The entity shall fulfil all their obligations as per requirements hereunder in order to provide **Evaluation Services of an application of a Biocidal Product and draft Assessment Report of an active substance in accordance with Regulation (EC) 528/2012 as implemented in Malta through Legal Notice 348 of 2013.**

The Malta Competition and Consumer Affairs Authority (MCCAA) is the Competent Authority responsible for regulation of Biocidal Products and their active substances, which are required to be authorized by the Competent Authority prior to their placing on the market.

As per Regulation 528/2012, **biocidal product** is defined as:

- "any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action";
- "any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action."

An active substance is subsequently defined as a substance or a micro-organism that has an action on or against harmful organisms.

1. DUTIES AND RESPONSIBILITES

(a) General Responsibilities

Interested parties are expected to satisfy the following mandatory requirements:

i. 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 a biocidal product on the market and active substances as required by Regulation (EU) 528/2012 provisions for one of the Competent Authorities responsible of evaluations of Biocidal Products and their active substances in any Member State of the EU;

ii. The parties entrusted with handling the evaluation must be 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;

iii. MCCAA is involved in ongoing works and informed of ongoing progress at all times.

(b) Biocidal Products Authorisations

i. For **new National Authorisations** the following deadlines have to be adhered to:

- Evaluate application and recommend to MCCAA if this is considered as valid or whether it considers that the application is incomplete within 20 days from the date of being notified of application. In the latter case, MCCAA should be informed as to what additional information is required for the validation of the application, in which case, the recommendation must reach MCCAA within 110 days if additional information in relation with the applications is requested from the applicant.
- Prepare a draft Assessment report and forward to MCCAA within 290 days or 470 days if additional information is requested, from the validation of an application in accordance with Article 29 of Regulation 528/2012 and recommend whether authorisation can be granted in accordance with Article 19 of the same Regulation. During the evaluation, account shall be taken of the results of the comparative assessment carried out in accordance with Article 23, if applicable.
- Review comments received by applicant, and forward a final Assessment Report to MCCAA, taking into consideration the comments received within 30 days as from the date of notification by MCCAA. The final Assessment Report shall include a recommendation whether an authorisation can be granted.

ii. For **renewal of National Authorisations** the following deadlines have to be adhered to:

- On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for authorisation or, as appropriate, the previous renewal, evaluate, within 20 days from the date of being notified of application by MCCAA, in the light of current scientific knowledge, recommend whether, a full evaluation of the application for renewal is necessary taking account of all product-types for which the renewal is requested.
- Where MCCAA decides that a full evaluation of the application is necessary, the evaluation shall be carried out as follows:
    - A draft Assessment Report is to be compiled and forwarded to MCCAA within 290 days or 470 days if additional information is requested, from the validation of an application in accordance with Article 29 of Regulation

528/2012 and recommend whether an authorisation can be granted in accordance with Article 19 of the same Regulation. During the evaluation, account shall be taken of the results of the comparative assessment carried out in accordance with Article 23, if applicable.

- Review comments received by applicant, and forward a final Assessment Report to MCCAA, taking into consideration the comments received within 30 days as from of notification by MCCAA. The final Assessment Report shall include a recommendation whether an authorisation can be granted.
- Where MCCAA decides that a full evaluation of the application is not necessary, a recommendation on the renewal of the authorization shall be forwarded to MCCAA, within 160 days from the date of being notified by MCCAA.

iii. For **Simplified Authorisation Procedures** the following deadlines have to be adhered to:

- Prepare a draft Assessment report and forward to MCCAA within 80 days or 170 days if additional information is requested, from the date of being notified of application by MCCAA. The draft Assessment Report shall include a recommendation whether the biocidal product satisfies the conditions laid down in Article 25 of Regulation 528/2012, and authorisation can be granted.

iv. For **New Union Authorisations** the following deadlines have to be adhered to:

- Evaluate application and recommend to MCCAA if this is considered as valid or whether it considers that the application is incomplete. In the latter case, MCCAA should be informed as to what additional information is required for the validation of the application. Validation of application shall be carried out within 20 days from the date of being notified of application by MCCAA or within 110 days if additional information is requested.
- Prepare a draft Assessment report and forward to MCCAA within 290 days or 470 days if additional information is requested, from the validation of an application in accordance with Article 19 of Regulation 528/2012 including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 21(2) of the same Regulation.
- Review comments received by applicant, and forward a final Assessment Report to MCCAA, taking into consideration the comments received within 30 days as from the date of notification by MCCAA. The final Assessment Report shall include a recommendation whether an authorisation can be granted.

v. For **Renewal of Union Authorisation** the following deadlines have to be adhered to:

- On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for Union authorisation or, as appropriate, the previous renewal, evaluate, within 20 days from the date of being notified of application by MCCAA and recommend whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary.
- Where the MCCAA decides that a full evaluation of the application is necessary, the evaluation shall be carried out as follows:
  - A draft Assessment report is forwarded to MCCAA within 290 days or 470 days if additional information is requested, from the validation of an application in accordance with Article 19 of Regulation 528/2012 including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 21(2) of the same Regulation.
  - Review comments received by applicant, and forward a final Assessment Report to MCCAA, taking into consideration the comments received within 30 days as from the date of notification by MCCAA. The final Assessment Report shall include a recommendation whether an authorisation can be granted.
- Where MCCAA decides that a full evaluation of the application is not necessary, a recommendation on the renewal of the authorization shall be forwarded to MCCAA, within 160 days from the date of notification.

(c) Active Substances

i. For **approval of an active substance** the following deadlines have to be adhered to:

- Evaluate application and recommend to MCCAA if this is considered valid and if the data required in accordance with points (a) and (b) and, where relevant, point (c) of Article 6(1) of Regulation 528/2012, and any justifications for the adaptation of data requirements. Where it is considered that the application is incomplete, MCCAA should be informed as to what additional information is required for the validation of the application. Validation of application shall be carried out within 20 days from the date of being notified of application by MCCAA or within 110 days if additional information is requested.
- Prepare a draft Assessment report and forward to MCCAA within 290 days or 470 days if additional information is requested, from the validation of an application.

Evaluation shall be carried out in accordance with Articles 4 and 5, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 6(3) of Regulation 528/2012.

- Review comments received by applicant, and forward a final Assessment Report to MCCAA, taking into consideration the comments received within 30 days as from the date MCCAA provides the comments received. The final Assessment Report shall include a recommendation whether an approval can be granted.
- Where it is considered that there are concerns for human health, animal health or the environment as a result of the cumulative effects from the use of biocidal products containing the same or different active substances, documentation of concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 shall be prepared and include this as part of the conclusions.

ii. For **renewal of an active substance** the following deadlines have to be adhered to:

- On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for approval or, as appropriate, the previous renewal, within 80 days from the date of being notified of application by MCCAA and recommend whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all product-types for which renewal is requested.
- Where the MCCAA decides that a full evaluation of the application is necessary, the evaluation shall be carried out as follows:
    - Prepare a draft Assessment report and forward to MCCAA within 290 days or 470 days if additional information is requested, from the validation of an application. Evaluation shall be carried out in accordance with Articles 4 and 5 of Regulation 528/2012, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 6(3) of the same Regulation.
    - Review comments received by applicant, and forward a final Assessment Report to MCCAA, taking into consideration the comments received within 30 days as from the date MCCAA provides the comments received. The final Assessment Report shall include a recommendation whether an approval can be granted.

- Where it is considered that there are concerns for human health, animal health or the environment as a result of the cumulative effects from the use of biocidal products containing the same or different active substances, documentation of concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 shall be prepared and include this as part of the conclusions.

- Where MCCAA decides that a full evaluation of the application is not necessary, a recommendation on the renewal of the approval of the active substance shall be forwarded to MCCAA, within 160 days from the date of being notified by MCCAA

iii. Inclusion of Active Substance in Annex I in line with Commission Implementing Regulation 88/2014.

- Evaluate whether there is evidence that the substance does not give rise to concern in accordance with Article 28(2) of Regulation (EU) No 528/2012 and, where relevant, to which restrictions its use should be subject. It shall send an assessment report and the conclusions of its evaluation to the European Chemicals Agency (ECHA) set up under Regulation (EC) No 1907/2006 of the European Parliament and of the Council.
- Where the application concerns inclusion in category 1, 2, 3, 4 or 5 of Annex I to Regulation (EU) No 528/2012, the assessment report and the conclusions shall be submitted within 170 days of the payment of the fees referred to in the third subparagraph of Article 7(3) of that Regulation.
- Where the application concerns inclusion in category 6 of Annex I to Regulation (EU) No 528/2012, the assessment report and the conclusions shall be submitted within 355 days, or 535 days when a suspension of the evaluation is necessary to request further data to the applicant, from validation of that application including a 30-day commenting period as well as taking due account of these comments when finalizing the evaluation.
- Where it appears that additional information is necessary to carry out the evaluation, the MCCAA shall request that the applicant submit such information within a specified time limit and shall inform the ECHA accordingly.

2. TECHNICAL CAPACITY

(a) The parties shall submit details with the following minimum requirements:

i. List of principal services of a similar nature such as evaluations according to Regulation 528/2012.

ii. A list of the key experts, together with their relevant CVs, and other staff proposed for the execution of the contract. The CVs shall include information on the relevant experience mentioned in point (2) (b) (iv) and their ability to communicate in English.

(b) The successful parties shall meet the following minimum requirements:

i. Demonstrate adequate knowledge on evaluation of substances of Biocidal Products and Active Ingredients in line with requirements laid down in Regulation 528/2012.

ii. Be able to communicate in any one of the officially recognized languages in Malta.

iii. 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.

iv. Have available experts to evaluate the different sections of the dossier. The pool of experts should have at least five years of proven experience in the provision of evaluation services for the authorization and approval to place on the market biocidal products and an active substance as defined above, in accordance with Regulation (EC) 528/2012, for a Competent Authority responsible for such authorizations an approvals in any Member State (MS) of the European Union (EU) and be able to communicate in English language. The following criteria should also be satisfied:

- 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/biocidal products.
- 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/biocidal products.
- 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/biocidal products.
- 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/biocidal products.

- 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/biocidal products.
- 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/biocidal products.
- 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/biocidal.

3. 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 validation of application, when formally notified of acceptance in writing, within ten working (10) days, by the MCCAA and upon presentation of an invoice; and

ii. 40% of the value shall be paid upon the delivery of the draft assessment report, when formally notified of acceptance in writing, within ten working (10) days, by the MCCAA and upon presentation of an invoice; and

iii. The remaining 40% 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 Biocidal 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 528/2012 (refer to point (2) (a) (i));
v. A list of the key experts, and other staff proposed for the execution of the contract together with their relevant CVs (refer to point (2) (a) (ii));
vi. Submit information / documentation as proof that the minimum requirement in point (2) (b) are met.

Eligible submitted notifications of interested entities shall reach MCCAA by not later than **20th February 2022** 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 Biocidal Product and active substances
Malta Competition and Consumer Affairs Authority

Mizzi House, National Road,
Blata l-Bajda HMR 9010
Malta.

Duration: Minimum of three years, with the possibility to extend for an additional two years if the Authority is satisfied with the Service. Provided 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:

i. 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 biocidal product on the market and active substances as required by Regulation (EU) 528/2012 provisions for one of the Competent Authorities responsible of evaluations of Biocidal Products and their active substances in any Member State of the EU;

ii. 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;

iii. MCCAA is involved in ongoing works and informed of ongoing progress at all times.

(b) Biocidal Products Authorisations

vi. For **new National Authorisations** the following deadlines have to be adhered to:

- Evaluate application and recommend to MCCAA if this is considered as valid or whether it considers that the application is incomplete within 20 days from the date of being notified of application. In the latter case, MCCAA should be informed as to what additional information is required for the validation of the application, in which case, the recommendation must reach MCCAA within 110 days if additional information in relation with the applications is requested from the applicant.
- Prepare a draft Assessment report and forward to MCCAA within 290 days or 470 days if additional information is requested, from the validation of an application in accordance with Article 29 of Regulation 528/2012 and recommend whether authorisation can be granted in accordance with Article 19 of the same Regulation. During the evaluation, account shall be taken of the results of the comparative assessment carried out in accordance with Article 23, if applicable.
- Review comments received by applicant, and forward a final Assessment Report to MCCAA, taking into consideration the comments received within 30 days as from the

date of notification by MCCAA. The final Assessment Report shall include a recommendation whether an authorisation can be granted.

vii. For **renewal of National Authorisations** the following deadlines have to be adhered to:

- On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for authorisation or, as appropriate, the previous renewal, evaluate, within 20 days from the date of being notified of application by MCCAA, in the light of current scientific knowledge, recommend whether, a full evaluation of the application for renewal is necessary taking account of all product-types for which the renewal is requested.
- Where MCCAA decides that a full evaluation of the application is necessary, the evaluation shall be carried out as follows:
    - A draft Assessment Report is to be compiled and forwarded to MCCAA within 290 days or 470 days if additional information is requested, from the validation of an application in accordance with Article 29 of Regulation 528/2012 and recommend whether an authorisation can be granted in accordance with Article 19 of the same Regulation. During the evaluation, account shall be taken of the results of the comparative assessment carried out in accordance with Article 23, if applicable.
    - Review comments received by applicant, and forward a final Assessment Report to MCCAA, taking into consideration the comments received within 30 days as from of notification by MCCAA. The final Assessment Report shall include a recommendation whether an authorisation can be granted.
    - Where MCCAA decides that a full evaluation of the application is not necessary, a recommendation on the renewal of the authorization shall be forwarded to MCCAA, within 160 days from the date of being notified by MCCAA.

viii. For **Simplified Authorisation Procedures** the following deadlines have to be adhered to:

- Prepare a draft Assessment report and forward to MCCAA within 80 days or 170 days if additional information is requested, from the date of being notified of application by MCCAA. The draft Assessment Report shall include a recommendation whether the biocidal product satisfies the conditions laid down in Article 25 of Regulation 528/2012, and authorisation can be granted.

ix. For **New Union Authorisations** the following deadlines have to be adhered to:

- Evaluate application and recommend to MCCAA if this is considered as valid or whether it considers that the application is incomplete. In the latter case, MCCAA should be informed as to what additional information is required for the validation of the application. Validation of application shall be carried out within 20 days from the date of being notified of application by MCCAA or within 110 days if additional information is requested.
- Prepare a draft Assessment report and forward to MCCAA within 290 days or 470 days if additional information is requested, from the validation of an application in accordance with Article 19 of Regulation 528/2012 including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 21(2) of the same Regulation.
- Review comments received by applicant, and forward a final Assessment Report to MCCAA, taking into consideration the comments received within 30 days as from the date of notification by MCCAA. The final Assessment Report shall include a recommendation whether an authorisation can be granted.

x. For **Renewal of Union Authorisation** the following deadlines have to be adhered to:

- On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for Union authorisation or, as appropriate, the previous renewal, evaluate, within 20 days from the date of being notified of application by MCCAA and recommend whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary.
- Where the MCCAA decides that a full evaluation of the application is necessary, the evaluation shall be carried out as follows:
    - A draft Assessment report is forwarded to MCCAA within 290 days or 470 days if additional information is requested, from the validation of an application in accordance with Article 19 of Regulation 528/2012 including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 21(2) of the same Regulation.
    - Review comments received by applicant, and forward a final Assessment Report to MCCAA, taking into consideration the comments received within 30 days as from the date of notification by MCCAA. The final Assessment Report shall include a recommendation whether an authorisation can be granted.

- Where MCCAA decides that a full evaluation of the application is not necessary, a recommendation on the renewal of the authorization shall be forwarded to MCCAA, within 160 days from the date of notification.

(c) Active Substances

iv. For **approval of an active substance** the following deadlines have to be adhered to:

- Evaluate application and recommend to MCCAA if this is considered valid and if the data required in accordance with points (a) and (b) and, where relevant, point (c) of Article 6(1) of Regulation 528/2012, and any justifications for the adaptation of data requirements. Where it is considered that the application is incomplete, MCCAA should be informed as to what additional information is required for the validation of the application. Validation of application shall be carried out within 20 days from the date of being notified of application by MCCAA or within 110 days if additional information is requested.
- Prepare a draft Assessment report and forward to MCCAA within 290 days or 470 days if additional information is requested, from the validation of an application. Evaluation shall be carried out in accordance with Articles 4 and 5, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 6(3) of Regulation 528/2012.
- Review comments received by applicant, and forward a final Assessment Report to MCCAA, taking into consideration the comments received within 30 days as from the date MCCAA provides the comments received. The final Assessment Report shall include a recommendation whether an approval can be granted.
- Where it is considered that there are concerns for human health, animal health or the environment as a result of the cumulative effects from the use of biocidal products containing the same or different active substances, documentation of concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 shall be prepared and include this as part of the conclusions.

v. For **renewal of an active substance** the following deadlines have to be adhered to:

- On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for approval or, as appropriate, the previous renewal, within 80 days from the date of being notified of application by MCCAA and recommend whether, in the light of current scientific knowledge, a full

evaluation of the application for renewal is necessary taking account of all product-types for which renewal is requested.

- Where the MCCAA decides that a full evaluation of the application is necessary, the evaluation shall be carried out as follows:
    - Prepare a draft Assessment report and forward to MCCAA within 290 days or 470 days if additional information is requested, from the validation of an application. Evaluation shall be carried out in accordance with Articles 4 and 5 of Regulation 528/2012, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 6(3) of the same Regulation.
    - Review comments received by applicant, and forward a final Assessment Report to MCCAA, taking into consideration the comments received within 30 days as from the date MCCAA provides the comments received. The final Assessment Report shall include a recommendation whether an approval can be granted.
    - Where it is considered that there are concerns for human health, animal health or the environment as a result of the cumulative effects from the use of biocidal products containing the same or different active substances, documentation of concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 shall be prepared and include this as part of the conclusions.
- Where MCCAA decides that a full evaluation of the application is not necessary, a recommendation on the renewal of the approval of the active substance shall be forwarded to MCCAA, within 160 days from the date of being notified by MCCAA

vi. Inclusion of Active Substance in Annex I in line with Commission Implementing Regulation 88/2014.

- Evaluate whether there is evidence that the substance does not give rise to concern in accordance with Article 28(2) of Regulation (EU) No 528/2012 and, where relevant, to which restrictions its use should be subject. It shall send an assessment report and the conclusions of its evaluation to the European Chemicals Agency (ECHA) set up under Regulation (EC) No 1907/2006 of the European Parliament and of the Council.
- Where the application concerns inclusion in category 1, 2, 3, 4 or 5 of Annex I to Regulation (EU) No 528/2012, the assessment report and the conclusions shall be

submitted within 170 days of the payment of the fees referred to in the third subparagraph of Article 7(3) of that Regulation.

- Where the application concerns inclusion in category 6 of Annex I to Regulation (EU) No 528/2012, the assessment report and the conclusions shall be submitted within 355 days, or 535 days when a suspension of the evaluation is necessary to request further data to the applicant, from validation of that application including a 30-day commenting period as well as taking due account of these comments when finalizing the evaluation.
- Where it appears that additional information is necessary to carry out the evaluation, the MCCAA shall request that the applicant submit such information within a specified time limit and shall inform the ECHA accordingly.

_____	_____
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 validation of application, when formally notified of acceptance in writing, within ten working (10) days, by the MCCAA and upon presentation of an invoice; and
- 40% of the value shall be paid upon the delivery of the draft assessment report, when formally notified of acceptance in writing, within ten working (10) days, by the MCCAA and upon presentation of an invoice; and
- The remaining 40% 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 Biocidal 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)
New National Authorisation (single biocidal product)	
New National Authorisation (biocidal product family)	
Renewal of National Authorisation (single biocidal product)	
Renewal of National Authorisation (biocidal product family)	
Simplified Authorisation Procedure (single biocidal product)	
Simplified Authorisation Procedure (biocidal product family)	
New Union Authorisation (single biocidal product)	
New Union Authorisation (biocidal product family)	
Renewal of Union Authorisation (single biocidal product)	
Renewal of Union Authorisation (biocidal product family)	
Approval of an Active Substance	
Renewal of an Active Substance	
Inclusion of Active Substance in Annex I	
Renewal of Active Substance in Annex I	

Annex V

Evaluation Type	Maximum number of evaluations which can be managed per year
New National Authorisation (single biocidal product)	
New National Authorisation (biocidal product family)	
Renewal of National Authorisation (single biocidal product)	
Renewal of National Authorisation (biocidal product family)	
Simplified Authorisation Procedure (single biocidal product)	
Simplified Authorisation Procedure (biocidal product family)	
New Union Authorisation (single biocidal product)	
New Union Authorisation (biocidal product family)	
Renewal of Union Authorisation (single biocidal product)	
Renewal of Union Authorisation (biocidal product family)	
Approval of an Active Substance	
Renewal of an Active Substance	
Inclusion of Active Substance in Annex I	
Renewal of Active Substance in Annex I	