Et bilde som inneholder Font, Grafikk, grafisk design, logo

KI-generert innhold kan være feil.

# **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** | |
| --- | --- |
| **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 | Sources  Have 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 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. |  |  |
| 29:1 | Data access  Is used data out of protection?  If yes, justifications for using data out of protection shall be submitted. |  |  |
| 30:1 | New studies  Are new tests or study reports included?  **If yes, justifications** (art 33.3 d) shall be submitted. |  |  |
| 31:1 | New studies  Are 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 | Sources  Have 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 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. |  |  |
| 29:2 | Data access  Is used data out of protection?  If yes, justifications for using data out of protection shall be submitted. |  |  |
| 30:2 | New studies  Are new tests or study reports included?  **If yes, justifications** (art 33.3 d) shall be submitted. |  |  |
| 31:2 | New studies  Are 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 | Sources  Have 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 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. |  |  |
| 29:3 | Data access  Is used data out of protection?  If yes, justifications for using data out of protection shall be submitted. |  |  |
| 30:3 | New studies  Are new tests or study reports included?  **If yes, justifications** (art 33.3 d) shall be submitted. |  |  |
| 31:3 | New studies  Are 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 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. |  |  |
| 33 | Information on co-formulants  For 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 submitted  Applicant’s proposal for **CLP-classification** of the plant protection product is attached. |  |  |
| 35 | Data access  Is used data out of protection?  If yes, justifications for using data out of protection shall be submitted. |  |  |
| 36 | New studies  Are new tests or study reports included?  **If yes,justifications**(art 33.3 d) shall be submitted. |  |  |
| 37 | Vertebrate studies  Are 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 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 |  |  |
| 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 Authority  Division plants, feed and drinking water, approvals department  E-mail: [postmottak@mattilsynet.no](mailto:postmottak@mattilsynet.no) and [pesticider@mattilsynet.no](mailto:pesticider@mattilsynet.no)  Or by post/courier to:  Mattilsynet / Norwegian Food Safety Authority  Division plants, feed and drinking water, approvals department  Glynitveien 30,  N-1400 Ski, Norway  All documents should be submitted in a digital, searchable format.  For further questions about this form, contact [postmottak@mattilsynet.no](mailto: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](mailto:pesticider@mattilsynet.no) and [postmottak@mattilsynet.no](mailto: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)