

Application form: Mutual recognition of a plant protection product authorisation in Norway

Regulation (EC) No. 1107/2009 (article 40)

### **How to complete this form**

* Complete all parts as appropriate. 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.
* For guidance on application of mutual recognition in Norway under regulation (EC) No. 1107/2009, please see the [“Guidance on the application of mutual recognition in Norway under regulation (EC) No. 1107/2009”](https://www.mattilsynet.no/planter_og_dyrking/plantevernmidler/godkjenning_av_plantevernmidler/veiledere__guidance_documents__plantevernmidler.36791)
* For further questions about this form, contact [postmottak@mattilsynet.no](mailto:postmottak@mattilsynet.no).
* **Send documentation and application form to:**

[pesticider@mattilsynet.no](mailto:pesticider@mattilsynet.no) and [postmottak@mattilsynet.no](mailto:postmottak@mattilsynet.no)

or by post/courier to:

Mattilsynet, avdeling nasjonale godkjenninger

Glynitveien 30

1400 Ski

Norway

### **Applicant**

Authorisation holder, i.e., the party responsible for placing of the plant protection product on the Norwegian market

| **No** | **Information** | | | |
| --- | --- | --- | --- | --- |
| 1 | Company name | | Organisation number | |
| Address | | Postal code and town | |
| Contact person | E-mail address | | Telephone no. (incl. country code) |
| 2 | 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 | | | |

### **Temporary representative [[1]](#footnote-2) (if applicable)**

Representing the authorisation holder (i.e. the applicant in point 4) **only during the application procedure**

| **No** | **Information** | | | |
| --- | --- | --- | --- | --- |
| 3 | Company name | | Organisation number | |
| Address | | Postal code and town | |
| Contact person | E-mail address | | Telephone no. (incl. country code) |
| 4 | 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 4) **during the authorisation period**

| **No** | **Information** | | | |
| --- | --- | --- | --- | --- |
| 5 | Company name | | Organisation number | |
| Address | | Postal code and town | |
| Contact person | E-mail address | | Telephone no. (incl. country code) |
| 6 | A representative should prove the appointed level of representation with **a letter of appointment** by the applicant in original.  **Letter of appointment as permanent representative** is attached | | | |

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

| **No.** | **Information** | | |
| --- | --- | --- | --- |
| 7 | Application fee will be paid by  Authorisation holder  Temporary representative  Permanent representative | | |
| Invoicing address | Postal code and town | |
| Contact person | Country | |
|  | E-mail address | Telephone no. (incl. country code) | Your reference no. |

### **Signature [[2]](#footnote-3)**

| **No** | **Information** | |
| --- | --- | --- |
| 8 | Applying company | Date (dd.mm.yyyy) |
| Signature | Name |

### **Application history**

| **No** | **Information** | |
| --- | --- | --- |
| 9 | Reference Member State | Authorisation no. in the reference Member State |
| Date of authorisation (dd.mm.yyyy) | Date of expiry (dd.mm.yyyy) |
| 10 | Zonal Rapporteur Member State | Date of application in the Zonal Rapporteur Member State |
| 11 | Does the plant protection product contain active substance(s) approved in accordance with Council Directive 91/414/EC?  Yes  No  **If yes**, please specify which | |
| 12 | Authorisation in the reference Member State was evaluated according to data requirements  < Choose alternative > | |

### **Product information**

| **No** | **Information** | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| 13 | Name of the product | | Product code | | | |
| 14 | Type of pesticide (function)  < Choose alternative > | | Other type (if applicable):  < Choose alternative > | | | |
| User category  < Choose alternative > | | | Is the active substance approved for use in organic production?  Yes  No | | |
| 15 | Type of product  Chemical  Biological[[3]](#footnote-4) | | | | | |
| 16 | Do the active substance(s) meet the low-risk criteria as specified in Article 47 of Regulation (EC) No 1107/2009?  Yes  No | | | | | |
| 17 | If the product contains a candidate for substitution, a comparative assessment shall be submitted  **Comparative assessment** is attached | | | | | |
| 18 | Active substance / Organism 1 | Candidate for substitution?  Yes  No | | | CAS no. / Organism 1 | Concentration        < Choose > |
| Active substance / Organism 2 | Candidate for substitution?  Yes  No | | | CAS no. / Organism 2 | Concentration        < Choose > |
| Active substance / Organism 3 | Candidate for substitution?  Yes  No | | | CAS no. / Organism 3 | Concentration        < Choose > |
| Safener | | | | CAS no. | |
| Synergist | | | | CAS no. | |
| 19 | Mandatory mixing partner  Yes  No | | | | If yes, specify name of the product / reg. no. in NO | |
| 20 | Packaging size | | | | Packaging material | |
| 21 | Formulation type  < Choose alternative > | | | | | |
| 22 | Formal statement that the plant protection product is identical to that authorised by the reference Member State shall be submitted  **Statement of identity** is attached | | | | | |
| Amendments of the product authorisation in the reference Member State  Have amendments of the **identity** of the plant protection product been applied for and approved in the reference Member State?  Yes  No  **If yes,** the application and associated documents, and decision letter shall be attached  Please specify the type of application | | | | | |
| 23 | 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 | | | | | |
| 24 | Copy of the authorisation certificate in the reference Member State shall be submitted, as well as a translation into English or Scandinavian language  **Copy of authorisation certificate** is attached | | | | | |
| 25 | A registration report (A-C) shall be submitted, in English or Scandinavian language  **Registration report (RR)** and related data package is attached  **RR** **Part A and national addenda from reference Member State** is attached | | | | | |
| 26 | Confirmatory data  Is confirmatory data requested in the approval for the active substance(s)?  Yes  No  **If yes,** state whether it has been evaluated by the  RMS  DMS  Other MS  Not evaluated yet  Please specify for which areas | | | | | |
| 27 | More adverse data  Have more adverse endpoints been generated after the approval of the active substance?  Yes  No  **If yes,** state whether these have been submitted to and evaluated by the  RMS  DMS  Other MS  Not evaluated yet  Please specify | | | | | |

### **Intended uses and label**

| **No** | **Information** | |
| --- | --- | --- |
| 28 | Intended uses - GAP  **Reference Member State’s GAP** is attached   **GAP for Norway** is attached | |
| Is the intended GAP for Norway identical with the GAP approved in the reference Member State?  Yes  No  **If no,** please **describe the changes** made to the GAP, and provide a **justification** for why the changes in the GAP are still covered by the risk assessment performed by the reference Member State: | |
| 29 | Area of use for the product (check all that apply) | |
| Field  Covered crops (all types of structures used for protecting crops, except greenhouse)  Greenhouse  Storage rooms | Seed treatment  Pre-harvest  Post-harvest |
| 30 | Crops (list all crops) | |
| 31 | Label  **Proposed national label in Norwegian** is attached. Different crop coverings shall be stated on the label  **Approved label from the reference Member State** translated to English or Scandinavian language is attached | |

**National requirements**

|  |  |
| --- | --- |
| **No** | **Information** |
| 32 | Documentation on risk assessment is according to the Norwegian requirements set out in the current version of *the “Guidance document on work-sharing in the northern zone in the authorisation of plant protection products”*. |
| 33 | **Risk mitigation options**  Necessary risk mitigation measures required in the reference Member State are also considered acceptable in NO according to the Guidance document for application in the Northern zone[[4]](#footnote-5)  Comments |
| 34 | In cases where an inhalation study has not been submitted, information concerning the size distribution of the particles/droplets shall be included (see our national requirements in Appendix IV of the Guidance Document on Works sharing in the Northern zone in the Authorisation of Plant Protection Products). |
| 35 | **Additional documentation on exposure assessment** is included  If yes, indicate which information has been included:  **Soil modelling**  Modelling with the model/tool specified in the Northern Zone Guidance document is included  Input and output (e.g. screenshots or files) as specified in the Northern Zone Guidance document is included  Input in accordance with the Northern Zone Guidance document is used  Output in accordance with the Northern Zone Guidance document is reported  **Surface water modelling**  Modelling with additional surface water scenarios required by Norway is included  Modelling report(s) are included  The endpoints used are identical to the endpoints used in the reference Member State  Application dates used for risk assessment cover the application time specified in the GAP  **Groundwater modelling**  Modelling with additional ground water scenarios required by Norway is included  Modelling report(s) are included  The endpoints used are identical to the endpoints used in the reference Member State  Application dates used for risk assessment cover the application time specified in the GAP  **If no additional documentation is included,** please provide justifications  Comments |
| 36 | **Additional documentation on ecotoxicological risk assessment** is included  If yes, indicate which information has been included:  **Risk assessment for birds and mammals**  Higher tier risk assessment in accordance with the Northern Zone Guidance document for birds and mammals  **Risk assessment for aquatic organisms**  Risk assessment with all relevant surface water scenarios required by Norway  If micro/mesocosm studies are needed to get acceptable risk, a justification for why the data is representative for Norwegian conditions  **Risk assessment for bees**  Risk assessment for bees according to the Northern Zone Guidance document  If field data/higher tier data is needed to get acceptable risk, a justification for why the data is representative for Norwegian conditions  **Risk assessment for soil dwelling organisms**  Risk assessment with PECsoil values estimated with model/tool specified in the Northern Zone Guidance document  If field data/higher tier data is needed to get acceptable risk, a justification for why the data is representative for Norwegian conditions  **Other Non-target organisms**  If field data/higher tier data is needed in order to get acceptable risk, a justification for why the data is representative for Norwegian conditions  **Other information**    **If no additional documentation is included,** please provide justifications  Comments |

### **Product safety information**

| **No** | **Information** | **Yes** | **No** |
| --- | --- | --- | --- |
| 37 | Classification for the plant protection product  Applicant’s proposal for classification of the plant protection product in accordance with Regulation (EC) No 1272/2008 (CLP) of substances and mixtures is **attached**. |  |  |
| 38 | SDS for the plant protection product  A **safety data sheet** (SDS), written in both English and Norwegian, is **attached**. |  |  |
| 39 | Information on active substances and co-formulants  A safety data sheet (SDS), of active substances and of all co-formulants, is **attached**. A statement confirming the most up to date version should co-formulants where the SDS’ revision date is older than two years from the date of application date. |  |  |
|  | Detailed chemical composition for all co-formulants is **attached.**  **If no,** suppliers have been requested to submit chemical composition of co-formulants. |  |  |

**Data ownership**

| **No** | **Information** | **Yes** | **No** |
| --- | --- | --- | --- |
| 40 | 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 forceshall be submitted |  |  |
| 41 | Data protection  Are studies used to support the authorisation out of protection?  If yes, justifications for using data out of protection shall be submitted  Comments |  |  |

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

| No | Information | Yes | No |
| --- | --- | --- | --- |
| 42:1 | Sources of active substance  All relevant equivalence reports are attached |  |  |
| 43:1 | 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 forceshall be submitted  If yes: Report on data match shall be submitted |  |  |
| 44:1 | Data access  Is used data out of protection?  If yes, justifications for using data out of protection shall be submitted |  |  |

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

| **No** | **Information** | **Yes** | **No** |
| --- | --- | --- | --- |
| 42:2 | Sources of active substance  All relevant equivalence reports are attached |  |  |
| 43:2 | 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 forceshall be submitted  If yes: Report on data match shall be submitted |  |  |
| 44:2 | Data access  Is used data out of protection?  If yes, justifications for using data out of protection shall be submitted |  |  |

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

| **No** | **Information** | **Yes** | **No** |
| --- | --- | --- | --- |
| 42:3 | Sources of active substance  All relevant equivalence reports are attached |  |  |
| 43:3 | 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 forceshall be submitted  If yes: Report on data match shall be submitted |  |  |
| 44:3 | Data access  Is used data out of protection?  If yes, justifications for using data out of protection shall be submitted |  |  |

### **Confidentiality**

| **No** | **Information** | **Yes** | **No** |
| --- | --- | --- | --- |
| 44 | Confidentiality request  Is certain information requested to be kept confidential?  If yes, the template available in SANCO/13169/2010 Rev. 11 shall be used. |  |  |

### **Further information**

| **No** | **Information** |
| --- | --- |
| 45 | Other comments |

1. 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-2)
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-3)
3. If the product contains **nematodes, insects or arachnids,** use the special application form for macroorganisms. [↑](#footnote-ref-4)
4. [↑](#footnote-ref-5)