | 24.1                            | 24.0                         | 23.8                   | 23.8                | 24.1                                 | 22.9                         | 24.8                   | 23.4                |
| Total-extract   | 25.0                            | 24.7                         | 24.7                   | 24.5                | 25.0                                 | 23.7                         | 25.8                   | 24.2                |

## Taint tests

Sensory qualities of young (soon after bottling for both trials) wine produced from fruit sampled following applications of GWN-9823 were compared to that produced from fruit sampled from untreated control plots by 'unstructured tasting diagram' on samples from both trials.

The sensory qualities (colour, taste, smell, overall impression) of wine produced from grapes sampled following multiple applications of GWN-9823 at 0.4 Kg product/ha, with fermentation both with and without cultured yeast, were found not to be consistently or significantly different to those of wine produced from grapes sampled from the untreated control plots on either of the trials.

## Raisin production

Processing (raisin production) and subsequent taint testing of the raisins has been carried out on fruit sampled from a total of 1 trial carried out in 2015 on grapevine. This trial was carried out within the Mediterranean climatic zone in Greece.

On this trial, multiple (3) applications were made of GWN-9832 at 0.4 Kg product/ha. Intervals between applications were within the range of 9-10 days and crop growth stage at the final application timings was at 81-85 (BBCH). The interval between the final application and sampling was 28 days.

## Measurements of the quality of the processed raisins

A summary of key quality parameter data for raisins from fruit sampled from this 1 trial is given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 3 do tekstu, który ma się tutaj pojawić.-5.

No problems or effects on raisin production processes or differences between that with fruit sampled following applications of GWN-9823 and that with fruit sampled following applications of the standard reference product (Valbon) were noted.

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 3 do tekstu, który ma się tutaj pojawić.-5: Key raisin quality parameter data following their production from grapes sampled following multiple applications of GWN-9823 at 0.4 Kg product/ha on grapevine**

| Treatment  | Size     | Colour    | Weight/100mL | Rotten % |
|------------|----------|-----------|--------------|----------|
| Electis CX | 4.1-8 mm | red-black | 37.33 g      | 0        |
| Valbon     | 4.1-8 mm | red-black | 37.04 g      | 0        |

## Taint tests

A summary of the triangle taint test results on raisins produced from grapes sampled from this trial is given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 3 do tekstu, który ma się tutaj pojawić.-6.

The gustatory qualities of raisins produced from grapes sampled following multiple applications of GWN-9823 at 0.4 Kg product/ha were not significantly different to those produced from grapes sampled following applications of the standard reference product on this trial.

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 3 do tekstu, który ma się tutaj pojawić.-6: Triangle taint test results on raisins produced from fruit sampled following 3 applications of GWN-9823 at 0.4 Kg product/ha on 1 trial on grapevine**

| Trial No.    | Variety           | Final application – sampling interval (days) | Taint test comparison | No. of assessors | No. of correct answers | Significant difference at 95% confidence interval |
|--------------|-------------------|--|-----------------------|------------------|------------------------|---|
| GWN-15-GR-35 | Corinthian raisin | 28   | GWN-9823 to Valbon    | 19               | 5                      | No  |



## **Fresh table grapes**

### **Taint tests**

Taint testing has been carried out on fresh table grapes sampled from a total of 2 trials carried out in 2015 on grapevine. Both trials were carried out in the Mediterranean climatic zone in Greece.

On both trials, multiple (3) applications were made of GWN-9823 at 0.4 Kg product/ha. Intervals between applications were within the range of 7-10 days and crop growth stage at the final application timings was within the range of 75-81 (BBCH). The interval between the final application and sampling was 28 days on both trials.

A summary of the triangle taint test results on fresh table grapes sampled from these 2 trials is given in **Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 3 do tekstu, który ma się tutaj pojawić.-7**.

The gustatory qualities of fresh table grapes sampled following multiple applications of GWN-9823 at 0.4 Kg product/ha were not significantly different to those of grapes sampled following applications of standard reference products on either of the trials.

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 3 do tekstu, który ma się tutaj pojawić.-7: Triangle taint test results on fresh grapes sampled following 3 applications of GWN-9823 at 0.4Kg product/ha on 2 trials on grapevine**

| Trial No.      | Variety    | Final application – sampling interval (days) | Taint test comparison    | No. of assessors | No. of correct answers | Significant difference at 95% confidence interval |
|----------------|------------|--|--------------------------|------------------|------------------------|---|
| GR15GWN392SD01 | Soultanina | 28   | GWN-9823 to Equation Pro | 18               | 8                      | No  |
| GWN-15-GR-34   | Soultanina | 28   | GWN-9823 to Valbon       | 18               | 8                      | No  |

### **Overall conclusions**

A total of 5 trials have been carried out in 2015 and 2017 in grapevine to produce samples of fruit for processing and taint testing following multiple application of GWN-9823. Of these trials, 2 were carried out within the Maritime climatic zone (both in Austria) and 3 were carried out within the Mediterranean climatic zone (all in Greece). Vinification and taint testing of wine was carried out on fruit sampled from 2 trials, processing and taint testing of raisins was carried out on fruit sampled from 1 trial and taint testing of fresh grapes was carried out on fruit sampled from the other 2 trials.

Overall, multiple applications of GWN-9823 at 0.4 Kg product/ha had no consistent effects on wine or raisin production processes and caused no significant taints of wine, raisins or fresh table grapes, compared to the untreated control or approved standard reference products applied according to label recommendations, on fruit sampled from any of these trials.

Based on the presented data, it is therefore reasonable to conclude that GWN-9823 applied at maximum label rates of 0.4-0.45 Kg product/ha and according to other label recommendations on grapevine has no adverse impact on any relevant processing procedures and causes no taints of processed or fresh commodities.

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

No new data on viability of plant parts for propagation are required or submitted.

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

No new data are required or submitted.

|                   |  |
|-------------------|--|
| Comments of zRMS: | <p><b>Effects on transformation processes</b></p> <p>The range of GWN-9823 (Reboot WG 66, Lieto 66 WG) re-registration remained the same as the previous registration (has not been altered or extended), therefore the applicant did not provided any new data on phytotoxicity to host crop, the effects on yield of treated plants or plant products and the effects on quality of plants and plant products. These data are not required and zRMS have agreed with applicant. The absence of adverse effects on processing procedures and taints, relevant to grapevine, potato and tomato, following applications of GWN-9823 according to label recommendations have been demonstrated by previously submitted data and proven through commercial use over a number of years.</p> <p><b>Quality assessment of fresh grapes.</b> The applicant has presented the new data of 5 trials carried out in 2015 and 2017 in grapevine for the purpose of generating samples for processing and taint tests, namely transformation processes, such as vinification (wine making) and raisins (raisins production). The trials were conducted in Maritime and Mediterranean climatic zones to demonstrate that GWN-9823 with multiple (3-4) application with intervals 7-10 days in grapevines, at the growth stages of BBCH 72-89, has no adverse impact on processing and causes no taints under conditions in all climatic zones relevant to the Central Registration zone.</p> <p><b>Vinification and wine quality.</b> Vinification and wine quality was assessed in 2 trials conducted in Austria (Maritime climatic zone). Grapevine was treated with GWN-9823 at 0.4 kg/ha at the growth stages BBCH 85-89. The quality parameters of grape fruits (BRIX content and acidity content), intended for processing and/or taint tests, following multiple (3) applications of GWN-9823 at the rate of 0.4 kg/ha in the absence of disease were evaluated in 3 trials conducted in 2015 in Mediterranean climatic zone in Greece. GWN-9823 caused no consistent differences in quality of the fruit at commercial harvest in terms of BRIX content (all 3 trials) and acid content (2 of the trials), compared to standard reference products applied at label rates, on any of these trials.</p> <p>Grapevines are grown mainly in the Mediterranean climatic zone and in Central Zone in countries such as: Romania, Austria, Hungary and Slovenia, so data of the trials obtained in Mediterranean zone (Greece) should support the re-registration of GWN-9823 in grapvines in the Central Zone countries. ZRMS accept it.</p> <p><b>Raisin production.</b> The raisin production processes and grapes properties evaluation were tested in 1 trial carried out in Greece (Mediterranean climatic zone). GWN-9823 applied at the label rate of 0.4 kg/ha had no consistent or marked effects on quality parameters of the fruit following sampling, key measurements of the vinification processes or quality parameters of the wine produced from fruit sampled 27-28 days after the last application.</p> <p>There were no differences in the quality parameter (size, colour, weight and rotten) between the fruits sampled following applications of GWN-9823 and that with fruit sampled following applications of the reference product.</p> <p>The gustatory qualities of raisins produced from grapes sampled following the applications of GWN-9823 were not significantly different to those produced from grapes sampled following applications of the standard reference product on this trial.</p> <p>In can be concluded that the multiple applications of GWN-9823 had no consistent effects on wine or raisin production processes and caused no significant taints of wine, raisins or fresh table grapes, compared to the untreated control or approved standard reference</p> |
|-------------------|--|

|  |   |
|--|---|
|  | products applied according to label recommendations, on fruit sampled from any of these trials. |
|--|---|

### 3.6 Other/special studies

No other studies are summarised.

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

Organisations involved in collection and testing of the sensitivity of fungal pathogens and reporting of studies summarised within this dossier followed established guidelines and methodology available at the time the studies were carried out and are recognised as competent to carry out such testing. Whilst full compliance with GEP and/or GLP is not a requirement of sensitivity monitoring, in most cases the organisations conducting the studies are GEP and/or GLP certified and the tests were conducted to these standards wherever possible.

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-1** gives information of the testing facilities and corresponding certificates valid at the time that trials were carried out, for all trials that generated samples for processing and taint testing.

All corresponding certificates are available in the GEP Certificate Database System (Certibase) (<http://www.gepcertibase.eu>) via the hyperlinks provided in the table.

**Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-1:List of test facilities**

| Organisation                          | Country | Trial numbers |          |          | GEP certification |             |  |
|---------------------------------------|---------|---------------|----------|----------|-------------------|-------------|--|
|                                       |         | 2015          | 2017-18  | Total    | Valid From        | Valid To    | Link   |
| Elanco Hellas SACI                    | EL      | 1             | -        | 1        | 19-Dec-2011       | 31-Dec-2015 | <br>Elanco GEP<br>2011-2015.pdf |
| ANADIAG Hellas Ltd                    | EL      | 2             | -        | 2        | 26-Jun-2012       | 31-Dec-2016 | <a href="#">1d5de6c7162</a>  |
| TB-Agrartechnik Service<br>Ges.m.b.H. | AT      | -             | 2        | 2        | 04-Aug-2016       | 31-Dec-2020 | <a href="#">1d5de6c7553</a>  |
| <b>Total</b>                          |         | <b>3</b>      | <b>2</b> | <b>5</b> |                   |             |  |

**Appendix 1:** List of data submitted in support of the evaluation

**List of data submitted and relied on**

| <b>Data points</b> | <b>Author(s)</b>                             | <b>Year</b> | <b>Title<br/>Source (where different from company)<br/>Company report No.<br/>GLP or GEP status (where relevant)<br/>Published or Unpublished</b>  | <b>Data protection claimed<br/>Y/N</b> | <b>Owner</b>               |
|--------------------|--|-------------|--|--|----------------------------|
| KCP<br>6.3/001     | Cooke L.R.                                   | 2017        | Studies on the sensitivity of European isolates of <i>Phytophthora infestans</i> to zoxamide (RH-7281), 1997-2014<br>School of Biological Sciences, The Queen's University, Belfast<br>n/a<br>n/a<br>Unpublished | Y                                      | Gowan Crop Protection Ltd. |
| KCP<br>6.3/002     | Dr Giraud F.                                 | 2013        | Sensitivity to zoxamide of grape Downy mildew populations collected during the 2013 season<br>Biorizon<br>13 21/02-M<br>n/a<br>Unpublished   | Y                                      | Gowan Crop Protection Ltd. |
| KCP<br>6.3/003     | Bleunven M.<br>Dr Giraud F.                  | 2015        | Sensitivity to zoxamide of grape Downy mildew populations collected during the 2014 season<br>Biorizon<br>14 21/02-M<br>n/a<br>Unpublished   | Y                                      | Gowan Crop Protection Ltd. |
| KCP<br>6.3/004     | Bleunven M.<br>Dr Lebaudy A.<br>Dr Giraud F. | 2016        | Sensitivity to zoxamide of grape Downy mildew populations collected during the 2015 season<br>Staphyt<br>15 21/03-M<br>n/a<br>Unpublished  | Y                                      | Gowan Crop Protection Ltd. |
| KCP<br>6.3/005     | Bleunven M.<br>Dr Giraud F.                  | 2016        | Sensitivity to zoxamide of grape Downy mildew populations collected in EU during the 2015 season<br>Staphyt<br>15 103/01-M<br>n/a<br>Unpublished   | Y                                      | Gowan Crop Protection Ltd. |
| KCP<br>6.3/006     | Bleunven M.<br>Dr Giraud F.                  | 2017        | Sensitivity to zoxamide of grape Downy mildew populations collected during the 2016 season<br>Staphyt<br>16 21/02-M<br>n/a<br>Unpublished  | Y                                      | Gowan Crop Protection Ltd. |
| KCP<br>6.3/007     | Bleunven M.<br>Dr Giraud F.                  | 2018        | Monitoring sensitivity of <i>Plasmopara viticola</i> to zoxamide<br>Staphyt<br>16 103/01-M version 3<br>n/a<br>Unpublished   | Y                                      | Gowan Crop Protection Ltd. |

| <b>Data points</b> | <b>Author(s)</b>            | <b>Year</b> | <b>Title<br/>Source (where different from company)<br/>Company report No.<br/>GLP or GEP status (where relevant)<br/>Published or Unpublished</b>                             | <b>Data protection claimed<br/>Y/N</b> | <b>Owner</b>   |
|--------------------|-----------------------------|-------------|---|--|--|
| KCP<br>6.3/008     | Bleunven M.<br>Dr Giraud F. | 2018        | Monitoring sensitivity of <i>Plasmopara viticola</i> to zoxamide<br>Season 2017<br>Staphyt<br>17 103/02-M<br>n/a<br>Unpublished   | Y                                      | Gowan Crop Protection Ltd.                                     |
| KCP<br>6.4.4/001   | Koutsompinas D.             | 2015        | Product: Electis 660 CX (cymoxanil + zoxamide)<br>Organoleptic and Quality Characteristics<br>Elanco Hellas SACI / ANADIAG Hellas Ltd<br>GR15GWN392DS01<br>GEP<br>Unpublished | Y                                      | Gowan Comercio Internacional e Serviços Lda<br>Sipcam Oxon SPA |
| KCP<br>6.4.4/002   | Bouras D.                   | 2015        | Organoleptic and quality characteristics for Sultana table grapes after the application of ELECTIS CX<br>ANADIAG Hellas Ltd<br>GWN-15-GR-34<br>GEP<br>Unpublished             | Y                                      | Gowan Comercio Internacional e Serviços Lda<br>Sipcam Oxon SPA |
| KCP<br>6.4.4/003   | Bouras D.                   | 2015        | Organoleptic and quality characteristics for Sultana table grapes after the application of ELECTIS CX<br>ANADIAG Hellas Ltd<br>GWN-15-GR-35<br>GEP<br>Unpublished             | Y                                      | Gowan Comercio Internacional e Serviços Lda<br>Sipcam Oxon SPA |
| KCP<br>6.4.4/004   | Dr Kempernek H.             | 2018        | Vinification trials with Reboot (330 g/Kg Cymoxanil, 330 g/Kg Zoxamide) in Austria in 2017<br>TB-Agrartechnik Service Ges.m.b.H.<br>GOW17-VITVI-F01<br>GEP<br>Unpublished     | Y                                      | Gowan Crop Protection Ltd                                      |
| KCP<br>6.4.4/005   | Dr Kempernek H.             | 2018        | Vinification trials with Reboot (330 g/Kg Cymoxanil, 330 g/Kg Zoxamide) in Austria in 2017<br>TB-Agrartechnik Service Ges.m.b.H.<br>GOW17-VITVI-F02<br>GEP<br>Unpublished     | Y                                      | Gowan Crop Protection Ltd                                      |