



Terms of reference for joint food enzyme dossiers

The following terms of reference (hereafter abbreviated as "ToR" and referred to as such) are established by Amfep¹ for the work on the preparation and submission of joint food enzymes dossiers under EC Regulation 1332/2008 on food enzymes (OJEU 2008, L 354/7) and EC Regulation 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJEU 2008, L354/1) and Commission Regulation (EC) No. 234/2011 (OJEU 2011, L64/15) as amended implementing EC Regulation 1331/2008.

The work on grouped food enzyme dossiers described in the following Terms of reference was initiated, and will be facilitated, by Amfep. This work will be open to all interested parties, as described in Clause 1.1 below, be they members of Amfep or not.

1. Purpose

- 1.1. The purpose of the present ToR is, always in full compliance with competition law as per Article 5 hereafter, to lay down essential principles governing activities of food enzymes producers and other Interested Parties during the preparation, submission and follow-up of joint dossiers for food enzymes with the ultimate purpose of receiving approval for these enzymes under EC Regulation 1332/2008 on food enzymes (OJEU 2008, L 354/7) and EC Regulation 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJEU 2008, L354/1) and Commission Regulation (EC) No. 234/2011 (OJEU 2011, L64/15) as amended implementing EC Regulation 1331/2008.
- 1.2. The following activities are expected to be performed by food enzyme producers during the work referred to in Clause 1.1.:
 - a. Establishing Working Groups for the work on specific food enzymes and appointing the person leading the work of this Working Group (hereafter referred to as the 'Leader').
 - b. Creating a template dossier to be used in the Working Groups in line with the Guidance of the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF) of the European Food Safety Authority on the Submission of a Dossier on Food Enzymes for Safety Evaluation by the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids.
 - c. Data sharing.
 - d. Cost sharing.
 - e. Read-across.
 - f. Drafting of joint dossiers for food enzymes.

¹ Amfep is the European Association of Manufacturers and Formulators of Enzyme Products (www.amfep.org).

- g. Submission of joint dossiers for food enzymes to the European Commission.
 - h. Answering possible queries of the European Commission and/or European Food Safety Authority.
- 1.3. The list under Clause 1.2 is non-exhaustive and other subjects of relevance to the activities referred to in Clause 1.1 may be discussed, all subject to Clause 4 (Organisation and Working Principles) and Clause 5 (Competition Law Compliance).
- 1.4. The work referred to in Clause 1.1 will be supervised by a Coordinator. The Coordinator is appointed by the Amfep Executive Committee. The Coordinator shall be assisted by the Amfep Secretariat and by the chairperson of the Amfep FIAP Implementation task force.

2. Membership

General considerations

- 2.1. Membership in Working Groups is open to all companies who (i) first place food enzymes on the EU market² as such, for their sale, and/or for their use in foods sold in the EU or (ii) who are for any other reason considered Interested Parties under Article 17 of EC Regulation 1332/2008 on food enzymes (OJEU 2008, L 354/7) and Article 3 of EC Regulation 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJEU 2008, L354/1).
- 2.2. Working Group consists of Members who fulfil the membership criteria set out in Clause 2.1 and who contribute to the work of the Working Group either financially or by any other means, which might include, but not limited to, bringing data and documentation for dossier building, writing of parts of the dossier, etc. The Amfep secretariat will be member of all Working Groups, without participating in the dossier preparation and cost sharing.
- 2.3. Each Working Group only works on the preparation, submission and follow-up of one dossier for one specific food enzyme (hereafter referred to as the "Dossier").
- 2.4. A Working Group Member may appoint and authorize a legal entity to represent it on its behalf in the Working Groups (such appointed and authorized legal entity hereinafter referred to as "Representative"). The Members shall request written documentation from the appointing Member confirming the appointment and authorization of a given Representative. The appointing Member shall ensure that its Representative (i) is fully aware of the obligations of these ToR and (ii) is bound by obligations which are equal to those of the appointing Member as set out herein. The appointing Member shall be responsible for any breach of the provisions under these ToR by such Representative. The other Members may at any time request written documentation to confirm that its Representative has undertaken the obligations referred to further above in this Clause. If the appointed Representative is already a Member of a Working Group, such Member agrees to be bound by the obligations set out in these ToR also when it (or any of its employees) is functioning as a Representative of another Member without any separate legal contracts needing to be signed. A Member may at any time withdraw and/or replace its representation by giving prior written notice to the other Members and the Secretariat of Amfep.
- 2.5. Working Group Members are expected to attend or be represented (as described in Clause 2.4 above) in all Working Group meetings.
- 2.6. Certain food enzymes share important features (e.g. but not limited to biological origin, enzyme activity as defined by the IUBMB system, applications in food processing). This may result in

² "first placing on the market" means the initial placing on the market of a food enzyme after its manufacture, the import of a food enzyme, or, where a food enzyme has been used in food manufacturing without being placed on the market, the first placing on the market of that food.

nearly identical dossiers. In this case, companies which are, or will become, member of the corresponding working groups may decide to informally work together on a template covering all such individual food enzymes.

Adherence of new Members to Working Groups

- 2.7. Membership in the Working Groups shall be open, before the first submission of the Dossier to the European Commission, to any applicant who fulfils the membership criteria set out in Clauses 2.1 and 2.2 and who is committed to signing the Letter of Accession (see Annex 1) and respect any decisions made prior to the accession date by the other Members, including those regarding payment and sharing of costs. Matters concerning adherence of an applicant shall be handled in a fair and non-discriminatory way, be based on the criteria laid out in Clauses 2.1 and 2.2 and be handled in accordance with applicable competition law. The initial Members of the Working Group, taking into account such factors as the work already performed by the members and the complexity of the Dossier, may decide to limit the period during which a new Member could join the Working Group. Such decision will be taken when the creation of the Working Group is materialized by the steps described in Clauses 2 and 4.
- 2.8. The Members may request that an applicant reasonably demonstrates that it fulfils the criteria for membership.
- 2.9. A new Member adheres to a Working Group by the signing of a Letter of Accession (see Annex 1) both by an entitled employee of the company joining the Working Group and the Secretary General of Amfep and after full payment of the entry fee referred to in Clause 2.15.
- 2.10. Upon receipt of an application for adherence to a Working Group, such application shall without undue delay be presented to the other Members of this Working Group, and to the Coordinator. If no reasonable and lawful objections are raised by a Member at the latest within ten (10) working days after such Member having received information of an application, the Secretary General of Amfep may sign the Letter of Accession provided the applicant fulfils the criteria of membership set out in Clause 2.1. In the event the majority of Members of the Working Group find that an applicant does not fulfil the criteria of membership of the Working Group, Members shall discuss this with at least one legal counsel from two different Members before making any decision in this respect. If the legal counsels agree that adherence to the Working Group can lawfully be refused in a given case, such decision shall be communicated to the applicant in a written letter clearly stating the reasons for such refusal and beforehand approved by such legal counsels. In the event the Members cannot agree on whether or not an applicant can be allowed to adhere to the Working Group, the Members shall without undue delay agree on appointing an independent attorney at law who shall decide on the question. The decision on which attorney to appoint may be made by majority decision if the Members cannot agree unanimously. The Members shall share the costs of such independent attorney evenly between them. The Secretary General of Amfep undertakes without undue delay to keep the other Members informed of new Members having adhered to the Working Group. In case the adherence of the applicant is finally refused, the Secretary General of Amfep shall inform the applicant in writing without undue delay outlining the reasons for such refusal in reasonable detail.
- 2.11. To the extent required to comply with applicable competition law, the initial Members of each Working Group shall establish reasonable means of bringing attention to the existence of the Working Groups to other potentially interested third parties.
- 2.12. Membership disputes are subject to Clauses 8.6 and 8.7.

Commitments of the members

- 2.13. Members of the Working groups commit to comply at all times with EU law and regulatory requirements with special attention to the following principles:

- a. Apply the most stringent as required under EU law and EU regulatory requirements in the production of food enzymes;
 - b. Maintain and apply an active program to avoid presence of contaminants in enzyme products.
- 2.14. Members of the Working Groups commit to loyally work towards achievement of the Purpose, cf. Clause 1, which includes but is not limited to include a commitment to comply with the dossier contents as written by the Working Group.

Entry fee

- 2.15. As a condition for adhering to a Working Group, any new Member (whether or not member of Amfep, full or associate) entering a Working Group more than two months after the Effective Date of the creation of the Working Group, referred to in Clause 4.2 shall pay an entry fee.
- 2.16. The entry fee shall be set at five thousand Euro (5000 €).
- 2.17. The purpose of the entry fee is to compensate for the costs and time spent, and the results achieved, by the original foundation Members and the Amfep secretariat, in relation to the preparation of a food enzyme dossier in the period of two months after the creation of the Working Group, such efforts from which a new Member will be expected to benefit instantly.
- 2.18. The entry fee shall be made by bank-to-bank electronic transfer to a bank account in the name of Amfep. A special code referring to the Working Group has to be attributed to the transfer. This code, as well as other payment details, shall be provided by the Secretary General of Amfep. The Secretary General of Amfep shall provide this information no later than at the date of the signature to the Letter of Accession. Payment of an entry fee shall be made no later than twenty (20) days following final execution of the Letter of Accession. The entry of the new Member shall become effective only when the full amount of the entry fee has been received by the Secretary General of Amfep.
- 2.19. Except as expressly provided for in these ToR, all amounts stated in these ToR shall be excluding VAT and other taxes. VAT and any other taxes shall be charged if required under applicable law.

3. Coordinator

- 3.1. The Coordinator shall perform the following tasks:
- Coordinating the work of the Leaders of all Working Groups.
 - Coordinating the discussions contemplated and needed to achieve the purpose of Working Groups.
 - Assisting in seeking general compliance with the obligations set out in the ToR in relation to the activities carried out hereunder.

For the avoidance of doubt, the Coordinator shall not be entitled to act or make binding commitments in the name and on behalf of the Members.

- 3.2. The Secretary General of Amfep shall perform the functions and responsibilities that are described in Clauses 3.2 and 3.3. The Coordinator may, however, decide that he or she shall be involved in some or all of the functions assigned to the Secretary General of Amfep e.g. the drafting, reviewing and/or approving of the minutes and/or of the meeting agendas and/or the planning of the activities in general. The Coordinator shall in such cases coordinate this with the Secretary General of Amfep.
- 3.3. The Secretary General of Amfep shall generally and upon request of the Coordinator assist the Coordinator with such tasks that are of a more secretarial and administrative character.

Obligations and liability of the Coordinator

- 3.4. The Coordinator shall use its best efforts to be impartial at all times and shall not function as a representative of any particular Member but at all times safeguard the general interests of the Working Group and all its Members.
- 3.5. However, notwithstanding Clauses 3.4, 3.6 and 3.7, the Coordinator does not in any way warrant, represent or guarantee that the Purpose or any other specific results may be achieved in the Working Group and shall in no event or for whatever reason be held responsible or liable for any such results or lack of results.
- 3.6. The Coordinator shall not be held responsible or be liable for the Members' activities contemplated and carried out in the Working Groups, including liable for any direct, indirect, punitive or consequential losses or damages in any way relating to the Working Groups and the activities carried out hereunder.
- 3.7. In relation to the Coordinator any Member shall be and remain individually and fully responsible for making sure that its activities at all times are lawful and in compliance with applicable law, including but not limited to applicable competition law, and no Member shall in any way hold the Coordinator (or the legal entity of the Member in which the Coordinator may be an employee, consultant, representative or in any other way related) responsible or liable for any lack of compliance done by itself or in which it has part.

Cost of the Coordinator

- 3.8. The services of the Coordinator and Amfep secretariat are provided at no cost to the Members of the Working Groups.

4. Organisation and working principles

- 4.1. These ToR and Working Groups contemplated herein shall not constitute or be deemed to constitute a joint venture, agency, partnership or other legal entity between the Members. These ToR merely establish a formal legal framework under which the discussions described in more detail under Clause 1.2 can take place.
- 4.2. The creation of every new Working Group is formalised by the signing of the Working Group agreement (see Annex 2) and is announced by the Secretary General of Amfep to the Members of Amfep via the internal Document Management System and, to third parties, via a publication made on a dedicated page of the public website of Amfep available at the following addresses: www.amfep.org and www.amfep.com. The date of publication of the announcement is considered as the Effective Date of the creation of the Working Group.
- 4.3. Provided all Members of the Working Group agree unanimously, certain subjects may be referred to a selected group of appointed Members if such limited forum is deemed convenient by the Members, merely to ensure speedy and effective discussions and work in the Working Groups.
- 4.4. Each Member shall bear its own costs and expenses (internal and external) incurred in the performance of these ToR unless otherwise expressly agreed in writing among the Members.
- 4.5. The cost of studies and data performed by one Member on behalf of the Working Group, prior to or during the preparation, submission and evaluation of the Dossier, will be compensated according to the cost sharing policy included in Annex 4 of the present ToR.
- 4.6. If the meeting or actions of the Working Group cause that certain external expenses of a more general nature are incurred (e.g. expenses connected to use of a physical location (a meeting room), appointment of a trustee (or an independent third party) commissioned for the purpose of ensuring competition law and/or confidentiality or for the use of certain services of Amfep or

any other (for instance the Coordinator), such costs and expenses shall be equally shared amongst the Members of the Working Group. Unless otherwise specifically agreed upon between the Members or part of a new Member's payment of entry fee (cf. Clauses 2.10 and following), a new Member shall only be requested to pay costs which are incurred after the effective date of signing the Letter of Accession.

- 4.7. The Members of each Working Group choose among them a Leader of the Working Group (hereafter referred to as the "Leader"). The Members of the Working Group may for instance choose to appoint as the Leader one of the Members, which already have relevant toxicological studies for the Dossier. In case there are several possible candidates, the Members of the Working Group shall select the Leader according to a simple majority vote, with one voting right per Member.
- 4.8. The Leader, in co-ordination with the Coordinator, shall be responsible for the organisation of the work of the Working Group.
- 4.9. The functions of the Leader shall include, but may not be limited to:
 - a. Chairing of the Working Group.
 - b. Define calendar and fix the milestones.
 - c. Writing summaries of the Dossier.
 - d. Editing the Dossier.
 - e. Evaluating the data provided by the Members.
 - f. Deciding on schedule of meetings or conference calls of the Working Group.
 - g. Convening such meetings with the assistance of the Secretary General of Amfep.
 - h. Informing the Coordinator about the meetings.
 - i. Consult the Members on all questions received by the Dossier applicant from the Commission or European Food Safety Agency.
 - j. Without prejudice of Section 6 (Confidentiality) below, provide an answer to the Dossier applicant who will forward it to the European Commission and/or European Food Safety Authority on behalf of the Working Group.

The Leader shall be responsible for the submission of the Dossier and shall be identified in the Dossier as the "person responsible for the dossier".

Amfep will be identified in the Dossier as the official "applicant" unless otherwise decided by the Members of the Working Group by a simple majority vote, with one voting right per Member.

All other Members of the Working Group will be identified in the Dossier as "manufacturers or interested parties" pursuant to Article 17 of EC Regulation 1332/2008 on food enzymes (OJEU 2008, L354/7) and Article 3 of EC Regulation 1331/2008 (as applicable).

- 4.10. The Members of the Working Group may decide to remunerate the Leader for one or several tasks described in Clause 4.9. The cost of the Leader shall consist of a fixed amount of five thousand Euro (5000 €) plus, if deemed necessary by the Working Group, an additional five hundred Euro (500 €) per Member of the Working Group. The total amount of the costs of the Leader shall be equally shared amongst the Members of the Working Group.
- 4.11. The Members of the Working Group may in agreement with the Leader decide to share the tasks of writing different parts of the Dossiers amongst themselves.
- 4.12. The Members appoint the Secretary General of Amfep as secretariat of the Working Groups. The Secretary General of Amfep shall participate in all meetings of the Working Groups.

- 4.13. At any time, the Members may, according to a simple majority vote, with one voting right per Member, agree to appoint a different person or organisation, independent from the Members, to provide secretarial services to the Working Group.
- 4.14. Each Member shall provide the Secretary General of Amfep with the name and contact information, including e-mail address, of an appointed contact person (hereinafter referred to as the "Contact Person") representing that Member in the Working Group. Each Member undertakes without undue delay to inform the Secretary General of Amfep of any change in the Contact Person and the contact information. Each Member can only appoint one Contact Person at a time. The Contact Person shall be an employee of the appointing Member or of its Representative.
- 4.15. Each Working Group shall provide the Secretary General of Amfep with the name and contact information, including e-mail address, of an appointed Leader of the Working Group, at least ten (10) working days before the date of the first meeting of the Working Group.
- 4.16. The Secretary General of Amfep shall keep an updated list of the Contact Persons of the Members as well as Leaders of the Working Groups. The contact details of such Contact Persons shall be made available only to the other Members of the Working Group. The composition of the Working Groups shall never be revealed to the persons or organisations who are not Members of the Working Group.
- 4.17. The Members shall meet at such place and time agreed on by the Members, and only when necessary. Meetings may also be held via telephone or video conference or by the use of other electronic means, unless a Member raises objections.
- 4.18. At least seven (7) working days prior to a meeting, the Leader of the Working Group shall draw-up an agenda and distribute it via the Secretary General of Amfep to each Contact Person of the Members of the Working Group and to the Coordinator. Each Member's Contact Person may require from the Leader to put a certain item on the agenda, such requirement to be addressed to the Secretary General of Amfep at least ten (10) working days prior to the meeting. The Members shall stick to the agenda during the meeting. A reminder of competition law compliance shall be a fixed agenda item.
- 4.19. To allow for relevant expertise at the meetings, each Member shall have the right to appoint one person (hereinafter referred to as the "Assistant Representative") to be present at the meetings. To safeguard efficiency in the meetings maximum one Assistant Representative per Member may be appointed. The appointed Assistant Representative may only be an employee of the Member or its Representative.
- 4.20. Prior to participating in any meetings the appointing Member shall ensure that its Assistant Representative is fully aware and is bound by obligations which are no less strict than those set out in Clauses 5 (competition law compliance) and 6 (confidentiality) of the ToR as well as by those Clauses which are relevant for the use and interpretation of said Clauses. The appointing Member shall be responsible for any breach of these Clauses by such person. The other Members may request written documentation to confirm that an Assistant Representative has undertaken the obligations referred to further above in this Clause. If an appointed Assistant Representative is employee in a legal entity which is already a Member of the Working Group, such Member hereby agrees that obligations no less strict than those set out in Clauses 5 (competition law compliance) and 6 (confidentiality) of the ToR (as well as those Clauses which are relevant for the use and interpretation of said Clauses) shall be extended to cover also the situation in which one of its employees is Assistant Representative of another Member without any separate legal contracts needing to be signed.
- 4.21. Each Member shall provide the Secretary General of Amfep with the name and contact information, including e-mail address, of the Assistant Representative. Each Member further undertakes without undue delay to inform the Secretary General of any replacement and/or

withdrawal of the appointment of an Assistant Representative and of any change in the contact information. Each Member shall always seek to maintain consistency in its appointment of assistant representation.

- 4.22. An Assistant Representative shall have no voting right or formal decision power in the Working Group. Voting right and formal decision power lies with the Contact Person of the Member. There will be one vote per Member.
- 4.23. The meeting of the Working Group can only pass resolutions if at least 2/3 of all Members are present. Unless otherwise stated herein, decisions of the Working Group shall be taken by a majority of 75% of all Members of the Working Group.
- 4.24. Following each meeting (irrespective of the form in which such meeting has been held), detailed written minutes shall be produced by the Secretary General of Amfep and distributed to the Members. The Members shall prior to a meeting agree on the required arrangements to be in place for such minutes to be made and distributed. The minutes shall in a true and fair way reflect any discussions and decisions made at the meetings. Each Member shall check that the minutes are true and fair and protest without undue delay in writing to the other Members if this is not the case. At the beginning of every meeting, competition law compliance shall be referred to and the minutes of the previous meeting are validated.
- 4.25. The working language of the Working Groups is English.
- 4.26. The Secretary General of Amfep shall ensure an accurate participation list of each meeting, to be signed by each participant.
- 4.27. There shall be no direct payment to Amfep regarding the services provided by the Secretary General of Amfep under these ToR. These costs are considered covered by existing resources in the Amfep secretariat already allocated and funded (outside the scope of these ToR) by the various Amfep Members. Should the effective costs exceed the resources allocated, the Secretary General of Amfep undertakes to bring this to the attention of the Executive Committee of Amfep.
- 4.28. The Secretary General of Amfep shall not have any other rights or obligations than those set forth in this ToR unless the Members so agree.

5. Competition law compliance

- 5.1. The Members are aware that activities under these ToR could represent a matter to which Articles 101 and 102 of the Treaty on the Functioning of the European Union apply. The Members explicitly agree to observe said articles and the Amfep statement on observance of competition law issued under Amfep reference Amfep/09/74 on 09 November 2009 attached hereto (Annex 3).
- 5.2. Should it become apparent at any time that these ToR, any provision of these ToR, or any activity or decision of the Members of the Working Group, can have a potentially restrictive effect on open and fair competition, in breach of any statutory provision, each Member shall take immediate steps to remedy that situation.

6. Confidentiality and non-use of confidential information

- 6.1. Each Member (the "Receiving Member") undertakes to treat all information disclosed in whatever form under these ToR by another Member (the "Disclosing Member") or any of its Affiliates (as defined below) as strictly confidential during the term of these ToR and thereafter for a period of ten (10) years. The Receiving Member may not disclose it to any third party or make any other use of it than for the Purpose envisaged under Clause 1 without the prior written consent of the Disclosing Member. Furthermore, the Receiving Member may not make any copies or in any way reproduce any of the confidential information except as strictly

necessary for the Purpose of these ToR. "Affiliates" shall mean any company or other business entity Controlling, Controlled by or under common Control of a Member and for such purpose "Control" shall mean direct or indirect ownership of at least fifty (50) per cent of the voting interest in such company or other business entity or otherwise having the right to exercise a dominant influence over such company or business entity at issue.

- 6.2. The confidentiality and non-use obligation described in Clause 6.1 shall not apply to:
- a. information, which prior to the effective date of these ToR was already in the public domain;
 - b. information, which after disclosure becomes part of the public domain through no violation of these ToR;
 - c. information, which the Receiving Member is able to prove by convincing evidence to have lawfully been in possession of prior to any disclosure;
 - d. information, which is hereafter disclosed by a third party to the Receiving Member under no violation of an effective obligation to treat the information as confidential; or
 - e. information, which is to be disclosed pursuant to (and only to the extent required by) a final and binding governmental and/or judicial obligation or order provided that the Receiving Member shall promptly notify the Disclosing Member in writing timely in advance (to the extent possible) so as to enable the Disclosing Member to object to such use or disclosure, or to request confidential treatment of information to the extent possible; or
 - f. information, which is developed by the Receiving Member independently of the information of the Disclosing Member, as established by the Receiving Member's written records.

Information disclosed under these ToR shall not be deemed to fall under the foregoing exceptions merely because such information is embraced by more general information in the public domain or in the possession of the Receiving Member. Neither will a combination of features be deemed to fall under the foregoing exceptions merely because individual features are in the public domain or in the Receiving Member's possession, unless the combination itself is in the public domain or in the Receiving Member's possession.

- 6.3. Notwithstanding the foregoing, a Receiving Member may disclose confidential information to its directors, officers, employees, consultants, Representatives and external experts and to its Affiliates and its Affiliates' directors, officers, employees, consultants and external experts to the extent required to pursue the Purpose of these ToR, provided that such persons are bound by obligations of confidentiality and non-use which are similar to those outlined in these ToR. The Receiving Member shall ensure that its directors, officers, employees, consultants, Representatives and external experts and its Affiliates and its Affiliates' directors, officers, employees, consultants and external experts are fully aware of and be bound by the obligations of these ToR and shall be responsible for any breach of the provisions under these ToR by such persons.
- 6.4. The Receiving Member shall use confidential information exclusively for the Purpose of these ToR, but for no other purpose.
- 6.5. The Receiving Member agrees and acknowledges that the exchange of confidential information does not imply any transfer of title and/or ownership to confidential information or the creation of any intellectual property rights, and thus title and ownership to confidential information shall remain vested at all times in the Disclosing Member. Further, no license is hereby granted directly or indirectly under patent, invention, discovery, copyright or other industrial property right held or licensable by either Member.

- 6.6. Confidential information will be provided without any warranties and representations as to its accuracy or suitability to reach the Purpose of these ToR. The Disclosing Member shall not be liable for any damage or loss, incurred by the Receiving Member as a result of the use of such confidential information.
- 6.7. Each Member acknowledges that damage alone would not be an adequate remedy for any material breach of these ToR and agrees that a Member shall be entitled to the remedies of injunction, specific performance or other equitable relief of other remedies available. Failure by a Member in exercising any right, power or privilege hereunder shall not act as a waiver, nor shall any single or partial exercise thereof preclude any further exercise of any right, power or privilege.
- 6.8. Notwithstanding Clause 6.7, in the event of breach or anticipated breach of the confidentiality and non-use obligations set out in Clause 6, the Members are entitled to exclude the breaching Member from any further cooperation under these ToR.
- 6.9. The Receiving Member agrees to return all confidential information at the Disclosing Member's request except that the Receiving Member may retain for its records one confidential copy of such information for purposes of evidencing compliance with these ToR.
- 6.10. Each Member shall have the right (but not the obligation) to mark its confidential information as "confidential". In case confidential information is disclosed in oral form each Member shall have the right to announce before disclosure that the information is considered confidential and/or to confirm in writing to the other Members after disclosure that such information is considered confidential. Further, each Member may request that it is stated in the minutes that specific confidential information was disclosed by a Member under a given Working Group meeting. However, neither of the actions described in this Clause shall be a condition or requirement of confidentiality.
- 6.11. Members can unanimously decide to mark specific parts of the Dossier as confidential. In this case verifiable justifications shall be provided in writing in the Dossier. Members agree to limit the number of confidential parts as much as possible and not to accept general requests for confidentiality. The Secretary General of Amfep shall ensure that only a sanitised version (where confidential information has been deleted) is available to the Members, including the Leaders and the Coordinator.
- 6.12. Any Working Group Member, after consulting the other Members, may decide to restrict the access of the other Members to specific data it is willing to include in the Dossier. Such data shall be gathered by the Secretary General of Amfep and be included only in the final Dossier sent to the EU Commission and/or to the European Food Safety Authority.

7. Term, withdrawal and exclusion of members

- 7.1. These ToR shall be effective as of the date of its approval by the Amfep Members via a written consultation procedure. The decision shall be taken by a simple majority of all Amfep Members votes referred to in Article 15§2 of the Amfep Statutes as consolidated on 07 October 2011.
- 7.2. The term of the ToR is the date of the publication of the Union list referred to in article 7 of EU Regulation 1332/2008 on food enzymes.
- 7.3. Any Member may subject to provisions of these ToR and no later than 1 month before the planned submission of the Dossier withdraw from any Working Group by giving written notice to the Leader of the Working Group, the Coordinator and the Secretary General of Amfep. No refund will be made to the Member withdrawing from the Working Group. The cost-sharing will be recalculated, taking into account the withdrawal.

Any Working Group may decide by simple majority of votes of its Members, to exclude a Member from the Working Group who,

- a. in the view of the majority of Members has acted contrary to the purpose of the Working Group;
- b. whose conduct brings it or the enzyme industry as such into disrepute, or
- c. who has committed a material breach of the commitments imposed on Members by these ToR, cf. Clauses 2.13 and/or 2.14.A breach of Clauses 2.13 and/or 2.14 is considered a material breach.

Exclusion shall be non-discriminatory and based on objective and transparent criteria.

- 7.4. The proposal for exclusion shall be sent to all Working Group members by the Working Group leader no later than 10 working days before the meeting where the vote will be taken. The said Member shall have the right to present a defence at the Working Group meeting at which voting is to occur. The decision of the Working Group shall have an immediate effect. .
- 7.5. Termination of these ToR as well as a Member's withdrawal or exclusion from these ToR shall not affect the obligations of confidentiality or non-use set forth in Clause 6 and undertaken by a Member upon signing of these ToR and incurred prior to the date of termination, expiry or withdrawal. Similarly, the provisions relating to applicable law, settlement of disputes, liability and indemnification in Clause 8, information shared as well as payment of its part of costs agreed to pursuant to Clauses 3 and 4 and incurred prior to termination, expiry or withdrawal shall survive termination, expiry or withdrawal. Clauses relevant for the use and interpretation of the above Clauses shall survive as well as Clauses which by their nature are meant to survive.

8. Amendments, miscellaneous

- 8.1. The legal relationship between the Members in relation to the Working Group shall be governed exclusively by the Agreement signed by all the Members of the Working Group.
- 8.2. Each Member shall exercise due care and diligence vis-à-vis other Members in observing rights and obligations arising from these ToR.
- 8.3. No Member shall be liable under these ToR to any other Member for any kind of loss or damage including, but not limited to direct damages, punitive damages, indirect or consequential loss, loss of profit, loss of revenue or loss of contracts. Notwithstanding the foregoing, each Member shall be liable towards the other Members for direct loss or damage incurred as a consequence of breach of the obligations of (a) confidentiality and non-use stipulated in Clause 6, or (b) to pay for its part of such costs which has been agreed upon pursuant to Clauses 3 and 4.
- 8.4. Each Member shall be solely liable for any loss, damage or injury to third parties resulting from the performance of such Member's obligations under these ToR.
- 8.5. The exclusions and limitations of liability stated above shall not apply in the case of damage caused by wilful misconduct or gross negligence.
- 8.6. All Members shall use their reasonable endeavours to settle all matters in dispute amicably. All disputes and differences ("Dispute") of any kind related to these ToR, which cannot be solved amicably by the Members within thirty (30) days of the start of the Dispute, shall be referred to arbitration.
- 8.7. All Disputes arising out of or in connection with these ToR shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce (ICC). The arbitration court shall consist of three (3) arbitrators. The arbitration, including appointment of arbitrators, shall be carried out in accordance with the valid rules of the ICC (excluding the conciliation procedure). The arbitration shall take place in Stockholm, Sweden, and shall be conducted in the English language. The award of the arbitrators shall be final and binding on both Members. The Members bind themselves to carry out the awards of the arbitrators.



- 8.8. These ToR shall be construed and interpreted pursuant to the laws of Belgium to the exclusion of any rule that would refer the subject matter to another forum.
- 8.9. Nothing in these ToR shall limit the Members right to seek injunctive relief or to enforce an arbitration award in any applicable competent court of law.
- 8.10. Should any provision of these ToR be or become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of these ToR. In such a case, the Members concerned shall be entitled to request that a valid and practicable provision be negotiated which fulfils the purpose of the original provision.
- 8.11. The amendment of the present ToR is possible only:
 - a. by unanimous decision of all Members of all Working Groups,
 - b. by decision of the Amfep Members that could be taken via a written consultation procedure. The decision shall be taken by a simple majority of all Amfep Members votes referred to in Article 15§2 of the Amfep Statutes as consolidated on 07 October 2011; or
 - c. by unanimous decision of all Members of an individual Working Group provided that the amended ToR shall only apply in the respective Working Group and the ToR remain unchanged in the other Working Groups. Any amendment must be in writing so as to be effective.

Annex 1: Letter of Accession

Letter of Accession to the Working Group working on the preparation, submission and follow up of the Dossier for [insert ID of enzyme].

Between:

The Members of the Working Group represented by the Secretary General of Amfep

and

[insert full name and address of acceding Member = X]

WHEREAS a number of interested parties within the enzyme business, primarily manufacturers and/or importers and/or formulators of enzymes and/or their authorised representatives (the "Members") have entered into an agreement (the "Agreement", attached as Annex 2) to establish a Working Group for the purpose of preparing, submitting and following-up of the Dossier with the overall purpose of obtaining the approval of this food enzyme under Regulation (EC) 1332/2008 and to reduce costs for the purpose of authorisation; and

WHEREAS "X" desires to adhere to the Agreement and to participate in the Working Group and is willing to accept the terms and conditions set forth in the Agreement and in any addenda to said Agreement;

1. As of the Effective Date "X" shall adhere to the Agreement thereby becoming a "Member" of the Working Group as defined in the Agreement and participate in the work of the said Working Group. "X" agrees to assume all rights and obligations of Member of the Working Group and of any addenda to the Agreement.

2. The accession shall have effect on the date of the last signature to this Letter of Accession ("Effective Date").

Date: _____

Name of "X"

Name:

Title:

Contact information of Contact Person of "X":

Date: _____

Secretary General of Amfep

Relevant company address of the Leader

Annex 2: Working Group agreement

Between:

Association of Manufacturers and Formulators of Enzyme Products (Amfep)

Sint-Michielslaan 77-79, 1040 Brussels, Belgium

and

[Company name]

[Address]

[insert additional companies]

Hereafter referred to as "Members" have decided to enter the following agreement covering their cooperation in the Working Group (this agreement, the Terms of Reference referred to below and all its Annexes and Addenda referred to as the "Agreement").

1. The Members agree to establish the Working Group with the purpose to facilitate the preparation, submission and follow up of the Dossier for [insert enzyme ID here] with the ultimate goal to obtain an official referred for this food enzyme under EC Regulation 1332/2008 on food enzymes (OJEU 2008, L 354/7) and EC Regulation 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJEU 2008, L354/1) and Commission Regulation (EC) No. 234/2011 (OJEU 2011, L64/15) as amended implementing EC Regulation 1331/2008.

2. The Members recognise the Terms of Reference for the work on food enzymes Dossiers (including all its Annexes and Addenda) established by Amfep and published on a dedicated page of the public website of Amfep available at the following address <http://www.amfep.org/content/food-enzymes-approvals-eu>, regard them as integral part of this Agreement and agree to apply the rules and principles laid down therein to the work within this Working Group.

The signature below relates to the Agreement establishing the Working Group for preparation, submission and follow up of the Dossier for [insert enzyme ID here] with the ultimate goal to obtain an official approval referred for this food enzyme under EC Regulation 1332/2008 on food enzymes (OJEU 2008, L 354/7) and EC Regulation 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJEU 2008, L354/1) and Commission Regulation (EC) No. 234/2011 (OJEU 2011, L64/15) as amended implementing EC Regulation 1331/2008, sent in PDF version on [DATE by email from XXXX] to the Members of the Working Group.

Association of Manufacturers and Formulators of Enzyme Products, Amfep

Name: Marc Leclerc

Title: Chairman of Amfep

Date:

Name: Gilles Morelle

Title: Vice-Chairman of Amfep

Date:

Company name

Name: [insert name of the person signing on company's behalf]

Title: [insert title of the person signing on company's behalf]

Date: [insert date of signature]



Annex 3: Competition law

Amfep/09/74

Amfep statement on observance of competition law

Purpose

The purpose of this document is to assist Amfep members and staff in gaining insight into the relevant aspects of European competition law applicable to the day-to-day business and activities of Amfep.

As the sector organisation of the European enzymes' industry, Amfep serves a pro-competitive and legitimate purpose. In accordance with its statutes, Amfep may legally engage in a wide variety of activities for the industry so long as they do not violate the competition laws of the EU or the countries in which its members operate businesses. Considerations of the various competition laws require, in particular, that Amfep refrains from any activity that might be construed as unlawfully limiting competition among its members and other stakeholders.

Competition between competitors

European competition law prohibits anti-competitive agreements, understandings or collusive behaviour between two or more competing businesses that “prevent, restrict or distort” competition.

To ensure compliance with European competition law, members must not come to agreements or understandings which seek to:

- fix prices
- fix other terms and conditions to be applied to members' customers or suppliers
- agree to refuse to supply particular customers
- share or allocate particular markets or customers
- limit production or supply
- affect competition in the relevant markets.

All such arrangements are unenforceable and illegal and can result in severe fines and criminal sanctions against those involved, whether any such arrangements are formal or informal, in written or in oral form.

Exchange of information between members

There may be competition law objections to the exchange of information between competing businesses. This is because the exchange of detailed information between competitors can reduce or remove uncertainty regarding the operation of the relevant market, thereby restricting competition between competitors.

It is important that information provided to members is limited to Amfep's legitimate purpose and activities. In the Amfep statutes, Amfep's purpose and activities are summarised as follows:

“The objectives of the association are:

- 1) to provide a platform for representing the interests of its members toward the institutions of the European Union, toward international organisations and national authorities;*
- 2) to assure a free flow of information between its members on developments related to the regulatory status of enzymes in the EU;*
- 3) to defend and promote the products of the enzyme industry;*
- 4) to inform its customers and other interested parties on the efficacy and safety aspects of its enzyme products;*
- 5) to liaise with related industry organisations.”*



Members must avoid exchanging individual company data on:

- quantities of products produced and sold
- prices and terms of discount
- non-public strategic plans
- customer classification
- credit terms
- general terms and sale, delivery and payment
- cost of goods
- operating expense; and
- margins.

Amfep will not act as a vehicle to facilitate the exchange of sensitive commercial data between its members.

This document applies to formal meetings of Amfep, and also to informal meetings and contact between members, for example, during social gatherings.

Annex 4: Cost sharing policy

1. Introduction

Food enzymes dossiers established under Art. 17.1 of EC Regulation 1332/2008 on food enzymes for the purpose of establishing the Community list of food enzymes for the first time, can be prepared according to Art. 3.1 of EC Regulation 1331/2008 by "*an interested party, who may represent several interested parties*".

Art. 8.5 of EC Regulation 234/2011 as amended by EC Regulation 562/2012 further specifies the conditions in which several food enzymes can be grouped into a single, joint dossier.

For this reason, enzyme manufacturers and formulators have agreed under the aegis of Amfep³ to develop tools and templates that will allow the building and submission of joint food enzyme dossiers. This exercise will be open to Amfep members as well as to interested parties which are not members of the association.

Amfep aims at producing overall policies and templates to be used as appropriate in the individual joint food enzyme dossiers.

In order for a food enzyme to be registered, a technical dossier must be submitted to DG SANCO of the European Commission. The dossier shall contain sufficient data for the European Food Safety Authority (EFSA) to assess the safety of the food enzyme for final consumers, according to section 4 of the EFSA Guidance on food enzyme dossiers⁴.

2. Purpose of the cost and data sharing policy

The present cost and data sharing policy defines fair, transparent, proportional and non-discriminatory methods for interested parties to share the cost of toxicological studies necessary for the purpose of submitting the joint food enzyme dossier and of complying with EFSA's and Member States' possible requirements for additional studies.

The present overall cost and data sharing policy shall apply to all members of Working Groups (as defined in sections 1 and 2 of the Terms of Reference), who signed the Working Group Agreement (Annex 2 of the ToR) or the Letter of Accession to the Working Group (Annex 1 of the ToR).

This document is meant as guidance only and does not substitute legal or otherwise expert advice. Amfep and its members do not accept any liability for use of this Policy or for activities contemplated and carried out under this Policy or a food enzyme joint dossier Working Group Agreement adhering to this policy.

3. Basic principles

3.1. Gathering information on tox studies

Each study owner shall provide the information as detailed in Annex 3 of this document. The provision of data is foreseen to be done anonymously through Amfep's Data Gathering System.

³ Amfep: the European Association of Manufacturers and Formulators of Enzyme Products (amfep.org).

⁴ Guidance of the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes for Safety Evaluation by the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids. *The EFSA Journal* (2009) **1305**, 1-26.

3.2. Qualifying studies

The criteria to qualify a toxicological study to be part of the cost and data sharing program within the Working Group are specified in Annex 3 of this document.

In the event the Leader and/or another Working Group Member based on the information provided from the study owner disagrees with the eligibility of the study as being qualified, the Leader shall notify the study owner in writing of its objection and give the study owner the opportunity to verify its qualification criteria within a period of 2 weeks from receipt of the Leader's written notification.

In case the Leader and study owner do not find an agreement on the correct qualification of the study, the Leader or another Working Group Member may impose on the study owner to submit the relevant study with all pertaining information and data to a neutral third party expert, provided that the third party expert has committed to treat all data and information received confidentially. The third party expert chosen by the Leader (hereafter referred to as "Third Party Expert") shall be asked to submit its final evaluation within a period of one (1) month to the Leader and study owner.

The evaluation of the relevant study's ability to meet the qualification criteria as judged by the Third Party Expert shall be deemed final and binding on all Working Group Members including study owner, Leader and the Working Group Member objecting to the original evaluation of the study owner.

The costs associated with such Third Party Expert evaluation shall be paid by the study owner in case the original evaluation of the study owner was corrected by the Third Party Expert.

In case the Third Party Expert confirms the original evaluation of the study owner and the objection was raised by the Leader alone or jointly with other Working Group Members, such costs shall be equally shared among all Working Group Members other than the study owner.

3.3. Determination of key study

A key study is selected from the pool of qualifying studies identified in 3.2 as the study that from a scientific point of view is identified as the most suitable to describe an endpoint from the perspective of quality, completeness and representativity of data.

The Leader shall select the key study after a discussion among the Working Group Members.

The Leader is authorized to select in its free discretion the key study from the studies provided by the Working Group Members or available applying read-across principles across several Working Groups provided that:

- (i) To the extent available within Working Group, key studies shall be qualifying and be from same study owner.
- (ii) Only if a complete set of qualifying studies from the same study owner are not available within the Working Group, the key studies may be chosen within all the qualifying studies available within the Working Group.
- (iii) If the available data is not sufficient or suitable for registration purposes, the Leader may decide on a case by case basis to initiate read-across procedures.

3.4. Letter of access – right to refer

Subject to the confidentiality and non-use obligations undertaken by Working Group Members pursuant to the ToR, the Leader shall have the right to refer to selected studies to be used in the joint dossier, provided that it has received a letter of access as outlined below.

The Leader shall inform the Working Group Members, which study has been chosen as key study and for which endpoint as soon as the Leader has taken the decision.

Furthermore, the Leader shall inform Working Group Members without undue delay in case the Leader revises the decision taken and chooses another key study.

Owners of key studies shall issue a letter of access to the Leader within a period of two (2) weeks upon written request of Leader, authorizing the Leader to use the study in the joint dossier.

The same applies to Leaders of other Working Groups requesting the said study in application of read-across principles.

The access rights granted under the Working Group Agreement and pursuant to this policy shall be for the purpose of registration under EC Regulation 1332/2008 of this food enzyme only, unless otherwise specifically agreed.

If a study is required for registration under EC Regulation 1332/2008 of another food enzyme by any other Working Group, a separate request for read-across shall be submitted to the Leader or the owner of the study.

3.5. Objects of cost sharing

Only the costs for key studies and only the cost of one key study per end point shall be shared. If the Leader chooses more than one study as key studies per end point, cost calculation should be based on the standard price of one study.

The key study compensation shall however be equally allocated to Working Group Members with registration obligations that hold a qualifying study for the same end point in order to ensure that scientific and not financial considerations will determine the key study selection.

Compensation will be allocated irrespective of the number of qualifying studies owned by each data holder for the same endpoint, meaning that the data holder will be compensated equally per endpoint whether it has one or more qualifying studies for that endpoint.

3.6. Information requirements specified in sections 1, 2, 3, 5 and 6 of the EFSA Guidance on food enzyme dossiers

Data required to fulfill information requirements specified in sections 1, 2, 3, 5 and 6 of the EFSA Guidance on food enzyme dossiers shall be shared without cost sharing and compensation allocation.

3.7. Subjects of cost sharing and compensation allocation

All Working Group Members shall contribute to the costs of the study with a share corresponding to the number of Working Group Members.

Cost sharing and compensation allocation shall be applied to each individual legal entity who is a Member of the Working Group.

3.8. Calculation of study cost to be shared / study compensation to be allocated

For the purpose of this policy, the cost of a key study is the standard price per study defined for each endpoint ("Study Value").

For study standard prices, reference is made to the table enclosed as Annex 4. The values included in the table are average costs of toxicological studies possibly needed for joint food enzyme dossiers. In order to assure independence of the cost level of the study prices to be applied, reference is made to the average study costs in the Fleischer paper⁵, where such are available for the relevant studies. For

⁵ Testing costs and testing capacity according to the REACH requirements – Results of a survey of independent and corporate GLP laboratories in the EU and Switzerland. *Journal of Business Chemistry*, **4(3)**, September 2007, 96-114. The attached values for safety and toxicological studies were obtained through a survey conducted in the

other relevant studies, the values are the average cost of each study type according to a survey in the Enzyme REACH Consortium (<http://enzymes-reach.org/>).

3.9. Read-across upon request from other Working Groups

Upon request from Leaders of other enzyme Working Groups, the study owner shall allow read-across provided that the members of such other Working Group accept to contribute to the study cost as calculated using the principles outlined in this policy and as if the members of such other Working Group had been members of the Working Group, in which the requested study is present.

Data owners, that are member of several Working Groups, are compensated only once for the cost of the study they make available to these Working Groups. They are compensated in the first Working Group that chooses the study.

3.10. Read-across requests to other Working Groups

If the Working Group does not have the necessary studies, the Leader may request other enzyme Working Groups to share data (read-across). In this case, cost sharing of costs associated with the read-across shall be calculated applying the above policy among the members of the requesting Working Group.

4. New studies prepared in Working Groups

Costs of new studies generated in the Working Group for registration of the food enzyme shall be shared following the principles for sharing of costs for existing studies as outlined in the above, with the following exception:

- Study standard prices (Annex 4) do not apply to new studies generated in the Working Group. Instead the cost to be shared is the actual study and administration costs as charged by the impartial contract research organization, chosen by the Working Group to perform the study.

The study owner will be the member who sponsors the study and who is fully responsible for the monitoring of the study.

5. Sharing of Leader management costs

As specified in section 4.9 of the ToR, the Members of the Working Group may decide to remunerate the Leader for one or several tasks described in Clause 4.6 of the ToR. The cost of the Leader shall consist of a fixed amount of five thousand Euro (5000 €) plus, if deemed necessary by the Working Group, an additional five hundred Euro (500 €) per Member of the Working Group. The total amount of the costs of the Leader shall be equally shared amongst the Members of the Working Group, including the Leader.

6. Invoicing

Payment is a prerequisite for the submission of the dossier by Amfep to the European Commission.

The balance shall be settled immediately after joint submission by Amfep upon the Leader's instructions.

In case new studies are required by EFSA, the balance will be updated upon submission of the data to the EFSA.

Enzyme REACH Consortium (<http://enzymes-reach.org/>). Input from members was anonymously consolidated, two outlier values were eliminated, and the arithmetic average of the values were calculated for each study.

7. Tools

Amfep will provide an appropriate IT (Excel) tool to manage the calculation of cost and compensation allocation in accordance with the method outlined in this Cost and Data Sharing Policy in due time before the first Working Group is open.

8. Annexes

Annex 1 Template letter of adherence

Annex 2 Template letter of access to data

Annex 3 Qualification criteria for toxicological studies

Annex 4 List of standard study values (as embedded)

Annex 1: Template letter of adherence to the cost and data sharing policy

Addressee: *[name and address of Leader]*

Re: Adherence to Amfep joint dossier policy on Cost and Data Sharing (the "Cost and Data Sharing Policy")

The undersigned, authorized to act in the name and on behalf of *[company name, registered seat and registration number with chamber of commerce or commercial register]*, candidate member of the Working Group for the registration of food enzyme *[designation of the IUBMB, biological origin]*, hereby adhere to the abovementioned Cost and Data Sharing Policy subject to the following conditions:

- We acknowledge to have received, read and fully understood the Cost and Data Sharing Policy.
- We agree with the Cost and Data Sharing Policy and accept to apply the Cost and Data Sharing Policy to determine the appropriate compensation for data requested for the joint dossier submission.

This adherence letter will become part of the Agreement to be entered into among the Working Group Members in order to manage joint submission of the food enzyme dossier (the "Working Group Agreement"). The adherence letter is, however, legally valid even if no Working Group Agreement is or will be signed. In this case, the adherence letter shall be governed by the laws of Belgium excluding its choice of law rules.

Place, Date

Name of the Company

Name of signatory

Title

Annex 2: Template letter of access to data

[Leader name and address]

Re.: Letter of Access to Data for the registration of the food enzyme under Regulation EC 1332/2008 of the European Parliament and of the Council of 16 December 2008

Food enzyme: **[food enzyme name and biological origin as specified in the intended registration dossier].**

Grantor: **[company name and address]**

Grantee: **[name and address of Working Group Leader]**

Studies: The data specified in Appendix A.

Dear Sirs,

Subject to the terms set forth in the Food Enzyme Working Group Agreement for registration under Regulation EC 1332/2008 dated **[xx/xx/xx]** (hereinafter referred to as the "Agreement") to which the Working Group Leader and the undersigned Grantor are parties, by this letter, the Grantor, grants the Working Group Leader access to the full study report of the below Studies and a perpetual, irrevocable and non-exclusive license to refer to the below Studies, for the purpose of preparation and submission to the European Commission DG SANCO of the registration dossier on the Food Enzyme only.

For the avoidance of doubt, any and all access rights granted under this Letter of Access shall be for the purpose of registration under Regulation EC 1332/2008 of this Food Enzyme only and may only be used by the Working Group Leader in accordance with the Working Group Agreement.

Grantor warrants that it has the authority to grant this Letter of Access and the rights stipulated herein. If Grantor is not data owner, Grantor shall enclose as Appendix B, documentation for such authority.

Received and agreed,

Date: _____

Date: _____

For Grantor:

For Grantee (Working Group Leader)

Name: [insert name]

Name: [insert name]

Title: [insert title]

Title: [insert title]

Appendix A: **[list relevant studies and insert description of the data, studies, summaries, testing proposals and/or assessments, insofar as relevant].**

Appendix B (if applicable): authorization of Grantor rights.

Annex 3: Qualification criteria for tox studies

Each study owner shall provide the information as detailed in the table below. The provision of data is foreseen to be done anonymously through Amfep's Data Gathering System. The criteria to qualify a toxicological study to be part of the cost and data sharing program within the Working Group is as **specified** in the table.

Parameter	<i>In vitro</i> genotoxicity assay	Subchronic oral toxicity
Claimed enzyme activity (if deviating from heading)		
Batch number		
Availability of characterization data	Study owners shall commit to provide the following characterization data: <ul style="list-style-type: none"> - Chemical composition: activity / TOS and % protein of three batches, chromatographic or electrophoretic data. - Specifications: Certificates of Analysis of three batches, covering JECFA specifications/ - Properties of the enzyme: method of analysis, temperature and pH curves expressed in % of activity. Should these data not be available, the corresponding toxicological studies cannot be chosen as representative studies for the joint dossier.	
Type of study	Drop down list: Gene mutation in bacteria (Ames); Mouse lymphoma; Chromosomal aberration; Micronucleus; Other (including <i>in vivo</i> studies): please specify	Please specify length and administration route Min. 13-week feeding study
Test animal used	NA ⁶ (unless <i>in vivo</i> study)	
Guidelines followed	Drop down list: OECD 471; OECD 476; OECD 473; OECD 487; other: please specify Compliance with relevant guideline	Drop down list: OECD 408; other: please specify Compliance with relevant guideline
Test according to GLP	(Yes/No)	(Yes/No)
Year of the study		
Test has been performed on a concentrate	(Yes/No)	(Yes/No)
Activity/TOS of batch available	(Yes/No)	(Yes/No)
Proof that batch complies to JECFA spec's, (CoA) available	(Yes/No)	(Yes/No)
Proof that batch is representative of	(Yes/No)	(Yes/No)

⁶ Not Applicable.

commercial product available		
Result	Drop down list: Favorable; Not favorable	NA
List all doses given on basis of mg TOS/kg bw/day	NA	
NOAEL on basis of TOS/kg bw/day	NA	A NOAEL is established
Authorities that evaluated and approved the test		
Remarks		

Annex 4: value of toxicological studies

	Value (*)	Source
4.1.1.1.i Assessment of genotoxicity		
<i>In vitro</i> gene mutation study in bacteria	3400 €	Fleischer (**)
<i>In vitro</i> cytogenicity study (chromosomal aberrations)	21104 €	ERC (***)
<i>In vivo</i> mutagenicity studies	16756 €	ERC
4.1.1.1.ii Assessment of systemic toxicity		
Short term (sub-acute) repeated dose toxicity study (28 days)	58748 €	Fleischer
Subchronic (90 days)	126761 €	Fleischer

(*)	Value:	Values compiled in 2009 by the Enzyme REACH Consortium (http://enzymes-reach.org/) were updated in Dec. 2012 with inflation (2% annual rate).
(**)	Fleischer:	Values compiled in: <i>Testing costs and testing capacity according to the REACH requirements - Results of a survey of independent and corporate GLP laboratories in the EU and Switzerland.</i> Journal of Business Chemistry, Vol. 4, issue 3, September 2007, pg. 96 - 114.
(**)	ERC:	Values not provided by the Fleischer publication. These values were obtained through a survey conducted in the Enzyme REACH Consortium (http://enzymes-reach.org/). Input from members was anonymously consolidated, two outlier values were eliminated, and the arithmetic average of the values were calculated for each study.