### 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 ServicePlant Protection DepartmentLielvardes street 36/38Riga, 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 GAPZonal core GAP (risk envelope GAP), if relevantComplete zonal GAP (indicating relevance for which Member State) | [ ] [ ] [ ]  | [ ] [ ] [ ]  |
| 14 | LabelProposed Latvian labelDraft master label**If LV** is the proposed zonal rapporteur, a *draft label for each Member State* should be submitted | [ ] [ ]  | [ ] [ ]  |
| 15 | Authorisation classClass 1: Product may only be used professionally by someone with a special licenseClass 2: Product may only be used professionally by someone who fulfils special knowledge requirementsClass 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 | SourcesHave 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 accessIs 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 submittedIs data out of protection used?**If yes**, *justifications for using data out of protection* should be submitted | [ ] [ ]  | [ ] [ ]  |
| 18:1 | New studiesAre new tests or study reports included? **If yes,** *justifications (art 33.3 d)* should be submittedAre 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 | SourcesHave 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 accessIs 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 submittedIs data out of protection used?**If yes**, *justifications for using data out of protection* should be submitted | [ ] [ ]  | [ ] [ ]  |
| 18:2 | New studiesAre new tests or study reports included? **If yes,** *justifications (art 33.3 d)* should be submittedAre 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 | SourcesHave 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 accessIs 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 submittedIs data out of protection used?**If yes**, *justifications for using data out of protection* should be submitted | [ ] [ ]  | [ ] [ ]  |
| 18:3 | New studiesAre new tests or study reports included? **If yes,** *justifications (art 33.3 d)* should be submittedAre 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 accessIs 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 submittedIs data out of protection used?**If yes**, *justifications for using data out of protection* should be submitted | [ ] [ ]  | [ ] [ ]  |
| 20 | New studiesAre new tests or study reports included? **If yes,***justifications (art 33.3 d*) should be submittedAre 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 | MRLIs a new MRL needed/required? (article 33(3) e)**If yes**, a copy of the application should be attached | [ ]  | [ ]  |
| 22 | Confirmatory dataIs 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 applicableComments      | [ ]  | [ ]  |
| 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)