MCCAA
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The entity shall fulfil all his/her obligations as per requirements hereunder in order to provide **Evaluation Services of a dossier of a Plant Protection Product and active substances in accordance with Regulation (EC) 1107/2009 as implemented in Malta through Legal Notice 284 of 2011**

The Malta Competition and Consumer Affairs Authority (MCCAA) is the Competent Authority responsible for regulation of Plant Protection Products and their active substances. These have to be authorized by the Competent Authority prior to their placing on the market.

Plant Protection Products are defined as products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses:

- protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products;
- influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient;
- preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives;
- destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants;

A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

- it shall be sufficiently effective;
- it shall have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available; or on groundwater;
- it shall not have any unacceptable effects on plants or plant products;
- it shall not cause unnecessary suffering and pain to vertebrates to be controlled;

- it shall have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted by the Authority to assess such effects are available:
- its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;
- its impact on non-target species, including on the ongoing behaviour of those species;
- its impact on biodiversity and the ecosystem.

Active substances are defined as substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products.
An active substance is approved in accordance with Annex II of Regulation 1107/2009, if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of Annex II of the same Regulation, plant protection products containing that active substance meet the requirements provided for in Article 4 (2) (3) of the regulation.

DUTIES AND RESPONSIBILITES

1. Plant Protection Products

Interested parties are expected to satisfy the following mandatory requirements:

a. The parties must have at least five years of proved experience in the provision of evaluation services of a dossier for the authorization to place a plant protection product on the market as required by Regulation (EC) 1107/2009 provisions for one of the Competent Authorities of Plant Protection Products in any of the Member States included in zone C as defined in Annex I to Regulation (EC) No 1107/2009 i.e. Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal, Croatia;
b. The parties entrusted with handling the evaluation must be contactable on working days and must be available to attend regular meetings with MCCAA when necessary.
c. MCCAA shall be involved in the ongoing works and informed of ongoing progress at all times
d. For authorisations in line with Article 33 of Regulation 1107/2009 the parties shall:
    i. carry out a completeness check of the dossier within a maximum of 6 weeks from the date when notified in writing by MCCAA.

ii. within 8 months (including 6 weeks for completeness check) or within 10 months if equivalence of active substance has to be determined, from when they are notified in writing by MCCAA issue a zonal RMS draft Registration Report (core assessment).

iii. Following 6 weeks commenting period issued by MCCAA, on the zonal RMS draft registration report, the parties will discuss comments received with MCCAA and finalize zonal RMS Registration Report within 6 weeks.

iv. The evaluation will be completed in a manner which satisfies all the requisites of Regulation (EC) 1107/2009 as implemented in Malta through Legal Notice 284 of 2011 and other relevant legislations cited in the same Directive and/or Legal Notice as well as relevant Guidance Documents recognized by the Commission.

2. Active Ingredients

Interested parties are expected to satisfy the following mandatory requirements:

a. The parties must have at least five years of proven experience in the provision of evaluation services of a dossier for the authorization to place an active substance as defined above, in accordance with Regulation (EC) 1107/2009, for a Competent Authority responsible for such active substance in any Member State (MS) of the EU;

b. The parties are expected to liaise and collaborate with any co-RMS, if established, and be available to attend regular meetings with the same co-RMS, either in the MS of the co-Rapporteur Member State (RMS) or in Malta as the RMS.

c. The parties, entrusted with handling the evaluation must be contactable on working days and must be available to attend regular meetings with MCCAA when necessary;

d. MCCAA shall be involved in the ongoing works and informed of ongoing progress at all times.

e. The parties should carry out a completeness check of the dossier, send written acknowledgement, including date of receipt to the applicant, check that any requests for confidentiality are in line with Article 8 (2) of the Regulation, and inform applicant of any missing elements within a maximum of 45 days from the date when notified in writing by MCCAA. In case of a complete dossier the entities shall inform MCCAA of the admissibility of the application and start assessing the substance.

f. The parties, should finalize a draft assessment report in the established format within 11 months of the date of the notification mentioned in the previous paragraph, which shall be extended by an additional period of a maximum of 6 months, if additional studies or information are necessary. This report shall assess whether the active substance can be

expected to meet the approval criteria of Article 4 to the regulation. It shall include also where relevant, a proposal to set maximum residue levels and forward it to MCCAA.

g. The parties should, together with a representative of MCCAA, where appropriate, attend consultation technical meetings relevant to the approval of the active substance which is being evaluated.
h. The parties should assess any additional information submitted by the applicant after this has been requested by EFSA and submit it to MCCAA at the latest within 55 days after receipt of the additional information.
i. Where the approval regulation requires the provision of additional data, the entities shall assess the additional information and submit the assessment to MCCAA at the latest five and a half months after the receipt of the additional information.

3. Technical Capacity

i. The entity shall meet the following minimum requirements:

a. List of principal services of a similar nature such as evaluations according to Regulation 1107/2009
b. A list of the key experts, together with their relevant CVs and other staff proposed for the execution of the contract. The CV should refer to the specific experience which the expert has on the particular topic.

ii. The successful entity shall meet the following minimum requirements:

a. Demonstrate adequate knowledge on evaluation of substances of Plant Protection Products and Active Ingredients.
b. Be able to communicate in any one of the officially recognized languages in Malta.
c. Experience in co-ordinating and implementing projects of comparable nature. Evidence should be included in the CV which is to be submitted together with the offer.

iii. Have available of a minimum of seven (7) experts to evaluate the different sections of the dossier. The pool of experts should satisfy the following criteria:

a. Key expert 1: Should cover Physical - Chemical area in the dossier. Expert must be in possession of at least a degree or equivalent (MQF Level 6) in Chemistry or in a relevant subject. Expert shall provide evidence of practical experience directly related to the evaluation of physical-chemical properties of active substances.
b. Key expert 2: Should cover Eco-toxicology area in the dossier. Expert must be in possession of at least a degree or equivalent (MQF Level 6) in Eco-Toxicology or in a relevant subject. Expert

shall provide evidence of practical experience directly related to the evaluation of eco-toxicological properties of active substances.

c. Key expert 3: Should cover Mammalian toxicology area in the dossier. Expert should be in possession of at least a degree or equivalent (MQF Level 6) in Toxicology or in a relevant subject. Expert shall provide evidence of practical experience directly related to the evaluation of mammalian toxicology properties of active substances.

d. Key expert 4: Should cover Classification area in the dossier. Expert must be in possession of at least a degree or equivalent (MQF Level 6) in Chemistry or in a relevant subject. Expert shall provide evidence of practical experience directly related to the evaluation of classification and labelling issues of active substances.

e. Key expert 5: Should cover Residues section in the dossier. Expert must be in possession of at least a degree or equivalent (MQF Level 6) in Chemistry or Biology or in a relevant subject. Expert shall provide evidence of practical experience directly related to the evaluation of residual issues of active substances.

f. Key expert 6: Should cover Environmental fate section in the dossier. Expert must be in possession of at least a degree or equivalent (MQF Level 6) in Chemistry or Biology or in a relevant subject. Expert shall provide evidence of practical experience directly related to the evaluation of environmental fate of active substances.

g. Key expert 7: Should cover Efficacy section in the dossier. Expert must be in possession of at least a degree or equivalent (MQF Level 6) in Agricultural sciences or in a relevant subject. Expert shall provide evidence of practical experience directly related to the evaluation of efficacy of active substances.

iv. As a minimum, each expert shall also satisfy the following conditions:

a. Each expert should have at least five years of proven experience in the provision of evaluation services for the authorization and approval to place plant protection products and an active substance as defined above, in accordance with Regulation (EC) 1107/2009, for a Competent Authority responsible for such authorisations and approvals in any Member State (MS) of the European Union (EU);

b. Able to communicate in English language.

4. TERMS AND CONDITIONS

(a) Payment Terms

Payments will be affected in the following manner:

i. 20% of the value shall be paid on the delivery of the completeness, when formally notified of acceptance in writing, within ten working (10) days, by the MCCAA and upon presentation of an invoice; and

ii. The remaining 80% of the value shall be paid upon the completion of the service provided and as approved in writing, within twenty working (10) days, by the MCCAA and upon presentation of an invoice.

(b) Penalties

Should there be a delay in completion of the analysis and the delivery of the results to the Authority, due to a direct responsibility of the Party, as the case may be, a penalty of two per centum (2%) of the contract sum for the first week of delay and of five per centum (5%) of the contract sum for the second week, followed by two per centum (2%) of the contract sum per calendar day every day as from the third week onwards, shall be applicable. The sum shall be computed for each day between the day on which the time for completion lapses and the actual date of completion. The party shall not be liable for any failure of or delay in the performance of this Agreement for the period that such failure or delay is due to causes beyond its reasonable control, such as delays in the submission of additional data by the applicant, and any force majeure event.

(c) Travel Costs

Unless travel costs for the specific meeting to be attended are covered by the relevant Institution, these have to be incurred by the awarding parties for the relevant experts and by MCCAA for MCCAA officials.

(d) Conflict of Interest

The party shall perform the Duties in a diligent, impartial and independent manner and in full observation of all the laws and standards applicable to the particular sphere of Plant Protection Products and their active substances. Should it have any conflict of interest in relation to the performance of its Duties, the party shall inform the Authority forthwith furnishing the Authority with all the relative details. The Authority shall have discretion as to how to deal with the particular matter in the circumstances.

4. PARTICIPATION IN EXPRESSION OF INTEREST

Interested entities shall submit the following documentation:

i. Duly filled in information requested in Annex I of this document;

ii. Duly filled in and signed declaration provided in Annex II and III of this document;

iii. Duly filled in tables provided in Annex IV and Annex V of this document;

iv. List of principal services provided according to Regulation 1107/2009 (refer to point (3) (i) and (3) (ii);

v. A list of the key experts, and other staff proposed for the execution of the contract together with their relevant CVs, where specific reference is made to their years of experience in the evaluation of the plant protection products and their active substances (refer to point (3) (iii) and (3) (iv);

vi. Submit information / documentation as proof that the minimum requirement in point (3) (i) and (3) (ii) are met and that the entity has provided services of a similar nature such as evaluations according to Regulation 1107/2009 in any of the Member States included in zone C as defined in Annex I to Regulation (EC) No 1107/2009 i.e. Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal, Croatia;

Eligible submitted notifications of interested entities shall reach MCCAA by not later than **10th May 2021** either through e-mail on trd.mccaa@mccaa.org.mt or in writing to:

The Director General (Technical Regulations Division)
EOI - Evaluation Services of a dossier of a Plant Protection Products and active substances
Malta Competition and Consumer Affairs Authority
Mizzi House, National Road,
Blata l-Bajda HMR 9010
Malta.

Duration: minimum of a three years, with a possibility to extend for an additional two years, provided that the Authority is satisfied with the services provided further that the quoted price shall remain fixed for a period of three years.

Annex I

Name of participating party	
Address of participating party	
Telephone Number of participating party	
E-Mail Address of participating party	
Name of responsible Person for execution of contract	
Name of contact Person for evaluations	

Annex II

I, _____ (insert name of responsible person) with identity or passport number _____ on behalf of _____ (name of party) declare that the following mandatory requirements are satisfied:

a. The parties have at least five years of proven experience in the provision of evaluation services of a dossier for the authorization to place a plant protection product on the market and active substances as required by Regulation (EU) 1107/2009 provisions in any of the Member States included in zone C as defined in Annex I to Regulation (EC) No 1107/2009 i.e. Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal, Croatia;
b. The parties entrusted with handling the evaluation are available for contact at all times during weekdays and must be available to attend regular meetings with MCCAA, applicants, Agency and European Institutions as necessary. Unless travel costs for the specific meeting are covered by the relevant Institution, these have to be incurred by the awarding parties for the relevant experts and by MCCAA for MCCAA officials;
c. MCCAA is involved in ongoing works and informed of ongoing progress at all times.
d. Evaluations shall be carried out within the following timelines:
    a. For applications in line with Article 33: The parties should carry out a completeness check of the dossier within a maximum of 6 weeks from the date when notified in writing by MCCAA; issue a draft Registration Report (core assessment) within 8 months (including 6 weeks for completeness check) or within 10 months if equivalence of active substance has to be determined, from when they are notified in writing by MCCAA, issue a final Registration Report (Parts A, B, C) within 6 weeks following a 6 weeks commenting period issued by MCCAA.
    b. For applications in line with Article 33 (fast track): The parties should carry out a completeness check of the dossier within a maximum of 3 weeks from the date when notified in writing by MCCAA; issue a draft Registration Report (core assessment) within 3 months (including 6 weeks for completeness check), issue a final Registration Report (Parts A, B, C) within 3 weeks following a 6 weeks commenting period issued by MCCAA.
    c. For applications in line with Article 34: The parties should prepare a draft Registration Report within 3 months from the date when notified in writing by MCCAA and issue a final Registration Report (Parts A and C) within 5 weeks following a 3 week commenting period issued by MCCAA.

d. For applications in line with Article 43: The parties should carry out a completeness check of the dossier within a maximum of four (4) weeks from the date when notified in writing by the Technical Regulations Division, issue within 4 months (including 4 weeks for completeness check), from when they are notified in writing by the Technical Regulations Division a zonal RMS draft Registration Report (core assessment) and finalise the zonal RMS Registration Report within six (3) weeks from receipt of the comments received following a three-week commenting period issued by the Technical Regulations Division on the zonal Rapporteur Member States draft registration report, the entity shall discuss and review comments received with the Division.

e. For applications in line with Article 4/22: The entity shall carry out a completeness check of the dossier and issue written acknowledgement, including date of receipt to the applicant, check that any requests for confidentiality are in line with Article 8 (2) of the Regulation, and inform applicant of any missing elements within a maximum of 45 days from the date when notified in writing by MCCAA. In case of a complete dossier the entity shall inform MCCAA of the admissibility of the application and start assessing the substance. Finalize a dAR in the established format within 11 months of the date of the notification mentioned above, which shall be extended by an additional period of a maximum of 6 months, if additional studies or information are necessary. This report shall assess whether the active substance can be expected to meet the approval criteria of Article 4 to the regulation. It shall include also where relevant, a proposal to set maximum residue levels and forward it to MCCAA. Where appropriate, the entity or any one of the appointed experts, together with a representative of MCCAA, attend consultation technical meetings relevant to the approval of the active substance which is being evaluated. Assess any additional information submitted by the applicant after this has been requested by EFSA and submit it to MCCAA at the latest within 55 days after receipt of the additional information. Assess additional information and submission of the assessment to MCCAA at the latest five and a half months after the receipt of the additional information, where the approval regulation of the relevant substance requires such additional data.

f. For applications in line with Article 38: The entity should check for data gaps and issue a draft Equivalence Report within two months from the date when notified in writing by MCCAA. It shall also prepare a final equivalence report within 6 weeks from receipt

of the comments received following a four-week commenting period issued by the Technical Regulations Division on the zonal Rapporteur Member State draft registration report, the entity shall discuss, and review comments received with the Division.

_____	_____
SIGNATURE	NAME OF PARTY
_____	_____
NAME IN FULL	DATE

Annex III

I, _____ (insert name of responsible person) with identity or passport number _____ on behalf of _____ (name of party) declare that I accept the following terms and conditions:

(a) Payment Terms

Payments will be affected in the following manner:

- 20% of the value shall be paid on the delivery of the completeness check of application, when formally notified of acceptance in writing, within ten working (10) days, by the MCCAA and upon presentation of an invoice; and
- The remaining 80% of the value shall be paid upon the completion of the service provided and as approved in writing, within twenty working (10) days, by the MCCAA and upon presentation of an invoice.

(b) Penalties

Should there be a delay in completion of the analysis and the delivery of the results to the Authority, due to a direct responsibility of the Party, as the case may be, a penalty of two per centum (2%) of the contract sum for the first week of delay and of five per centum (5%) of the contract sum for the second week, followed by two per centum (2%) of the contract sum per calendar day every day as from the third week onwards, shall be applicable. The sum shall be computed for each day between the day on which the time for completion lapses and the actual date of completion. The party shall not be liable for any failure of or delay in the performance of this Agreement for the period that such failure or delay is due to causes beyond its reasonable control, such as delays in the submission of additional data by the applicant, and any force majeure event.

(c) Travel Costs

Unless travel costs for the specific meeting to be attended are covered by the relevant Institution, these have to be incurred by the awarding parties for the relevant experts and by MCCAA for MCCAA officials;

(d) Conflict of Interest

The party shall perform the Duties in a diligent, impartial and independent manner and in full observation of all the laws and standards applicable to the particular sphere of Plant Protection Products and their active substances. Should it have any conflict of interest in relation to the performance of its Duties, the party shall inform the Authority forthwith furnishing the Authority with

all the relative details. The Authority shall have discretion as to how to deal with the particular matter in the circumstances.

_____	_____
SIGNATURE	NAME OF PARTY
_____	_____
NAME IN FULL	DATE

Annex IV

Evaluation Type	**Fee (in Euros, inclusive of all taxes)**
Evaluation of a dossier in conformity with Regulation 545/2011 as a zonal Rapporteur Member State (zRMS), of a Plant Protection Product as per Regulation (EC) 1107/2009	
FAST TRACK Evaluation of dossier in conformity with Regulation 545/2011 as a zonal Rapporteur Member State (zRMS), of a Plant Protection Product as per Regulation (EC) 1107/2009	
Evaluation of a dossier in conformity with Regulation 545/2011as a zonal Rapporteur Member State (zRMS), of a Plant Protection Product as per Regulation (EC) 1107/2009 FOR LOW RISK PRODUCTS	
Evaluation of a dossier in conformity with Regulation 545/2011 as a zonal Rapporteur Member State (zRMS), of a Plant Protection Product as per Regulation (EC) 1107/2009: FOR LOW RISK PRODUCTS FOR ORNAMENTAL USE ONLY	
Evaluation of dossier according to Article 43 to Regulation (EC) 1107/2009	
Evaluation of dossier according to Article 34 to Regulation 1107/2009	
Market Authorisation of an Active Substance (including one representative product)	
Market Authorisation of a low risk Active Substance (including one representative product)	
Evaluation of a dossier regarding the technical equivalence for an active substance regulated under Regulation (EC) 1107/2009	

Annex V

Evaluation Type	**Maximum number of evaluations which can be managed per year**
Evaluation of a dossier in conformity with Regulation 545/2011 as a zonal Rapporteur Member State (zRMS), of a Plant Protection Product as per Regulation (EC) 1107/2009	
FAST TRACK Evaluation of dossier in conformity with Regulation 545/2011 as a zonal Rapporteur Member State (zRMS), of a Plant Protection Product as per Regulation (EC) 1107/2009	
Evaluation of a dossier in conformity with Regulation 545/2011as a zonal Rapporteur Member State (zRMS), of a Plant Protection Product as per Regulation (EC) 1107/2009 FOR LOW RISK PRODUCTS	
Evaluation of a dossier in conformity with Regulation 545/2011 as a zonal Rapporteur Member State (zRMS), of a Plant Protection Product as per Regulation (EC) 1107/2009: FOR LOW RISK PRODUCTS FOR ORNAMENTAL USE ONLY	
Evaluation of dossier according to Article 43 to Regulation (EC) 1107/2009	
Evaluation of dossier according to Article 34 to Regulation 1107/2009	
Market Authorisation of an Active Substance (including one representative product)	
Market Authorisation of a low risk Active Substance (including one representative product)	
Evaluation of a dossier regarding the technical equivalence for an active substance regulated under Regulation (EC) 1107/2009	