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|  | **SECRETARIATUL COMISIEI NAŢIONALE DE OMOLOGARE A PRODUSELOR DE PROTECŢIE A PLANTELOR**  Ministerul Agriculturii si Dezvoltării Rurale  Bulevardul Carol I, nr. 2-4, Sector 3, Bucuresti  Romania  **SECRETARIAT OF THE NATIONAL COMISSION FOR REGISTRATION OF PLANT PROTECTION PRODUCTS**  Ministry of Agriculture and Rural Development  2-4, Carol I, Blvr., Sector 3, Bucharest  Romania | Tel.: +40 (02) 21-3072386;  Fax: +40 (02) 21-3072485  E-mail: fitosanitar@madr.ro  **Website**: [www.madr.ro](http://www.madr.ro) | |
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| **Cererea nr*. …………………..***  ***Application Form no.***  **Cerere pentru reinnoirea autorizatiei unui produs de protectie a plantelor**  ***Application for the renewal of an existing authorisation of a plant protection product)***  **Depunere conform articolului 43 din Regulamentul (CE) Nr. 1107/2009 al Parlamentului European si al Consiliului din 21 octombrie 2009 privind introducerea pe piata a produselor fitosanitare si de abrogare a Directivelor 79/117/CEE si 91/414/CEE ale Consiliului.**  ***Submission under Article 43 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.*** | | | |

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| **Când se foloseste acest formular**  In termen de 3 luni de la data aplicării (D.A.) reinnoirii aprobarii substantei active, detinatorii omologarilor trebuie sa depuna o cerere pentru reinnoirea omologarii fiecarui produs ce contine substanta activa respectiva. Nedepunerea cererii va conduce la expirarea omologării produsului in cauză intr-un interval de timp agreat. Acest formular de cerere trebuie folosit si pentru sustinerea reinnoirii omologarii celei de a doua denumiri comerciale, precum si a extinderilor pentru utilizări minore sustinute de catre detinatorul omologarii in procesul de reinnoire a omologarii produsului.  ***When to use this form***  *Within three months of the Date of Application (DoA) of the renewal of an active substance, authorisation holders should submit an application to renew each product containing the renewed active substance. Failure to submit an application will result in expiry of the existing product authorisation within agreed timeframe.This form must also be used for the administrative back to back (identical) products and Extensions of Authorisation for Minor Use supported for renewal by the product applicant.* |

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| **Cand nu se foloseste acest formular**  Cereri pentru produse de protectie a plantelor după cum urmeaza:   * Omologarea unui produs; * Eliberarea permisului de testare; * Prelungirea certificatului de omologare; * Extinderea omologarii pentru utilizari minore; * Eliberarea permisului de comert paralel; * Eliberarea certificatului de abilitare pentru import mostre de produse de protectie a plantelor.   **When not to use this form**  Applications for authorisation of a plant protection product as follows:   * New product authorisation; * Administrative permit for trial purposes; * Administrative authorisation prolongation; * Extension of authorisation of a minor use of a plant protection product; * Permit for Parallel Trade. * Issuing the Certificate of empowerment to import samples of plant protection products . |

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| **Cum se completeaza formularul**  ***How to complete this form***   * Completati toate partile de la A la G si Anexa dupa cum este cazul   *Complete all parts from A to G and the Appendix as required.*   * Aveti grija sa nu stergeti sau modificati textul existent   *Take care not to delete or amend existing text.*   * Pentru a” *bifa casuta*” dati dublu click pe casuta respectiva, selectati ”*verificat*” dupa care apasati ”*OK*”.   *To check ‘tick boxes’, double click on the box, select ‘checked’ and press ‘ok’.*   * Folositi functia” Copiere si lipire” pentru a adauga randuri/ tabele suplimentare.   *‘Copy and paste’ to add additional rows/tables in the Appendix.*   * Pentru intrebari legate de completarea acestui formular contactati:   *For questions about this form, contact* :  **SECRETARIATUL COMISIEI NATIONALE DE OMOLOGARE A PRODUSELOR DE PROTECTIE A PLANTELOR**  Tel.: +40 (02) 21-3072386;  Fax: +40 (02) 21-3072485  E-mail: [fitosanitar@madr.ro](mailto:fitosanitar@madr.ro)  **Website**: [www.madr.ro](http://www.madr.ro) |

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| **Unde se trimite acest formular**  Salvati o copie a formularului completat si depuneti-l impreună cu celelalte documente relevante pentru sustinerea reinnoirii omologării produsului la:  **SECRETARIATUL COMISIEI NATIONALE DE OMOLOGARE A PRODUSELOR DE PROTECTIE A PLANTELOR**  Ministerul Agriculturii si Dezvoltarii Rurale  Bulevardul Carol nr. 2-4, Sector 3, Bucuresti  Romania  Tel.: +40 (02) 21-3072386;  Fax: +40 (02) 21-3072485  E-mail: [fitosanitar@madr.ro](mailto:fitosanitar@madr.ro)  **Website**: [www.madr.ro](http://www.madr.ro)  ***Where to send this form***  *Save a copy of your completed form and submit it with all other relevant supporting documents for product renewal at*:  **SECRETARIAT OF THE NATIONAL COMISSION FOR REGISTRATION OF PLANT PROTECTION PRODUCTS**  Ministry of Agriculture and Rural Development  2-4, Carol Blvr., Sector 3, Bucharest  Romania  Tel.: +40 (02) 21-3072386;  Fax: +40 (02) 21-3072485  E-mail: fitosanitar@madr.ro  **Website**: [www.madr.ro](http://www.madr.ro) |

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| **Partea A– Informatii privind solicitantul**  *Applicant details* | | | | | |
| **1.** | Solicitant  *Applicant* | Numele persoanei de contact  *Contact name* |  | Titlu  *Title* |  |
| Denumirea companiei  *Company name* |  | | |
| Adresa  *Address* |  | | |
| Telefon  *Telephone* |  | | |
| E-mail |  | | |
| Data intocmirii  Date |  | | |
| Confirm că informatiile furnizate in acest formular sunt adevarate dupa cunostintele mele  *I confirm that the information given in this application form is true to the best of my knowledge.*  (bifati pentru a confirma/*please tick to confirm*) | | | |
| **2.** | Adresa pentru facturare, (daca este diferita)  *Address for invoicing (if different)* | Numele persoanei de contact  *Contact name* |  | Titlu  *Title* |  |
| Denumirea companiei  *Company name* |  | | |
| Adresa  *Address* |  | | |
| Telefon  *Telephone* |  | | |
| E- mail |  | | |
| **3.** | Alte informatii (daca sunt necesare)  *Other information (if needed)* | |  | | |

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| **Partea B –Identitatea produsului**  *Product identity* | | | |
| **4.** | **Detalii privind omologarea existenta - trebuie intotdeauna completate aceste rubrici**  Details as currently authorised –must always be completed | | |
| **4a** | Denumirea comerciala a produsului in Romania  *Product name in Romania* | |  |
|  | Codul produsului (in UE)  *Product Code (across EU)* | |  |
| **4b** | Numarul certificatului de omologare  *Registration number* | |  |
| **4c** | Detinatorul omologarii  *Authorisation holder* | Denumirea companiei  *Company name* |  |
| Adresa  *Address* |  |
| **4d** | Producător -entitatea legală  (daca este diferita)  *Manufacturing legal entity (if different)* | Denumirea companiei  *Company name* |  |
| Adresa  *Address* |  |

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| **5.** | Descrierea produsului  *Product description* | Tipul produsului:  *Product Type:* | | Tipul formularii:  *Formulation type:* | |
| **6.** | Identitatea substantei active reinnoite si concentratia in produs  *Identity of the renewed active substance and content* |  | | Data reinnoirii *Renewal Date* |  |
| **7.** | Alte substante active prezente in formulare, concentratia si data actuala a expirarii aprobarii  *Other active substance(s) present in formulation, content & current active date of expiry* |  | | Data expirarii  *Expiry Date* |  |
|  | | Data expirarii  *Expiry Date* |  |
|  | | Data expirarii  *Expiry Date* |  |
| **8.** | Categoria de utilizatori ce pot folosi produsul de protective a plantelor  *The categories of users allowed to use the plant protection product* | Utilizare de catre profesionisti  *Professional use* | Utilizare de catre neprofesionisti  *Non-professional use* | | Utilizare de catre amatori *Amateur use* |  |

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| **9.** | **Cea de a doua denumire comerciala**  *2nd trade name authorisation* | | |
| Dacă produsul in cauza are omologata in Romania cea de a doua denumire comercială conform Ordinului MADR nr. 60 din 7 martie 2013 pentru aprobarea Regulamentului de organizare si functionare a Comisiei Nationale de Omologare a Produselor de Protectie a Plantelor si aprobarea Procedurilor privind omologarea, comertul paralel si de aprobare a celei de a doua denumiri comerciale pentru un produs de protectie a plantelor omologat pe teritoriul Romaniei, solicitantul trebuie sa completeze rubricile de mai jos daca sustine cea de a doua denumire comercială in procesul de reinnoire a omologarii.  *If this product is currently authorised in Romania with administrative 2nd trade name procedure according to MARD Order No. 60/2013, then please detail below all such authorisations that you wish to maintain following renewal.* | | |
| **Denumirea comerciala a produsului**  *Product name* | **Certificat de omologare nr.**  *Authorisation no.* | **Compania care il comercializeaza**  *Marketing Company* |
|  |  |  |
| \*De retinut ca pentru solicitarile de reinnoire care se bazeaza pe scrisoare de acces (LoA), aceasta trebuie sa acopere si cea de-a 2-a denumire comerciala a produsului.  \**Note that if the application relies upon a letter of access (LoA) you must ensure that the supplied LoAs encompass the 2nd trade name of the product.* | | |

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| **10.** | **10.1 Utilizari omologate**  *Registered uses* | | | | | | | |
|  | **Cultura**  *Crop(s)* | **Organismul ţintă**  *Target* | **Doza**  *Rate* | **Stadiul aplicarii**  *Application stage* | | **Numarul de tratamente**  *Number of applications* | | **Intervalul de pauza pana la recoltare**  *Pre-harvest interval (days)* |
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|  |  |  |  | |  | |  |
| (Adaugati randuri daca este nevoie/*Insert extra rows if necessary*) | | | | | | | |
| **10.2 Utilizari sustinute la reinnoirea omologarii**  *Uses supported for renewal* | | | | | | | |
| **Cultura**  *Crop(s)* | **Organismul tinta**  *Target* | **Doza**  *Rate* | **Stadiul aplicarii**  *Application stage* | | **Numarul de tratamente**  *Number of applications* | | **Intervalul de pauza pana la recoltare**  *Pre-harvest interval (days)* |
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| (Adaugati randuri daca este nevoie/Insert extra rows if necessary) | | | | | | | |
| **10.3 Utilizari minore**  *Extensions of Authorisation for Minor Use* | | | | | | | |
| Daca omologarea produsului include utilizari minore, completati rubricile de mai jos indicand utilizarile sustinute pentru reinnoirea omologarii produsului.  If this product is currently authorised for minor uses please indicate these below and highlight whether the minor use is being supported under this application. | | | | | | | |
| **Cultura**  *Crop(s)* | **Organismul tintă ; Doza**  *Target ; Rate* | | | **Detinatorul datelor**  *Data Owner* | | **Este utilizarea susţinută in această solicitare de reinnoire?**  *Use supported under this application?* | |
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| (Adaugati randuri daca este nevoie/Insert extra rows if necessary) | | | | | | | |

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| **Partea C – Declaratii**  *Declarations* | |
| **11. Trebuie intotdeauna completat – Dacă, din oricare motiv, aceste declaratii nu pot fi confirmate, in principiu produsul in cauza nu poate face subiectul procesului de reinnoire. O cerere conform articolului 33 a Regulamentului (CE) nr. 1107/2009 trebuie depusă pentru modificarea certificatului de omologare.**  *Must always be ticked – If, for any reason, these declarations cannot be confirmed then in principle the product is not suitable for consideration via the renewal process. An application according Article 33 of Regulation (EC) no. 1107/2009 for amended application will be required.* | |
| Prin prezenta confirmam ca produsul/produsele de protectie a plantelor prezentat/prezentate mai sus corespunde cerintelor (condiţiilor si restrictiilor) prevăzute in regulamentul de reinnoire a aprobarii substantei active, asa cum este detaliat la puncul 6  *I confirm that the plant protection product(s) detailed above comply with the requirements (conditions and restrictions) set out in the Regulation on the renewal of the approval of the active substance detailed in box 6.* | ( bifati pentru a confirma  *please tick to confirm*) |
| Prin prezenta confirmam ca sursa/ sursele de material tehnic de substanta activa reinnoita este omologata pentru a fi utilizata in produsul de protecţie a plantelor/produsele de protectie a plantelor prezentat/prezentate mai sus si corespunde cerintelor (conditiilor si restrictiilor) prevazute in regulamentul de reinnoire a aprobarii substantei active, asa cum este detaliat la punctul 6  *I confirm that the source(s) of technical material of the renewed active substance that are currently authorised for use in the plant protection product(s) detailed above comply with the requirements (conditions and restrictions) set out in the Regulation on the renewal of the approval of the renewed active substance detailed in box 6.* | (bifati pentru a confirma *please tick to confirm*) |

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| **Partea D – Tipul reinnoirii**  **Type of renewal** | | | |
| **12. Detalii cu privire la SMRZ- trebuie completate intotdeauna**  *zRMS details - Must always be completed* | | | |
| Romania a fost de acord să fie SMRZ pentru reinnoirea omologării produsului.  *Romania has agreed to act as zRMS for the renewal of this product.* | (bifati pentru a confirma *please tick to confirm)* | Lista SMI agreate  *List agreed cMS* |  |
| Un alt SM a fost de acord să fie SMRZ pentru reinnoirea omologarii produsului. Romania este SMI.  *Another MS has agreed to act as zRMS for the renewal of this product. Romania is a cMS.* | (bifati pentru a confirma *please tick to confirm)* | Confirmarea identităţii SMRZ  *Confirm zRMS identity* |  |
| **13. Natura depunerii - trebuie completate intotdeauna**  *Nature of submission - Must always be completed* | | | |
| Aceasta reinnoire a omologarii include o evaluare completa de risc, actualizata la noile puncte finale.  *This renewal includes a complete risk assessment updated to the latest endpoints.* | (bifati pentru a confirma *please tick to confirm)* |  |  |
| Depunerea evaluarii complete a riscului pentru acest produs este intarziata intrucat produsul contine o alta substanta activa al carei termen de reinnoire expira in interval de 12 luni.  Submission of complete risk assessment for this product is delayed because the product contains a different active substance whose renewal term expires within 12 months. | (bifati pentru a confirma *please tick to confirm)* | Menţionati data expirarii celei de-a 2-a substante active  *Please confirm the expiry date of the second active* |  |
| Depunerea evaluarii complete a riscului pentru acest produs este intarziata pentru generarea datelor din categoria 4 a sectiunii 3.3 din ghidul SANCO/2010/13170/rev.13. Tabelul din Anexa acestui formular a fost completat.  *The submission of a complete risk assessment for this product will be delayed pending data that falls under Category 4 of section 3.3 of SANCO/2010/13170/rev.13. The appendix to this application form has been completed* | (bifati pentru a confirma *please tick to confirm)* | Mentionati termenul limita propus pentru depunere.  *Please confirm proposed submission deadline* |  |

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| **Partea E – Cand este depusa o evaluare actualizata a riscului**  Where an updated risk assessment has been provided | | | | |
| **14** | **Bifati casutele din dreptul sectiunilor din evaluarea de risc existenta (Raportul de Evaluare) care au fost actualizate după reinnoirea aprobarii substantei active.**  *Tick the boxes reflecting which sections of the existing risk assessment (Registration Report) have been updated following renewal of the active substance* | | | |
| **Sectiunea de evaluare**  *Evaluation module* | | **Nu este necesara actualizare**  *No update required* | **Evaluare de risc actualizata**  *Updated Risk assessment* | **Detalii privind actualizarea necesara pentru evaluarea de risc**  **(unde este necesar)**  *Detail of the update needed to risk assessment (where required)* |
| **Chimie**  *Chemistry* | |  |  |  |
| **Metode de analiza**  *Methods of Analysis* | |  |  |  |
| **Toxicitate la mamifere**  *Mammalian toxicology* | |  |  |  |
| **Expunerea operatorului**  Operator exposure | |  |  |  |
| **Reziduuri**  *Residues* | |  |  |  |
| **Comportare in mediu**  *Fate & behaviour* | |  |  |  |
| **Ecotoxicologie**  Ecotoxicology | |  |  |  |
| Eficacitate*Efficacy* | |  |  |  |

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| **Partea F –Proprietatea datelor**  *Data ownership* | | |
| **15.** | **Date despre substanta activă reinnoita**  *Renewed active substance data* | |
| Denumirea substantei active  *Active substance(s) names(s)* | |  |
| Sunt toate datele referitoare la substanta active in proprietatea detinatorului omologarii sau reprezentantului sau legal? *Are all data on the active substance owned by the authorisation holder or its legal representative?* | | **Da (Yes)**  **Nu (No)**  A fost depusa scrisoarea de acces si/sau  tabelul de conformitate completat.  *A Letter of Access and/or a completed data matching table has been supplied.* |
| **16.** | **Proprietatea datelor referitoare la formulare/ datele conform Anexei III**  *Formulation/Annex III data ownershipdata ownership* | |
| Sunt toate datele in proprietatea detinatorului omologarii sau reprezentantului sau legal? *Are all data owned by the authorisation holder or it’s legal representative****?*** | | **Da (Yes)**  **Nu (No)**  A fost depusa scrisoarea de acces si/sau  tabelul de conformitate completat.  *A Letter of Access and/or a completed data*  *matching table has been supplied.* |

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| **Partea G – Date depuse impreună cu formularul - a fi completate de catre toti solicitantii**  *Enclosures – to be completed by all applicants* | | | |
| Scrisoare de inaintare  *Covering letter* |  | Date suport  *Supporting Data* |  |
| dRR ce contine evaluarea completa a riscului produsului si care contine indicatii clare cu privire la partile din evaluare actualizate pentru a reflecta noile cerinte sau criterii privind datele.  *dRR containing complete product risk assessment which clearly indicates where the assessment has been updated to reflect new data requirements or criteria.* |  | Lista datelor prezentate cu o justificare ca fiecare studiu furnizat sustine o cerinta de date sau criterii care nu era in vigoare la momentul acordarii omologarii.  *List of submitted data with justification that each study supplied is to address a data requirement or criteria that was not in force when the authorisation was granted.* |  |
| Propunerea de eticheta in care este evidentiata orice modificare propusa fata de eticheta existenta.  *Draft label highlighting any changes proposed from existing label.* |  | Scrisoare de acces  (acolo unde este cazul)  *Letter(s) of access*  *(where applicable)* |  |
| O copie a certificatului de omologare in România. Cand Romania este SMRZ, se depune si o copie a certificatelor de omologare din fiecare SMI.  *Copy of the existing RO authorisation (Where RO is zRMS a copy of the authorisation certificates from the cMS(s) is also required).* |  | Un raport al informatiilor privind monitorizarea atunci când produsul a fost autorizat cu conditia monitorizarii.  *A report on the monitoring information, where the authorisation was subject to monitoring.* |  |
| Data matching / Data access table |  |  |  |

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| **Anexa – Date categoria 4 (unde este cazul)**  ***Appendix – Category 4 data (where applicable)*** |
| **Completati acest tabel pentru cererile pentru care se solicită depunerea cu intarziere in baza articolului 43.6 pentru studii din Categoria 4 asa cum sunt detaliate in sectiunea 3.3 din ghidul SANCO / 2010/13170 rev.13. Prezentati mai jos acele studii care sunt direct legate de un (nou) punct final si pentru care timpul a fost prea scurt de la publicarea concluziei EFSA pentru a le produce in timp util pentru termenul limita de depunere.**  *Please complete this table for applications for which a delayed submission is requested on the grounds of Article 43.6 and as detailed under category 4 of section 3.3 of SANCO/2010/13170 rev.13. Please summarise below those studies which are directly related to a (new) endpoint and for which the time was too short from the publication of the EFSA conclusion to produce in time for the application deadline.* |

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| **Punctul din anexă**  *Annex Point* | **Titlul studiului**  **(daca este disponibil) sau tipul studiului**  *Study title (if available ) or study type* | **Durata studiului**  Study duration | **Data finalizarii/ numarul raportului**  **(daca este disponibil)**  *Completion date/report number (if available)* | **Justificare**  **(inclusiv dacă studiul este**  **un studiu cat4)**  *Justification (including if study is a cat.4 study)* |
| XXX | Studii in camp..... |  | Ex. 2017-10-15 | Ex. Date privind eficacitatea necesare ca urmare a schimbarii punctului final AI\_ studiu cat.4  *Efficacy data required following change in endpoint for AI\_ Cat 4 study* |
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