###

### Application

The numbers in the drop down list refers to the numbers in the price list with application fees for plant protection products.

| No. | Information |
| --- | --- |
| 1 | Type of product | Type of amendment (only one amendment per application) | Proposed zonal rapporteur Member state, zRMS      |

### Product information

| No. | Information |
| --- | --- |
| 2 | Name of the product      | Authorisation no.      | Low-risk product[[1]](#footnote-1) |

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

|  |  |  |
| --- | --- | --- |
| 3 | Applying company       | Date      |
| Signature | Printed name      |

|  |  |
| --- | --- |
| **Send the documentationto:** Danish EPATolderlundsvej 5DK-5000 Odense CAtt. The pesticide division”Application for amendment of authorisation” or to: pesticider@mst.dk  | **Payment:**The Danish EPA makes a decision on the application fee and sends the decision together with an invoice. The invoice states the amount to be paid and how to pay it. A list of application fees is available at MST’s website. |

### Applicant

Current authorisation holder or the permanent representative

| No. | Information |
| --- | --- |
| 4 | Name      | Company´s registration no. (see no. 5 below)      |
| Address      | Telephone no. (incl. country code)      |
| Postal code and town      | Contact person      |
| Country      | E-mail address      |
| 5 | A company/corporation certificate should be submitted by all companies that have no previously authorised plant protection product in Denmark. Company/corporation certificates can also be required if there have been changes since the last product authorisation or if more than 6 months has elapsed since the last application was filed.[ ]  **Applying company´s/corporation´s certificate** is attached |

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

Representing the authorisation holder (i.e. the applicant in no. 4 above) **only during the application procedure**

| No. | Information |
| --- | --- |
| 6 | Company name      | Company´s registration no.      |
| Address      | Telephone no. (incl. country code)      |
| Postal code and town      | Contact person      |
| Country      | E-mail address      |
| 7 | A representative should prove the appointed level of representation by the applicant in original. [ ]  **Power of attorney as temporary representative** is attached |

### Invoicing address for application fee

| No. | Information |
| --- | --- |
| 8 | Application fee will be paid by[ ]  Authorisation holder[ ]  Temporary representative[ ]  Permanent representative |
| Invoicing address      | Company´s VAT-no.      |
| Postal code and town      | Country      |
| Contact person (name & phone)      | E-mail address      |
| PO-number (if applicable)      | EAN-number (if applicable)      |

## Type of amendment

### Amendment of use or conditions for use (large)

An application for amendment may require a new assessment, where the same requirements as for an authorisation, have to be met.

| No. | Information |
| --- | --- |
| 9 | Crop(s)      | Pest(s)      |
| 10 | Dose/ha      | Dose active substance/ha      | Number of applications      | Time between applications (days)      |
| 11 | Growth stage at application (BBCH)      | Post harvest interval (PHI)      |
| 12 | Type of amendment[ ]  New crop[ ]  Change of BBCH outside the risk envelope[ ]  Higher dose[ ]  Other |
| 13 | When submitting data required according to sections 3.1 – 3.8, Regulation (EU) No 284/2013, please use a GAP-table in accordance with the guidance on draft Registration Reports[[4]](#footnote-4).[ ]  GAP-table is attached |
| 14 | Instruction for use[ ]  Complete instruction for use, with both present and new use areas (in Danish language) is attached |
| 15 | Documentation[ ]  Signed cover letter[ ]  New annex III studies relevant for the amendment  |
| 16 | Registration report[ ]  Update of all relevant original RR sections with the applied changes highlighted |
| 17 | Part A[ ]  Update of the original Part A with the applied changes highlighted |

### Amendment of use or conditions for use (minor)

An application for amendment may require a new assessment, where the same requirements as for an authorisation, have to be met.

| No. | Information |
| --- | --- |
| 18 | Crop(s)      | Pest(s)      |
| 19 | Dose/ha      | Dose active substance/ha      | Number of applications      | Time between applications (days)      |
| 20 | Growth stage at application (BBCH)      | Post harvest interval (PHI)      |
| 21 | Type of amendment[ ]  New pest (within the application pattern of the original authorisation)[ ]  Lowering the dose[ ]  Change of BBCH within the risk envelope[ ]  Other |
| 22 | When submitting data required according to sections 3.1 – 3.8, Regulation (EU) No 284/2013, please use a GAP-table in accordance with the guidance on draft Registration Reports5. [ ]  GAP-table is attached |
| 23 | Instruction for use[ ]  Complete instruction for use, with both present and new use areas (in national language) is attached |
| 24 | Documentation[ ]  Signed cover letter[ ]  Annex III studies relevant for the amendment  |
| 25 | Registration report[ ]  Update of the original efficacy RR section with the applied changes highlighted |
| 26 | Part A[ ]  Update of the original Part A with the applied changes highlighted |

### Amendment of source and/or manufacturing process for active substance requiring assessment of equivalence

| No. | Information |
| --- | --- |
| 27 | Type of amendment[ ]  Changed/additional manufacturer of the active substance[ ]  Changed/additional source of active substance, equivalence report available on CIRCABC |
| 28 | Documentation[ ]  Signed cover letter[ ]  **Complete** documentation for the assessment of equivalence |
| 29 | Registration report[ ]  Update of the original Part C with the applied changes highlighted |

### Amendment of composition (significant)

If formulants are included in the product, the full composition of those formulants has to be stated. If the formulant composition is unknown, the applicant must contact the manufacturer and ask them to send the full composition directly to The Danish EPA. When the information is submitted it shall be stated which product and application the information relates to. The Danish EPA will treat all information regarding composition as confidential.

Distinction between significant and non-significant formulation changes should be based on guidance document on significant and non-significant changes[[5]](#footnote-5).

An application for amendment may require a new assessment, where the same requirements as for an authorisation, have to be met.

| No. | Information |
| --- | --- |
| 30 | Type of amendment[ ]  Change of co-formulant[ ]  Other |
| 31 | Composition[ ]  Complete composition statement for the **current formulation** is attached[ ]  Complete composition statement for the **new formulation** is attached |
| 32 | If **new co-formulants** are added, safety data sheets and specification should be submitted[ ]  Safety data sheets for the new co-formulant(s) are attached[ ]  Safety data sheet, updated for the product, is attached |
| 33 | Ananlytical methods[ ]  New analytical method for the formulation if relevant |
| 34 | Statement[ ]  Statements on the effects on efficacy, mammalian toxicology and ecotoxicology |
| 35 | Documentation[ ]  Signed cover letter[ ]  New phys-chem annex III studies relevant for the amendment |
| 36 | Registration report[ ]  Update of the relevant original RR section(s) with the applied changes highlighted[ ]  Update of the original Part C with the applied changes highlighted |

### Amendment of composition (non-significant)

If formulants are included in the product, the full composition of those formulants has to be stated. If the formulant composition is unknown, the applicant must contact the manufacturer and ask them to send the full composition directly to The Danish EPA. When the information is submitted it shall be stated which product and application the information relates to. The Danish EPA will treat all information regarding composition as confidential.

Distinction between significant and non-significant formulation changes should be based on guidance document on significant and non-significant changes[[6]](#footnote-6).

An application for amendment may require a new assessment, where the same requirements as for an authorisation, have to be met.

| No. | Information |
| --- | --- |
| 37 | Type of amendment[ ]  Addition of new source of co-formulant[ ]  Other |
| 38 | Composition[ ]  Complete composition statement for the **current formulation** is attached[ ]  Complete composition statement for the **new formulation** is attached |
| 39 | If **new sources of co-formulants** are added, safety data sheets and specification should be submitted[ ]  Safety data sheets for the new co-formulant(s) are attached[ ]  Safety data sheet, updated for the product, is attached |
| 40 | Documentation[ ]  Signed cover letter |
| 41 | Registration report[ ]  An update of the original Part C with the applied changes highlighted |

### Amendment of classification

| No. | Information |
| --- | --- |
| 42 | Statement[ ]  Statement on the amendment of classification  |
| 43 | Documentation[ ]  Documentation relevant for amendment [ ]  Signed cover letter  |
| 44 | Registration report[ ]  Update of the relevant original RR section(s) with the applied changes highlighted |

### Amendment of packaging

| No. | Information |
| --- | --- |
| 45 | Amendment[ ]  New packaging material [ ]  New packaging size/type |
| 46 | Documentation [ ]  Packaging specifications for new and current packagings are attached[ ]  Two years storage stability study is attached[ ]  Accelerated storage stability study is attached[ ]  Signed cover letter  |
| 47 | Registration report[ ]  Update of the original phys-chem RR section with the applied changes highlighted |

### Amendment/addition of manufacturing site for product

| No. | Information |
| --- | --- |
| 48 | Type of amendment[ ]  Additional manufacturing site[ ]  Amendment of manufacturing site |
| 49 | Documentation[ ]  Cover letter [ ]  Update of the original Part C/Dok J with the applied changes highlighted |

### Product transfer

| No. | Information |  |
| --- | --- | --- |
| 50 | Name(s) of the product(s)                | Registration no.                |
| 51 | Documentation[ ]  Cover letter with effective date of transfer and new product name(s). (See requirements on our [website](https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/requirements-subsequent-to-the-decision/advertising/)).[ ]  Letter of access[ ]  Letter of acceptance for the transfer from the current and the new authorisation holder |

### Name change for the product

| No. | Information |  |
| --- | --- | --- |
| 52 | Amendment[ ]  Name change of authorised product(s) |  |
| 53 | Current product name(s)                | Registration no.                |
| 54 | Documentation[ ]  Cover letter with effective date of change and new product name(s). (See requirements on our [website](https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/requirements-subsequent-to-the-decision/advertising/)) |  |

### Name or address change of approval holder

| No. | Information |  |
| --- | --- | --- |
| 55 | Amendment[ ]  Name change of approval holder[ ]  Address change of approval holder |  |
| 56 | Approval holders authorised products                 | Registration no.                |
| 57 | Documentation[ ]  Cover letter with effective date of change, new name/address of the approval holder. |  |

### Withdrawal

| No. | Information |
| --- | --- |
| 58 | Withdrawal datedd yyyy |
| 59 | Product(s) to be withdrawn                 | Registration no.                |
| 60 | Reason to withdrawal[ ]  Cover letter with effective date and reason for the withdrawal |

### Amendment of label

| No. | Information |
| --- | --- |
| 61 | Documentation [ ]  Describtion of in which section changes have been made[ ]  In case of new package size, documentation for identical label layout is attached[ ]  In case of different label layouts, all package sizes are submitted for approval[ ]  Label draft as editable PDF-file (ready-to-print, not scanned) is attached |

### Other amendment

| No. | Information |
| --- | --- |
| 62 | Describe the amendment      |

## Annexes

Please observe that all of the studies referred to in this application must be made available to the Danish EPA in full text, including those where access is provided through a Letter of Access. A Letter of Access should in relevant cases be attached to this application.

Data requirements according Regulation (EU) No 284/2013 must be met either by new documentation or by a justification showing that the original assessment covers the intended amendment.

| See No. | Issue | Comments | Attached? | Annex No |
| --- | --- | --- | --- | --- |
| Yes | No |
| All | Signed cover letter |       | [ ]  | [ ]  |       |
| 5 | Applying company´s/corporation´s certificate |       | [ ]  | [ ]  |       |
| 7 | Power of attorney as temporary representative |       | [ ]  | [ ]  |       |
| 13+22 | GAP-table |       | [ ]  | [ ]  |       |
| 14+23 | Complete instruction for use |       | [ ]  | [ ]  |       |
| 15+24  | New annex III studies |       | [ ]  | [ ]  |       |
| 16 | Update of the original RR section(s) |       | [ ]  | [ ]  |       |
| 17+26 | Update of the original Part A |       | [ ]  | [ ]  |       |
| 25 | Update of the original efficacy RR section  |       | [ ]  | [ ]  |       |
| 28 | Documentation for equivalence assessment |       | [ ]  | [ ]  |       |
| 29 | Update of the original Part C  |       | [ ]  | [ ]  |       |
| 31+38 | Composition – current formulation |       | [ ]  | [ ]  |       |
| 31+38 | Composition – new formulation |       | [ ]  | [ ]  |       |
| 32+39 | Safety data sheet(s) – new co-formulant(s) |       | [ ]  | [ ]  |       |
| 32+39 | Safety data sheet – updated for the product |       | [ ]  | [ ]  |       |
| 33 | New analytical method for the formulation |       | [ ]  | [ ]  |       |
| 34 | Statements on the effects on efficacy, mammalian toxicology and ecotoxicology |       | [ ]  | [ ]  |       |
| 35 | New phys-chem annex III studies  |       | [ ]  | [ ]  |       |
| 36 | Update of the original RR section(s)  |       | [ ]  | [ ]  |       |
| 36+41 | Update of the original Part C  |       | [ ]  | [ ]  |       |
| 42 | Statement on the amendment of classification  |       | [ ]  | [ ]  |       |
| 43 | Documentation relevant for amendment  |       | [ ]  | [ ]  |       |
| 44 | Update of the original RR section(s)  |       | [ ]  | [ ]  |       |
| 46 | Packaging specification, new and current packagings |       | [ ]  | [ ]  |       |
| 46 | Two years storage stability study |       | [ ]  | [ ]  |       |
| 46 | Accelerated storage stability study |       | [ ]  | [ ]  |       |
| 47 | Update of the original phys-chem RR section |       | [ ]  | [ ]  |       |
| 49 | Update of the original Part C/Dok J |       | [ ]  | [ ]  |       |
| 51 | Letter of access |       | [ ]  | [ ]  |       |
| 51 | Letter of acceptance for the transfer from the current and the new authorisation holder |       | [ ]  | [ ]  |       |
| 61 | Describtion of in which section changes have been made |       | [ ]  | [ ]  |       |
| 61 | Documentation for identical label layout |       | [ ]  | [ ]  |       |
| 61 | All package sizes are submitted |       | [ ]  | [ ]  |       |
| 61 | Label draft as editable PDF-file (ready-to-print, not scanned) |       | [ ]  | [ ]  |       |
| 62 | Description of other amendment |       | [ ]  | [ ]  |       |

1. According to article 47 in Regulation (EC) No 1107/2009. [↑](#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 should be submitted. [↑](#footnote-ref-2)
3. The authorisation holder is fully responsible for the placing of a plant protection product on the MS market. The representative cannot hold the authorisation. [↑](#footnote-ref-3)
4. Guidance document on the [presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC](http://ec.europa.eu/food/plant/protection/resources/drr_guidance_doc.zip) in the format of a (draft) Registration Report - Annexes (doc. SANCO/6895/2009) [↑](#footnote-ref-4)
5. Guidance document on significant and non-significant changes of the chemical

composition of authorised plant protection products under Regulation (EC) No

1107/2009 of the EU Parliament and Council on placing of plant protection products on

the market and repealing Council Directives 79/117/EEC and 91/414/EEC. (doc. SANCO/12638/2011) [↑](#footnote-ref-5)
6. Guidance document on significant and non-significant changes of the chemical

composition of authorised plant protection products under Regulation (EC) No

1107/2009 of the EU Parliament and Council on placing of plant protection products on

the market and repealing Council Directives 79/117/EEC and 91/414/EEC. (doc. SANCO/12638/2011) [↑](#footnote-ref-6)