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|  | P.I. „NATIONAL CENTER FOR ANIMAL HEALTH, PLANT AND FOOD SAFETY”  16A Sarmizegetusa str.  2032 Chisinau  Republic of Moldova | **Telephone**: +373 22 639002  **Fax:** : +373 22 639030  **Email:** centrul@pesticide.md  **Web page**: www.pesticide.md | |
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| **Application Form**  **Application for commercial authorisation of a Plant Protection Product- Recognition Procedure** | | | |

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| **When to use this form**  Applications for **commercial** authorisation of a **plant protection product** (first authorisation or amendment to an existing authorisation) where:   * an identical product is authorised in an EU ‘reference’ country |

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| **When not to use this form**  Applications for authorisation of a **plant protection product** as follows:   * Where the product has not been authorised by an appropriate EU reference country and where no human health or environmental safety assessment has been carried out and is available to support the Plant Protection Product. |

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| **How to complete this form**   * Complete all parts of A to G and Appendices 1 & 2 as appropriate. * Where additional rows/tables in Parts D/E and Appendices are required please add these on a separate sheet. |

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| **Where to send this form**  Please submit your completed form with all other relevant supporting information/data, one paper copy + CD to the Director of National Center by post:  **P.I. „NATIONAL CENTER FOR ANIMAL HEALTH, PLANT AND FOOD SAFETY” of Republic of Moldova**  **16A Sarmizegetusa str.**  **2032 Chisinau**  **Republic of Moldova** |

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| **Part A – Applicant details** | | | | | |
| **1** | **Applicant** | **Contact name** |  | **Title** |  |
| **Company name** |  | | |
| **Address** |  | | |
| **Telephone** |  | | |
| **E mail** |  | | |
| **2** | **Address for invoicing (if different)** | **Contact name** |  | **Title** |  |
| **Company name** |  | | |
| **Address** |  | | |
| **Telephone** |  | | |
| **e mail** |  | | |

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| **Part B – Type of application** | |
| **3a** | **Tick the box(es) that best describe your application** |
|  | **New plant protection product** |
|  | **Administrative amendment- e.g. change of tradename, authorisation holder** |
|  | **Amendment to an existing authorisation e.g. new crop(s) or change of rates/timings/application method (specify below)** |
|  |
|  | **Change to active substance technical specification or new active substance manufacturing site** |
|  | **Minor change in the composition of the formulation** |
|  | **Packaging change** |
|  | **Other (specify below)** |
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| **3b** | **Have State efficacy trials been completed** |
|  | **Yes- provide details below** |
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|  | **No- explain below why trials are not required for this application** |
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| **Part C – Product identity** | | | |
| **4** | **Proposed details in Moldova–must *always* be completed** | | |
| **4a** | **Product name intended for use in Moldova** | |  |
| **4b** | **Approval certificate number (if product already approved and if application is for amendment of an existing authorisation)** | |  |
| **4c** | **Authorisation holder** | **Company name** |  |
| **Address** |  |
| **4d** | **Marketing company (if different)** | **Company name** |  |
| **Address** |  |

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| **5** | **Active substance(s) and content (**Names and ID codes for the active substance; ISO common name; Number CIPAC, EINECS and ELINCS for active substance) | |  | | | |
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| **6** | **Product type** | **Herbicide** | **Fungicide** | **Insecticide** | | **Other (specify)** |
| **7** | **Field of use** | **Professional** | **Amateur** | |  | |

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| **8** | **Details as currently authorised in Moldova - only complete if different to 4 above** | | |
| **8a** | **Product name** | |  |
| **8b** | **Authorisation certificate number** | |  |
| **8c** | **Authorisation holder** | **Company name** |  |
| **Address** |  |
| **8d** | **Marketing company (if different)** | **Company name** |  |
| **Address** |  |

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| **9** | **Details of the EU ‘reference ‘ product supporting the Plant Protection Product applied for in the Republic of Moldova. Please also complete Appendix 3 (GAP Table).** | | | |
| **9a** | **Product name** | |  | |
| **9b** | **EU Reference Country** | |  | |
| **9c** | **Authorisation holder** | **Company name** |  | |
| **Address** |  | |
| **9d** | **Marketing company (if different)** | **Company name** |  | |
| **Address** |  | |
| **9e** | **Date and number of authorisation certificate for recognition** | |  | |
| **9f** | **Date and number of all authorisation certificates of the product (all changes made)** | |  | |
| **9g** | **Is a complete Registration Report/ safety evaluation of the reference product available and been submitted with this application?** | | Yes  No – if no, explain why you consider certain information is not relevant or required for this application. | |
| **9h** | **Has the source of technical material to be used in the product been considered equivalent by the EU?** | | Yes, if so please submit evidence of this  No - please ensure appropriate data is submitted to allow the source to be considered. | |
| **9i** | **Details of MRLs established in the EU for the crops applied for in Moldova (add further rows where required)** | | **Crop** | **MRL established (mg/kg)** |
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| **Part D –Data ownership in EU** | | | | | |
| **10** | **Active substance data in EU MS (if more than one a.s. copy and paste table below)** | | | | |
| **Active substance(s) names(s)** | | |  | | |
| **Are all data on the active substance owned by the company applying for authorisation?** | | | **Yes**  **No  If all or some data are not owned by applicant specify all ownership below (including specific data owned by applicant)** | | |
|  | | **Data owner(s)** | **Letters of Access** | | |
| **Not needed- owned by applicant** | **Required** | **Not needed- unprotected data** |
| **5 batch analysis data for technical specification** | |  |  |  |  |
| **A.s. data package** | |  |  |  |  |

**Add additional tables if required.**

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| **11** | **Formulation data ownership in EU MS** | | | | |
| **Are all data on the formulation owned by the company applying for approval?** | | | **Yes**  **No  If all or some data are not owned by applicant specify all ownership below(including specific data owned by applicant)** | | |
| **D**a**ta owner(s)** | | **Specific type of data e.g. (residues, efficacy) or ‘all data’** | **Letters of Access** | | |
| **Not needed- owned by applicant** | **Required** | **Not needed- unprotected data** |
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**‘Copy and paste’ additional rows above if necessary**

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| **Part E –Active substance and Formulation details** |
| **Complete sections 12-14 below, providing details of the active substance technical material and the formulation** |

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| **12** | **Tick box if the source of active substance/specification to be used in the Plant Protection Product in Moldova is an approved EU source (either the EU reference specification or has been assessed and considered equivalent in the EU)** | |  |
| **If the manufacturing source has been authorised for use in other Plant Protection Products in Moldova, please list these product below with their Certificate of Approval numbers** | | | |
| **Product** | | **Approval number** | |
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| **13** | **Technical specification of active substance - please complete the following table detailing the specification of active substance to be used in the Plant Protection Product. If the product is a mixed active product please copy and paste further tables underneath (one table per active substance)** | | | | | |
| **Active substance name:** | | |  | | | |
| **Manufacturing site(s), name and address (of factory):** | | |  | | | |
| **5 batch analysis data owner:** | | |  | | | |
| **Component (CAS/IUPAC name)** | | **CAS number** | | **Content (state min or max)** | **Chemical structure** | **Chemical group/**  **family name** |
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**Add additional tables on a separate page if required.**

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| **14** | **Formulation composition - must be completed for all products to be registered in Moldova**  **(new or existing formulations)** | | | | | | | |
| **Product name** | | | | |  | | | |
| **Other formulation development code numbers/formulation names** | | | | |  | | | |
| **Formulation type** | | | | |  | | | |
| **Formulation site(s), name and address** | | | | |  | | | |
| **Tolerance limits of active substance(s) in the formulation** | | | | |  | | | |
| **Relative density of the formulation** | | | | |  | | | |
| **Chemical name** | | **CAS/ Colour Index / EC (ELINCS/ EINECS) no(s)** | **Chemical description** | **Tradename(s)** | | **Function** | **Content (state**  **(g/kg,%w/w,**  **% w/v or g/l)** | **MSDS provided?**  **(Y/N)** |
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**Add additional tables on a separate page if required.**

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| **Part F – Packaging details** | | |
| **15** | **Packaging as currently authorised in EU reference country** | |
|  | **Pack sizes** | **Pack material and design** |
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| **16** | **Proposed packaging in Moldova** | |
|  | **Pack sizes** | **Pack material and design** |
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**Copy and paste’ additional rows above if necessary or press ‘tab’ key with cursor in bottom right cell**

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| **Part G Signed declaration** | | | |
| **You must sign the following declaration:** | | | |
| **I confirm that the information given in this application form is true to the best of my knowledge, information and belief:** | | | |
| **Signed** |  | **dated** |  |

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| **Checklist of documents to submit with the application form** | |
| **Authorised copy of Certificate issued by reference country of EU** |  |
| **Authorised translation of Certificate issued by reference country of EU in Romanian language** |  |
| **Draft label for proposed Moldovan product, in Romanian language** |  |
| **Authorised original label of the product in the EU reference country with translation on Romanian language** |  |
| **Declaration that the product proposed for recognition is the same as authorised in reference country of EU** |  |
| **Product Registration Report/ other safety evaluation document from the EU reference country** |  |
| **EU Technical Equivalence Report(s) for the a.s. manufacturing site(s)** |  |
| **Letters of Access to a.s. data package(s)** |  |
| **Letters of Access to formulation data package(s)** |  |
| **SDS in Romanian language, MSDS for all components of the product (in Romanian language or English language)** |  |
| **BAD (CD copy)** |  |

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| **Appendix - Good Agricultural Practice - must be completed** |

**GAP authorised in the Member State of EU**

| **Crop and/**  **or situation (a)** | **MS** | **Product**  **name** | **F / G** | **Pests or Group**  **of pests controlled**  **(c)** | **Formulation** | | **Application** | | | | **Application rate per treatment** | | | | **PHI** | **Remarks:**  **Re-entry period in days for to crops, buildings or spaces treated**  **(m)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **or I (b)** | **Type (c-d)** | **Conc. of a.s.**  **(i)** | **method, kind (f-h)** | **growth stage**  **(j)** | **number min-max**  **(k)** | **interval between applications (min)** | **g a.s./ha min-max** | **product/**  **ha**  **min-max** | **g a.s./hl min-max** | **water l/ha min-max** | **(days) (l)** |
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**GAP to be authorised in the Republic of Moldova**

| **Crop and/**  **or situation (a)** | **Product**  **name** | **F / G** | **Pests or Group**  **of pests controlled**  **(c)** | **Formulation** | | **Application** | | | | **Application rate per treatment** | | | **PHI** | **Remarks:**  **Re-entry period in days for to crops, buildings or spaces treated**  **(m)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **or I (b)** | **Type (c-d)** | **Conc. of a.s.**  **(i)** | **method, kind (f-h)** | **growth stage**  **(j)** | **number min-max**  **(k)** | **interval between applications (min)** | **g a.s./ha min-max** | **Product (kg, L)/**  **ha**  **min-max** | **water l/ha min-max** | **(days) (l)** |
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| **Remarks:**  (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)  (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)  (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds  (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), etc  (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989  (f) All abbreviations used must be explained  (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated | (i) g/kg or g/l  (j) Growth stage during treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application  (k) The minimum and maximum number of application possible under practical conditions of use must be provided  (l) PHI - minimum pre-harvest interval  (m) Remarks may include: Extent of use/economic importance/restrictions, **R**e-entry period in days for to crops, buildings or spaces treated |