

# **Application – Authorisation of new, renewal, or label extension (LEX) of a plant protection product**

According to article 33 (new product or LEX) and article 43 (renewal) in Regulation (EC) No 1107/2009.

| **Application** |
| --- |
| No | Information |
| 1 | Type of authorisation (choose alternative)New product | Proposed zonal rapporteur Member State (MS)      |
| 2 | Type of product[ ]  Chemical [ ]  Biological[[1]](#footnote-2) | In case of renewal, Norwegian authorisation no.      |
| 3.1 | In case of renewal: Is an amendment made in connection with the application for renewal?[ ]  Yes [ ]  No | **If yes**, please describe the change of the conditions:      |
| 3.2 | In case of label extension, please describe amendments:      |

| **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-3) |
| --- |
| 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-4) (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)      |

| **Other concerned Member States** |
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| **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 |

| **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 stated 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.

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| **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 used data out of protection?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 used data out of protection?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. | [ ]  | [ ]  |

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| **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-5) 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 documentation and application form to:**  |
| --- |
| Norwegian Food Safety AuthorityDivision plants, feed and drinking water, approvals departmentE-mail: postmottak@mattilsynet.no and pesticider@mattilsynet.no Or by post/courier to:Mattilsynet / Norwegian Food Safety AuthorityDivision plants, feed and drinking water, approvals departmentGlynitveien 30, N-1400 Ski, NorwayAll documents should be submitted in a digital, searchable format.For further questions about this form, contact postmottak@mattilsynet.no. |

| **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 |       | [ ]  | [ ]  |       |
| **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-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. The applicant is fully responsible for the placing of a plant protection product on the Norwegian market. The representative cannot hold an authorization. [↑](#footnote-ref-4)
4. Should be sent per email to pesticider@mattilsynet.no and postmottak@mattilsynet.no, or delivered to Norwegian Food Safety Authority, Division plants, feed and drinking water, approvals department, Glynitveien 30, N-1400 Ski, Norway. [↑](#footnote-ref-5)