### Application

| No | Information | | |
| --- | --- | --- | --- |
| 1 | Type of application | | Proposed Zonal Rapporteur Member State |
| 2 | In case of re-authorisation, Latvian authorisation No | | |
| 3 | Is a change of conditions made in connection with the application for **Re-authorisation**?  Yes  No | **If yes**, short description of the change of the conditions: | |

### Product

| No | Information | | |
| --- | --- | --- | --- |
| 4 | Name (indicate complete name of the product) | | Product code |
| Active substance/organism 1 | | CAS No/Organism 1 |
| Active substance/organism 2 | | CAS No/Organism 2 |
| Active substance/organism 3 | | CAS No/Organism 3 |
| Safener | | CAS No |
| Synergist | | CAS No |
| Type of product | Category | Additional category (if applicable) |

### Applying company and signature[[1]](#footnote-1)

|  |  |  |
| --- | --- | --- |
| 5 | Applying company | Date |
| Signature | Name |

|  |  |
| --- | --- |
| **Send one copy of documentation[[2]](#footnote-2) to:**  State Plant Protection Service  Plant Protection Department  Lielvardes street 36/38 Riga, LV – 1006, Latvia | **Payment:**  After receiving the application, the State Plant Protection Service will send an **invoice** in which the amount due is stated, including how the state tax and deposit should be transmitted.  **Do not make a payment until receiving the invoice**. |

### Applicant

Current or future authorisation holder, i.e. the party **responsible** for initial placing of the plant production product on the market of Latvia

| No | Information | |
| --- | --- | --- |
| 6 | Company name | Organisation number |
| Mailing address | Telephone number |
| Postal code and town | Contact person |
| Country | E-mail address |

### **Temporary** representative[[3]](#footnote-3) (if applicable)

Representing the future authorisation holder (i.e. the applicant in point 6) **only during the application procedure**

| No | Information | |
| --- | --- | --- |
| 7 | Company name | Organisation number |
| Mailing address | Telephone number |
| Postal code and town | Contact person |
| Country | E-mail address |
| A representative should prove the appointed level of representation with a **letter of appointment** by the applicant in original.  **Letter of appointment as temporary representative** is attached | |

### **Permanent** representative (if applicable)

Representing the future authorisation holder (i.e. the applicant in point 6) also **during the approval period**

| No | Information | |
| --- | --- | --- |
| 8 | Company name | Organisation number |
| Mailing address | Telephone number |
| Postal code and town | Contact person |
| Country | E-mail address |

### Application - Authorisation and re-authorisation

| No | Information |
| --- | --- |
| 9 | Is the application submitted to other Member States in the Northern zone?  Yes  No  **If yes**, indicate to which Member State(s):  DK – Denmark  EE – Estonia  FI – Finland  IS – Iceland  LT – Lithuania  LV – Latvia  NO – Norway  SE – Sweden |
| Is the product intended for use in green house, pre- or post harvest, in storage rooms or as seed treatment?  Yes  No  **If yes**, indicate in which Member State(s):  AT Austria  BE Belgium  BG Bulgaria  CY Cyprus  CZ Czech Republic  DE Germany  DK Denmark  EE Estonia  EL Greece  ES Spain  FI Finland  FR France  HU Hungary  IE Ireland  IS Iceland  IT Italy  LT Lithuania  LU Luxembourg  LV Latvia  MT Malta  NL Netherlands  NO Norway  PL Poland  PT Portugal  RO Romania  SE Sweden  SI Slovenia  SK Slovakia  UK United Kingdom |

### Application - Mutual recognition

| No | Information | |
| --- | --- | --- |
| 10 | Reference Member State | Authorisation No (in that Member State) |
| Date of authorisation (dd month yyyy)  dd  yyyy | Date of expiry (dd month yyyy)  dd yyyy |
| 11 | A copy of the authorisation in the reference Member State should be submitted.  Copy of authorisation is attached | |
| 12 | A registration report should be submitted, in English or Latvian.  Registration report is attached | |

### Intended uses, label and authorisation class

| No | Information | Yes | No |
| --- | --- | --- | --- |
| 13 | GAP  Latvian GAP  Zonal core GAP (risk envelope GAP), if relevant  Complete zonal GAP (indicating relevance for which Member State) |  |  |
| 14 | Label  Proposed Latvian label  Draft master label  **If LV** is the proposed zonal rapporteur, a *draft label for each Member State* should be submitted |  |  |
| 15 | Authorisation class  Class 1: Product may only be used professionally by someone with a special license  Class 2: Product may only be used professionally by someone who fulfils special knowledge requirements  Class 3: Product may be used by anyone | | |

### Annex II data – Active substance No 1: <Name of the active substance>

| No | Information | Yes | No |
| --- | --- | --- | --- |
| 16:1 | Sources  Have all sources been evaluated by a Member State?  **If yes**, *all relevant equivalence reports* should be submitted  **If no**, *all relevant documentation* should be submitted |  |  |
| 17:1 | Data access  Is all data on the active substance owned by the applicant?  **If no**, *Letter of Access* in original and/or  *Data sharing agreement/task force* and/or  *Report on data match* should be submitted  Is data out of protection used?  **If yes**, *justifications for using data out of protection* should be submitted |  |  |
| 18:1 | New studies  Are new tests or study reports included?  **If yes,** *justifications (art 33.3 d)* should be submitted  Are studies on vertebrates included?  **If yes**, *justifications of new vertebrate studies* and/or  *Information of efforts reaching an agreement* should be submitted |  |  |

### Annex II data – Active substance No 2: <Name of the active substance>

| No | Information | Yes | No |
| --- | --- | --- | --- |
| 16:2 | Sources  Have all sources been evaluated by a Member State?  **If yes**, *all relevant equivalence reports* should be submitted  **If no**, *all relevant documentation* should be submitted |  |  |
| 17:2 | Data access  Is all data on the active substance owned by the applicant?  **If no**, *Letter of Access* in original and/or  *Data sharing agreement/task force* and/or  *Report on data match* should be submitted  Is data out of protection used?  **If yes**, *justifications for using data out of protection* should be submitted |  |  |
| 18:2 | New studies  Are new tests or study reports included?  **If yes,** *justifications (art 33.3 d)* should be submitted  Are studies on vertebrates included?  **If yes**, *justifications of new vertebrate studies* and/or  *Information of efforts reaching an agreement* should be submitted |  |  |

### Annex II data – Active substance No 3: <Name of the active substance>

| No | Information | Yes | No |
| --- | --- | --- | --- |
| 16:3 | Sources  Have all sources been evaluated by a Member State?  **If yes**, *all relevant equivalence reports* should be submitted  **If no**, *all relevant documentation* should be submitted |  |  |
| 17:3 | Data access  Is all data on the active substance owned by the applicant?  **If no**, *Letter of Access* in original and/or  *Data sharing agreement/task force* and/or  *Report on data match* should be submitted  Is data out of protection used?  **If yes**, *justifications for using data out of protection* should be submitted |  |  |
| 18:3 | New studies  Are new tests or study reports included?  **If yes,** *justifications (art 33.3 d)* should be submitted  Are studies on vertebrates included?  **If yes**, *justifications of new vertebrate studies* and/or  *Information of efforts reaching an agreement* should be submitted |  |  |

### Annex III data – Product

| No | Information | Yes | No |
| --- | --- | --- | --- |
| 19 | Data access  Is all data on the product owned by the applicant?  **If no**, *Letter of Access* in original and/or  *Data sharing agreement/task force* should be submitted  Is data out of protection used?  **If yes**, *justifications for using data out of protection* should be submitted |  |  |
| 20 | New studies  Are new tests or study reports included?  **If yes,***justifications (art 33.3 d*) should be submitted  Are studies on vertebrates included?  **If yes**, *justifications of new vertebrate studies* and/or  *Information of efforts reaching an agreement* should be submitted |  |  |

### Further information

| No | Information | Yes | No |
| --- | --- | --- | --- |
| 21 | MRL  Is a new MRL needed/required? (article 33(3) e)  **If yes**, a copy of the application should be attached |  |  |
| 22 | Confirmatory data  Is confirmatory data requested in the inclusion for the active substance?  **If yes**, state whether it has been submitted and evaluated by the  RMS  DMS  Other MS  Not applicable  Comments |  |  |
| 23 | Is the product authorised in other Member State(s)?  Yes  No  If **yes**, indicate in which Member State(s)  AT Austria  BE Belgium  BG Bulgaria  CY Cyprus  CZ Czech Republic  DE Germany  DK Denmark  EE Estonia  EL Greece  ES Spain  FI Finland  FR France  HU Hungary  IE Ireland  IS Iceland  IT Italy  LT Lithuania  LU Luxembourg  LV Latvia  MT Malta  NL Netherlands  NO Norway  PL Poland  PT Portugal  RO Romania  SE Sweden  SI Slovenia  SK Slovakia  UK United Kingdom | | |

### Annexes

| See No | Issue | Comments | Attached? | | Annex No |
| --- | --- | --- | --- | --- | --- |
| Yes | No |
| 5 | Letter of authorisation to sign |  |  |  |  |
| 6 | Applicant´s registration certificate |  |  |  |  |
| 7 | Letter of appointment |  |  |  |  |
| 8 | Representative´s registration certificate |  |  |  |  |
| 11 | Copy of authorisation |  |  |  |  |
| 12 | Registration Report |  |  |  |  |
| 13 | Latvian GAP |  |  |  |  |
| 13 | Zonal core GAP |  |  |  |  |
| 13 | Complete zonal GAP |  |  |  |  |
| 14 | Latvian label |  |  |  |  |
| 14 | Draft master label |  |  |  |  |
| 14 | Draft label, for each country |  |  |  |  |
| 16:1 | Equivalence report, or other documentation |  |  |  |  |
| 17:1 | Letter of Access, Annex II data (in original) |  |  |  |  |
| 17:1 | Data sharing/task force |  |  |  |  |
| 17:1 | Report on data match |  |  |  |  |
| 17:1 | Justification for using data out of protection |  |  |  |  |
| 18:1 | New tests - justifications (art 33.3 d) |  |  |  |  |
| 18:1 | Vertebrate studies – justifications new studies |  |  |  |  |
| 18:1 | Vertebrate studies – reaching agreement |  |  |  |  |
| 16:2 | Equivalence report, or other documentation |  |  |  |  |
| 17:2 | Letter of Access, Annex II data (in original) |  |  |  |  |
| 17:2 | Data sharing/task force |  |  |  |  |
| 17:2 | Post inclusion data match |  |  |  |  |
| 17:2 | Justification for using data out of protection |  |  |  |  |
| 18:2 | New tests - justifications (art 33.3 d) |  |  |  |  |
| 18:2 | Vertebrate studies – justifications new studies |  |  |  |  |
| 18:2 | Vertebrate studies – reaching agreement |  |  |  |  |
| 16:3 | Equivalence report, or other documentation |  |  |  |  |
| 17:3 | Letter of Access, Annex II data (in original) |  |  |  |  |
| 17:3 | Data sharing/task force |  |  |  |  |
| 17:3 | Post inclusion data match |  |  |  |  |
| 17:3 | Justification for using data out of protection |  |  |  |  |
| 18:3 | New tests - justifications (art 33.3 d) |  |  |  |  |
| 18:3 | Vertebrate studies – justifications new studies |  |  |  |  |
| 18:3 | Vertebrate studies – reaching agreement |  |  |  |  |
| 19 | Letter of access, Annex III data (in original) |  |  |  |  |
| 19 | Justification for using data out of protection |  |  |  |  |
| 20 | New tests - justifications (art 33.3 d) |  |  |  |  |
| 20 | Vertebrate studies – justifications new studies |  |  |  |  |
| 20 | Vertebrate studies – reaching agreement |  |  |  |  |
| 21 | Application of a new MRL |  |  |  |  |
|  |  |  |  |  |  |
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If more rows are needed, just press the “TAB-tangent” in the last table cell.

1. If the signature is done by someone other than the applying company, a letter of authorisation confirming the right to sign the application on behalf of the applicant should be submitted. [↑](#footnote-ref-1)
2. LV Electronic submission requirements- all data package (see Northern Zone GD Appendix V) including dRR and national addenda (dRR in word processing format; studies can be in Caddy).

   LV paper copy requirements – Cover letter; LV label text; list of ref. to new AnnexII data; LV national addenda;

   Draft Registration Report (LV Part A; core Part B Sections 1-7; core Part C; no studies or document K); letters

   of access. [↑](#footnote-ref-2)
3. The applicant is fully responsible for the placing of a plant protection product on the market of Latvia. The representative cannot hold an authorisation [↑](#footnote-ref-3)