

Application – Authorisation of new, renewal, or mutual recognition of a Plant Protection Product

### **Application**

| **No** | **Information** |
| --- | --- |
| 1 | Type of authorisation< Choose alternative > | Proposed zonal rapporteur Member State (MS)      |
| 2 | Type of product[ ]  Chemical [ ]  Biological[[1]](#footnote-1) | In case of renewal, Norwegian authorisation no.      |
| 3 | Is an amendment made in connection with the application for renewal?[ ]  Yes [ ]  No | **If yes**, please describe the change of the conditions:      |

### **Product information**

| **No** | **Information** |
| --- | --- |
| 4 | Name of the product      | Product code      |
| 5 | Type of pesticide (function)< Choose alternative > | Other type (if applicable):< Choose alternative > |
| Main crops (list all crops)      |
| 6 | Active substance / Organism 1      | CAS no. / Organism 1      | Concentration (g/kg or g/L)      |
| Active substance / Organism 2      | CAS no. / Organism 2      | Concentration (g/kg or g/L)      |
| Active substance / Organism 3      | CAS no. / Organism 3      | Concentration (g/kg or g/L)      |
| Safener      | CAS no.      |
| Synergist      | CAS no.      |
| 7 | Packaging size      | Packaging material      |
| 8 | Physical state of the product       |

### **Signature [[2]](#footnote-2)**

| **No** | **Information** |
| --- | --- |
| 9 | Applying company       | Date (dd.mm.yyyy)      |
| Signature | Name      |

### **Applicant**

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

| **No** | **Information** |
| --- | --- |
| 10 | Company name      | Organisation number      |
| Address      | Postal code and town      |
| Contact person       | E-mail address      | Telephone no. (incl. country code)      |

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

Representing the authorisation holder (i.e. the applicant in point 10) **only during the application procedure**

| **No** | **Information** |
| --- | --- |
| 11 | Company name      | Organisation number      |
| Address      | Postal code and town      |
| Contact person       | E-mail address      | Telephone no. (incl. country code)      |
| 12 | 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 10) **during the authorisation period**

| **No** | **Information** |
| --- | --- |
| 13 | Company name      | Organisation number      |
| Address      | Postal code and town      |
| Contact person       | E-mail address      | Telephone no. (incl. country code)      |

### **Invoicing address for application fee**

| **No.** | **Information** |
| --- | --- |
| 14 | Application fee will be paid by[ ]  Authorisation holder[ ]  Temporary representative[ ]  Permanent representative |
| Invoicing address      | Contact person      |
| Postal code and town      | E-mail address      |
|  | Country      | Telephone no. (incl. country code)      |

### **New or renewal of authorisation**

| **No** | **Information** |
| --- | --- |
| 15 | 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 |

### **Mutual recognition**

| **No** | **Information** |
| --- | --- |
| 16 | Reference Member State      | Authorisation no. (in the reference MS)      | Date of application in rMS      |
| Date of authorisation (dd.mm.yyyy)      | Date of expiry (dd.mm.yyyy)      | Application is evaluated under regulation< Choose alternative > |
| 17 | Copy of the authorisation in the reference MS shall be submitted, as well as a translation into English or Norwegian[ ]  **Copy of authorisation** are attached |
| 18 | A registration report (A-C) shall be submitted, in English or Norwegian[ ]  **Registration report** is attached |
| 19 | Formal statement that the plant protection product is identical to that authorised by the reference MS shall be submitted[ ]  **Statement of identity** is attached |
| 20 | Statement of comparable agriculture practice and climate shall be submitted[ ]  **Statement of comparability** is attached |
| 21 | Dossier for the plant protection product and the active ingredients[ ]  **Annex II dossier** is attached[ ]  **Annex III dossier** is attached |
| 22 | Documentation on exposure assessment (soil, groundwater, surface water) according to the Norwegian requirements in the Guidance document for application in the Northern zone shall be submitted\*[ ]  **Additional documentation on exposure assessment** is included |
| 23 | If others than authorisation holder is applying for mutual recognition (art 40.2) and the use is of general interest for Norway[ ]  **Consent of the authorisation** holder is attached |

### **Intended uses, label and authorisation class**

| **No** | **Information** |
| --- | --- |
| 24 | Intended uses - GAP [ ]  **Complete zonal GAP**, including indication of relevant MS, is attached [ ]  **Zonal core GAP** (risk envelope GAP) is attached (if relevant) |
| 25 | Label[ ]  **Proposed national label** is attached. Also different coverings shall be state on the label.[ ]  **Draft master label** is attached If Norway is the proposed zonal rapporteur, a draft label for each Member State shall be submitted |
| 26 | User category< Choose alternative > |

\* Guidance Document on Work-Sharing in the Northern Zone in the Authorization of Plant Protection Products.

### **Active substance no. 1:** < Name of the active substance > < CAS no. >

| No | Information | Yes | No |
| --- | --- | --- | --- |
| 27:1 | SourcesHave all sources been evaluated by a Member State?**If yes,** all relevant**equivalence reports** shall be submitted**If no,** all relevant**documentation**shall be submitted | [ ]  | [ ]  |
| 28:1 | 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 forceshall be submittedIf yes, Report on data match shall be submitted  | [ ]  | [ ]  |
| 29:1 | Data accessIs used data out of protection?If yes, justifications for using data out of protection shall be submitted | [ ]  | [ ]  |
| 30:1 | New studiesAre new tests or study reports included? **If yes, justifications** (art 33.3 d) shall be submitted | [ ]  | [ ]  |
| 31:1 | New studiesAre studies on vertebrates included? If yes, justifications of new vertebrate studies *and/or* Information of efforts reaching an agreement shall be submitted | [ ]  | [ ]  |

### **Active substance no. 2:** < Name of the active substance > < CAS no. >

| **No** | **Information** | **Yes** | **No** |
| --- | --- | --- | --- |
| 27:2 | SourcesHave all sources been evaluated by a Member State?**If yes,** all relevant**equivalence reports** shall be submitted**If no,** all relevant**documentation**shall be submitted | [ ]  | [ ]  |
| 28:2 | 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 forceshall be submittedIf yes, Report on data match shall be submitted  | [ ]  | [ ]  |
| 29:2 | Data accessIs data out of protection used?**If yes,** justifications for using data out of protection shall be submitted  | [ ]  | [ ]  |
| 30:2 | New studiesAre new tests or study reports included? **If yes, justifications** (art 33.3 d) shall be submitted | [ ]  | [ ]  |
| 31:2 | New studiesAre studies on vertebrates included? If yes, justifications of new vertebrate studies *and/or* Information of efforts reaching an agreement shall be submitted | [ ]  | [ ]  |

### **Active substance no. 3:** < Name of the active substance > < CAS no. >

| **No** | **Information** | **Yes** | **No** |
| --- | --- | --- | --- |
| 27:3 | SourcesHave all sources been evaluated by a Member State?**If yes,** all relevant**equivalence reports** shall be submitted**If no,** all relevant**documentation**shall be submitted | [ ]  | [ ]  |
| 28:3 | 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 forceshall be submittedIf yes, Report on data match shall be submitted  | [ ]  | [ ]  |
| 29:3 | Data accessIs data out of protection used?**If yes,** justifications for using data out of protection shall be submitted  | [ ]  | [ ]  |
| 30:3 | New studiesAre new tests or study reports included? **If yes, justifications** (art 33.3 d) shall be submitted | [ ]  | [ ]  |
| 31:3 | New studiesAre studies on vertebrates included? If yes, justifications of new vertebrate studies *and/or* Information of efforts reaching an agreement shall be submitted | [ ]  | [ ]  |

### **Product data**

| **No** | **Information** | **Yes** | **No** |
| --- | --- | --- | --- |
| 32 | Data accessIs all data on the product owned by the applicant?**If no,** **Letter of Access** in original *and/or* Data sharing agreement/task forceshall be submitted | [ ]  | [ ]  |
| 33 | Information on co-formulantsFor all co-formulants which is going to be used in the plant protection product, a safety data sheet (SDS) not older than 2 years shall be submitted. SDS for all co-formulants is **attached**.For all of the co-formulants, which are mixtures, the detailed complete composition shall be provided. If the applicant do not have access to proprietary data of suppliers of the co-formulants, please ask supplier to submit the data to the Norwegian Food Safety Authority.[[4]](#footnote-4) The information will be treated as strictly confidential. The information **will be provided** within two weeks after submission of application. | [ ] [ ]  | [ ] [ ]  |
| 34 | Classification and SDS for the plant protection product. Applicant shall propose a CLP-classification of the plant protection product.A **safety data sheet** not older than two years is submittedApplicant’s proposal for **CLP-classification** of the plant protection product is attached | [ ] [ ]  | [ ] [ ]  |
| 35 | Data accessIs used data out of protection?If yes, justifications for using data out of protection shall be submitted | [ ]  | [ ]  |
| 36 | New studiesAre new tests or study reports included? **If yes,justifications**(art 33.3 d) shall be submitted | [ ]  | [ ]  |
| 37 | Vertebrate studiesAre studies on vertebrates included? If yes, justifications of new vertebrate studies *and/or*Information of efforts reaching an agreement shall be submitted | [ ]  | [ ]  |

### **Further information**

| **No** | **Information** | **Yes** | **No** |
| --- | --- | --- | --- |
| 38 | Maximum residue level (MRL)Is new MRL needed/required? (article 33.3 e)**If yes**, a **copy of the application** shall be submitted | [ ]  | [ ]  |
| 39 | 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      | [ ]  | [ ]  |
| 40 | Authorisation in other Member State(s)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 |
| 41 | Other comments      |

**Send application form to:**

Norwegian Food Safety Authority, Regional Office Stor-Oslo, P.O. Box 383, N – 2381 Brumunddal, Norway

Or e-mail: postmottak@mattilsynet.no

**Send three full sets of documentation to:**

Norwegian Food Safety Authority, National Registration Department, Regional Office Stor -Oslo, Glynitveien 30,
N-1400 Ski, Norway

The application form shall be submitted as signed original. All other documents, including the copy of the application form, should be delivered on CD or in another digital form.

### **Completeness check for annexes**

Annexes listed in the table below are required for the authorisation procedure. If not attached, a justification shall be given.

| See No | Issue | Comments | Attached? | Annex No |
| --- | --- | --- | --- | --- |
| Yes | No |
| Applicant/representative |
| 9 | Letter of authorisation to sign  |       | [ ]  | [ ]  |       |
| 12 | Letter of appointment as temporary representative |       | [ ]  | [ ]  |       |
| Mutual recognition |
| 17 | Copy of authorisation – original MS language |       | [ ]  | [ ]  |       |
| 17 | Translation of authorisation – English or MS language |       | [ ]  | [ ]  |       |
| 18 | Registration report (dRR, A-C.) |       | [ ]  | [ ]  |       |
| 19 | Statement of identity |       | [ ]  | [ ]  |       |
| 20 | Statement of comparability |       | [ ]  | [ ]  |       |
| 21 | Annex II dossier  |       | [ ]  | [ ]  |       |
| 21 | Annex III dossier  |       | [ ]  | [ ]  |       |
| 22 | Additional documentation on exposure assessment |       | [ ]  | [ ]  |       |
| 23 | Consent of the authorisation holder |       | [ ]  | [ ]  |       |
| Intended uses, label and authorisation class |
| 24 | Complete zonal GAP |       | [ ]  | [ ]  |       |
| 24 | Zonal core GAP |       | [ ]  | [ ]  |       |
| 25 | Proposed national label(s) (in Norwegian) |       | [ ]  | [ ]  |       |
| 25 | Draft master label |       | [ ]  | [ ]  |       |
| Active substance no. 1 |
| 27:1 | Equivalence report or other documentation |       | [ ]  | [ ]  |       |
| 28:1 | Letter of Access – Active substance data (in original) |       | [ ]  | [ ]  |       |
| 28:1 | Data sharing agreement/task force |       | [ ]  | [ ]  |       |
| 28:1 | Report on data match |       | [ ]  | [ ]  |       |
| 29:1 | Justification for using data out of protection |       | [ ]  | [ ]  |       |
| 30:1 | New studies – justifications (art 33.3 d) |       | [ ]  | [ ]  |       |
| 31:1 | Vertebrate studies – justifications new studies |       | [ ]  | [ ]  |       |
| 31:1 | Vertebrate studies – reaching agreement |       | [ ]  | [ ]  |       |
| Active substance no. 2 |
| 27:2 | Equivalence report or other documentation |       | [ ]  | [ ]  |       |
| 28:2 | Letter of Access – Active substance data (in original) |       | [ ]  | [ ]  |       |
| 28:2 | Data sharing agreement/task force |       | [ ]  | [ ]  |       |
| 28:2 | Report on data match |       | [ ]  | [ ]  |       |
| 29:2 | Justification for using data out of protection |       | [ ]  | [ ]  |       |
| 30:2 | New studies – justifications (art 33.3 d) |       | [ ]  | [ ]  |       |
| 31:2 | Vertebrate studies – justifications new studies |       | [ ]  | [ ]  |       |
| 31:2 | Vertebrate studies – reaching agreement |       | [ ]  | [ ]  |       |
| Active substance no. 3 |
| 27:3 | Equivalence report or other documentation |       | [ ]  | [ ]  |       |
| 28:3 | Letter of Access – Active substance data (in original) |       | [ ]  | [ ]  |       |
| 28:3 | Data sharing agreement/task force |       | [ ]  | [ ]  |       |
| 28:3 | Report on data match |       | [ ]  | [ ]  |       |
| 29:3 | Justification for using data out of protection |       | [ ]  | [ ]  |       |
| 30:3 | New studies – justifications (art 33.3 d) |       | [ ]  | [ ]  |       |
| 31:3 | Vertebrate studies – justifications new studies |       | [ ]  | [ ]  |       |
| 31:3 | Vertebrate studies – reaching agreement |       | [ ]  | [ ]  |       |
| Product data |
| 32 | Letter of Access – Product data (in original) |       | [ ]  | [ ]  |       |
| 32 | Data sharing agreement/task force |       | [ ]  | [ ]  |       |
| 33 | SDS on all co-formulants |       | [ ]  | [ ]  |       |
| 33 | Composition of co-formulants |       | [ ]  | [ ]  |       |
| 34 | Applicant’s proposal on CLP-classification |       | [ ]  | [ ]  |       |
| 34 | A safety data sheet for the product |       | [ ]  | [ ]  |       |
| 35 | Justification for using data out of protection |       | [ ]  | [ ]  |       |
| 36 | New studies – justifications (art 33.3 d) |       | [ ]  | [ ]  |       |
| 37 | Vertebrate studies – justifications new studies |       | [ ]  | [ ]  |       |
| 37 | Vertebrate studies – reaching agreement |       | [ ]  | [ ]  |       |
| Further information |
| 38 | Application of a new MRL (copy) |       | [ ]  | [ ]  |       |
|      |       |       | [ ]  | [ ]  |       |
|      |       |       | [ ]  | [ ]  |       |
|      |       |       | [ ]  | [ ]  |       |
|      |       |       | [ ]  | [ ]  |       |
|      |       |       | [ ]  | [ ]  |       |

1. Product with microorganisms. If the product contains **nematodes, insects or arachnids,** use the special application form for macroorganisms. [↑](#footnote-ref-1)
2. If the signature is done by someone other than the applying company, a power of attorney confirming the right to sign the application on behalf of the applicant shall be submitted. [↑](#footnote-ref-2)
3. The applicant is fully responsible for the placing of a plant protection product on the Norwegian market. The representative cannot hold an authorisation [↑](#footnote-ref-3)
4. Norwegian Food Safety Authority, National Registration Department, Regional Office Stor-Oslo, Glynitveien 30, N-1400 Ski, Norway, or
 pesticider@mattilsynet.no. [↑](#footnote-ref-4)