

## **BID Document**

### **Tender for Appointment of GLP Accredited Laboratory for Conducting Toxicity Study for SHELLAC SHEFEXIL, Kolkata.**

**Tender No. :1/SHEFEXIL/SHELLAC/2017-18**



**(SHEFEXIL)**  
**Shellac & Forest Products Export Promotion**  
**Council Formerly known as Shellac Export**  
**Promotion Council**  
***(Sponsored by Ministry of Commerce &***  
***Industry, Govt. of India)***

## Table of Contents

| Section | Title                                                                 | Page No. |
|---------|-----------------------------------------------------------------------|----------|
| I       | Notice Inviting Tender(NIT)                                           | 3        |
|         | Information to be given by the Bidder                                 | 4        |
| II      | Instructions to Bidders                                               | 6        |
| III     | General Conditions of Contract                                        | 19       |
| IV      | Special Conditions of Contract                                        | 23       |
| V       | Scope and Definition of Work                                          | 25       |
| VI      | Bid Form                                                              | 30       |
| VII     | Performance Security Bond Form                                        | 31       |
|         | Performa for Letter of Authorization for attending the Bid<br>Opening | 34       |
|         | Pre stamped Receipt ( for Refund of EMD )                             | 35       |
| VIII    | Price Schedule                                                        | 36       |

## SECTION I

### NOTICE INVITING TENDER

Office of Issue : Shellac & Forest Products Export Promotion Council  
(SHEFEXIL), Kolkata.

Tender no : 1/SHEFEXIL/SHELLAC/2017-18

Tender Document : Details as given below

Due date/Time of receipt : 22<sup>nd</sup> November, 2017 by 18.00 hrs.

Opening Date/Time : 5<sup>th</sup> December, 2017 at 10.30 hrs.

Sealed tenders in two parts are invited on behalf of SHEFEXIL, Kolkata for engagement of GLP accredited laboratories for conducting Toxicity Studies for Shellac (E 904).

#### **Eligibility of Bidder:**

GLP Accredited laboratories for carrying out the entire Scope of Study specified in Section V of the Bid Document and who fulfill other eligibility criteria explained in the Bid Document are eligible to participate in this tender.

Bid Security (EMD) of Rs. 50,000 (Rupees Fifty Thousand) in the form of demand draft in favour of Shellac & Forest Products Export Promotion Council, payable at Kolkata shall be submitted by the Bidders.

Intending Bidders may obtain copy of the tender document by downloading the same from [www.shellacepc.com](http://www.shellacepc.com). Completed tenders together with Bid Security of Rs. 50,000/- (Rupees Fifty Thousand) should reach The Chairman, SHEFEXIL, Vanijya Bhavan, International Trade Facilitation Centre, 1/1 Wood Street, 2<sup>nd</sup> Floor, Kolkata - 700016 by 22<sup>nd</sup> November, 2017 by 18.00 hrs.

Chairman,  
SHEFEXIL, Kolkata.

## **SECTION II**

### **INSTRUCTIONS TO BIDDERS**

#### **A. Introduction**

##### **1. The Bidding Process :**

- 1.1 The Bidding Process shall be a two stage process. The Financial Bids of the Bidders whose Technical Bids have been found to be responsive shall be opened in terms of this Bid Document.
- 1.2 All interested Bidders who wish to participate in the bid and who fulfil all eligibility conditions in this Bid Document shall submit their bids in terms of this Bid Document along with the Bid Security of Rs. 50, 000/- (Rupees Fifty Thousand only) by way of a Demand Draft drawn in favour of "SHEFEXIL, Kolkata" payable at Kolkata. The Bid Security shall be non-refundable.
- 1.3 The Bidder who is qualified as per this Bid Document and whose bid is found to be otherwise satisfactory, acceptable and sufficient by SHEFEXIL and who submits the lowest Financial Bid shall be declared the selected bidder (hereinafter referred to as the "Selected Bidder").
- 1.4 Each Bidder is eligible to submit only one Bid. Multiple bids submitted by a Bidder are liable to be rejected.
- 1.5 Any entity which has been barred by any Central and/or State Government agency to bid or has been blacklisted shall not be eligible to submit its bid.
- 1.6 Any bid with a condition attached to it shall be liable for rejection.
- 1.7 The Bid Document with all its annexures, schedules and appendices shall always remain the property of SHEFEXIL.
- 1.8 A Bidder shall not have a conflict of interest which would affect the bidding process. Any bidder having a conflict of interest shall be disqualified.

##### **2. Eligible Bidders**

- 2.1 The Selected Bidder shall be an Indian Analytical Institution /Laboratories etc. meeting the following eligibility criterion:
  - i. The Bidder should be the owner of a Laboratory for carrying out the entire Scope of Study specified in Section V of the Bid Document having Good Laboratory Practice (GLP) certification for undertaking the entire Scope of Study contained in

Section V of the Bid Document. The Bidder shall under no circumstances outsource the work assigned to it.

- ii. A minimum annual turnover of Rs.120 lakhs during the last three years.
- iii. A minimum of 10 years experience in undertaking chemical analysis and in conducting toxicity studies on food products especially natural products used as food additives including Shellac. Preference shall be given to those who have experience in dealing with quality requirements for export shipments of natural products.
- iv. Availability of requisite subject matter manpower. The Bidder should have at least 2 experienced toxicologists/board certified pathologists in their in house team.
- v. The Bidder should have access and availability of certified and quality animals.
- vi. Any Bidder involved in the Shellac and Lac based industry directly or indirectly through associate company, holding company, subsidiary company or group company or any combination thereof shall not be eligible.
- vii. Previous experience in dealing with European Union (EU)/European Food Safety Authority (EFSA).

Explanation :-

- (i) "associate company" in relation to another company means a company in which that other company has a significant influence, but which is not a subsidiary company of the company having such influence and includes a joint venture company.
- (ii) "significant influence" means control of at least twenty percent of total share capital or of business decisions under an agreement.
- (iii) "holding company" in relation to one or more other companies means a company of which such companies are subsidiary companies.
- (iv) "subsidiary company" or "subsidiary" in relation to any other company (that is to say the holding company), means a company in which the holding company –
  - (a) controls the composition of the board of directors; or
  - (b) exercises or controls more than one-half of the total share capital either at its own or together with one or more of the subsidiary companies.
- (v) "group company" means two or more enterprises which, directly or indirectly, are in a position to :
  - (a) exercise twenty-six percent or more of voting rights in any other enterprise; or
  - (b) appoint more than fifty percent of members of board of directors in the other enterprise.

2.2 A Declaration specifying that the conditions contained in 2.1(i) to 2.1(vii) are fulfilled should be submitted alongwith the Technical Bid. Documentary proof (attested copies of relevant documents) for the above facts shall be attached.

2.3 The Bidder shall submit Documentary proof i.e. attested copies of documents certifying its compliance with the eligibility criteria contained in point Nos.2.1(i) to 2.1(vii) above.

- 2.4 The Bidder shall read and study the Bid Document including all instructions, forms and other information contained herein in detail before submitting their bids. It shall be deemed that a Bidder has carefully studied and examined the Bid Document with full understanding of its implications. Failure to furnish all information required as mentioned in the Bid Document or submission of a Bid not substantially responsive to the Bid Document in every respect shall result in the rejection of the Bid.

### 3. Cost of Bidding

The Bidder shall bear all costs associated with the preparation and submission of the Bid. SHEFEXIL will in no case, be responsible or liable for these costs, regardless of the conduct or outcome of the bidding process.

### 4. Documents comprising the Bid

- 4.1 The Bid shall contain of the Technical Bid and the Financial Bid.

- 4.2 The **Technical Bid** shall inter-alia comprise of the followings:-

- (i) Copy of the Bid Document together with all addenda and corrigenda duly signed by the authorized signatory of the Bidder and seal of the Bidder company if applicable, shall be affixed on all pages;
- (ii) Qualification information and documents as required in accordance with stipulations and other materials required to be submitted by the Bidder in accordance with this Bid Document;
- (iii) Earnest money Deposit in terms of this Bid Document;
- (iv) Power of Attorney authorizing the person to sign the bid on behalf of the Bidder;
- (v) Covering letter in the format contained in **Appendix I** hereto;
- (vi) General Information in the format contained in **Appendix II** hereto;
- (vii) Application Form in the format contained in **Appendix III** hereto;
- (viii) Letter of Authorisation in favour of representative of Bidder for attending Bid Opening in the format contained in **Appendix IV** hereto;
- (ix) Experience Certificates evidencing compliance with the points mentioned in Clause 2.1 hereof;
- (x) A declaration specifying that the conditions contained in Clause nos. 2.1(i) to 2.1(vii) above have been fulfilled;

- (xi) Articles and Memorandum of Association or Partnership Deed/Proprietorship Deed or any other document establishing the status of the participating Bidder; and
- (xii) Copy of valid GLP certification of the Bidder.

4.3 The **Financial Bid** shall contain the price bid of the Bidder in the format contained in **Appendix- V** hereto.

4.4 The Bidder is expected to examine all instruction, forms, terms and specifications in the Bid Documents. Failure to furnish all information required as per the Bid Documents or submission of bids not substantially responsive to the Bid Documents in every respect will be at the Bidder's risk and shall result in rejection of the bid.

4.5 The Bidder shall furnish, as part of his Bid, documents establishing the conformity of his bid to the Bid Document.

4.6 The documentary evidence of conformity to the Bid Documents may be in the form of literature, degrees, certificates etc. and the Bidder shall furnish:

- (a) A detailed description of the services and performance characteristics of the Bidder in the formats contained in the Appendices hereto;
- (b) A clause-by-clause compliance of SHEFEXIL's Technical specifications and commercial conditions demonstrating responsiveness to the Bid conditions. For this the Bidder needs to sign at every page of the Bid Document along with seal indicating its acceptance of terms and conditions. The Chairman, SHEFEXIL will be the competent authority to accept or reject any deviations to the terms of the Bid Document. A committee of members having technical and financial experience may assist the Chairman to consider such deviations. Once decided such decisions shall be binding on all the Bidders.

## **5. AMENDMENT OF BID DOCUMENTS:**

5.1 At any time, prior to the date of submission of bids, SHEFEXIL may, for any reason, whether at its own initiative or in response to a clarification requested by a prospective Bidder, modify the Bid Documents by amendments.

5.2 The amendments shall be notified in writing to all Bidders and these amendments shall be binding on the Bidders.

- 5.3 In order to afford prospective bidders reasonable time in which to take the amendments in account in preparing their bids, SHEFEXIL may, at its own discretion, extend the deadline for the submission of bids suitably.

## **6. BID SECURITY**

- 6.1 The Bidder shall furnish, as part of the Technical Bid, bid security for an amount of Rs. 50,000/- (Rupees Fifty Thousand only)
- 6.2 The Bid Security shall be in the form of a crossed demand draft or bank guarantee from a scheduled Bank in favour of "Shellac and Forest Products Export Promotion Council" payable at Kolkata. Payment in any other form is not acceptable.
- 6.3 A Bid not accompanied by the Bid Security shall be rejected by SHEFEXIL as non-responsive.
- 6.4 The Bid Security of the unsuccessful Bidders will be discharged/ returned as promptly as possible, but not later than 30 days after the expiry of the period of bid validity prescribed by SHEFEXIL.
- 6.5 The Selected Bidder's Bid Security will be discharged upon the Bidder's acceptance of the work order and furnishing the performance security.
- 6.6 The Bid Security may be forfeited by SHEFEXIL without prejudice to any other right or remedy that may be available to it :-
- (a) If a Bidder withdraws his Bid during the period of bid validity contained herein,
  - (b) In the case of the selected Bidder, if the Bidder fails
    - i) to sign the contract in accordance with this Bid Document, or
    - ii) to furnish performance security in accordance with this Bid Document;
  - (c) If a Bidder engages in a corrupt practice, fraudulent practice, coercive practice, undesirable practice or restrictive practise.

## **7. PERIOD OF VALIDITY OF BIDS**

- 7.1 The Bid submitted shall remain valid for 180 days after the date of Bid Opening prescribed by SHEFEXIL. A Bid valid for a shorter period shall be rejected by SHEFEXIL as non-responsive.
- 7.2 In exceptional circumstances, SHEFEXIL may request the Bidder's consent for an extension to the period of bid validity. The request and the responses thereto shall be made in writing. The Bid Security provided shall also be suitably extended. A Bidder accepting the request and granting extension will not be permitted to modify his Bid.

## **8. FORMAT AND SIGNING OF BIDS**

- 8.1 The Bidder shall submit the Bid in two separate non-transparent closed envelopes, which are duly sealed, one for Technical Bid and the other for Financial Bid, clearly indicating the same on the envelopes. The two envelopes shall be placed in an outer non-transparent closed envelope duly sealed containing the heading "Bid for Appointment of GLP Accredited Laboratory for Conducting Toxicity Study".
- 8.2 The Bid shall be typed or printed and signed by the Bidder or a person duly authorized by the Bidder to submit the bid in terms thereof by a Power of Attorney. A copy of the said Power of Attorney shall be provided with the bid. A photo copy of the present Bid Document duly initialled as token of acceptance on all pages by the authorised signatory of the Bidder together with seal of the Bidder must be provided with the Bid.
- 8.3 The Bid shall contain no interlineations, erasures or overwriting except as necessary to correct errors made by the Bidder in which case such corrections shall be signed by the person/persons signing the Bid.
- 8.4 The Bidder shall provide all the information sought in this Bid Document. SHEFEXIL will evaluate only those Bids that are received in the required formats and complete in all respects. Incomplete Bids shall be liable to be rejected.
- 8.5 The Bid shall be typed or written in indelible ink. All alterations, omissions, additions or any other amendments to the bid shall be initialled by the person submitting the Bid.
- 8.6 The following conditions shall be adhered to while submitted the Bid :-
- a. the Bidder should attach clearly marked and referenced continuation sheets in the event the space provided in the prescribed formats is insufficient; and
  - b. information supplied by the Bidder must apply to the Bidder and not to other associated companies or firms.

## **9. SUBMISSION OF BIDS:**

- 9.1 The Bids shall conform to the followings :
- (a) addressed to SHEFEXIL at the following address: Chairman, SHEFEXIL, Vanijya Bhavan, International Trade Facilitation Centre, 1/1 Wood Street, 2<sup>nd</sup> Floor, Kolkata-700 016.
  - (b) Bearing the Tender Number
  - (c) The inner and outer envelopes shall indicate the name and address of the Bidder to enable the bid to be returned unopened in case it is received late.

(d) Tenders shall be dropped in the Tender Box at the 2<sup>nd</sup> Floor, C/o. SHEFEXIL, Kolkata.

(e) SHEFEXIL shall not be responsible if the bids are delivered elsewhere.

9.2 If the envelopes are not sealed and marked as required by this Bid Document, the Bids are liable to be rejected.

**10. TIME FOR SUBMISSION OF BIDS:**

10.1 Bids must be received by SHEFEXIL at the address herein not later than 18.00 Hrs. on 22<sup>nd</sup> November, 2017.

10.2 SHEFEXIL may, at its discretion, extend the deadline for the submission of the Bids in which case all rights and obligations of the SHEFEXIL and the Bidders will be subjected to the deadline as extended.

**11. LATE BIDS:**

Any Bid received by the SHEFEXIL after the deadline for submission of Bids prescribed by the SHEFEXIL shall be rejected and returned unopened to the Bidder.

**12. OPENING OF BIDS BY SHEFEXIL**

12.1 SHEFEXIL shall open the Bids in the presence of Bidder or its authorised representatives who choose to attend at 10.30 hrs on 5<sup>th</sup> December, 2017. The Bidder's representatives, who are present shall sign in the attendance register. Authority letter to this effect shall be submitted by the Bidder before they are allowed to participate in Bid opening. A format of the Authority letter is contained in **Appendix IV** hereof.

12.2 A maximum of two representatives for any Bidder shall be authorised and permitted to attend the Bid opening.

**13. CLARIFICATION OF BIDS:**

13.1 To assist in the examination, evaluation and comparison of Bids, SHEFEXIL may, at its discretion, ask the Bidder for clarification of its bid. The request for clarification and the response shall be in writing. However, no post-bid clarification at the initiative of the Bidder shall be entertained.

**14. EVALUATION OF BIDS:**

14.1 Tender will be evaluated in two phases. First, Technical Bid evaluation will be done. The Financial bids of only those Bidders who qualify in the Technical Bid evaluation will be opened.

- 14.2 SHEFEXIL shall evaluate the Bids to determine whether they are complete, whether any computational errors have been made, whether the documents have been properly signed and whether the Bids are generally in order.
- 14.3 If there is a discrepancy between words and figures, the amount in words shall prevail. If the Bidder does not accept the correction of the errors made by SHEFEXIL, his Bid shall be rejected.
- 14.4 Prior to detailed evaluation, SHEFEXIL will determine the responsiveness of each Bid to the Bid Documents. For purposes of this clause, a responsive Bid is one, which conforms to all the terms and conditions of the Bid Documents without material deviations.
- 14.5 A Bid determined as non-responsive will be rejected by SHEFEXIL and cannot, subsequent to the Bid opening be made responsive by the Bidder by correction of the non-conformity.
- 14.6 SHEFEXIL, at its discretion, may waive any minor infirmity or non-conformity or irregularity in a Bid, which does not constitute a material deviation.
- 14.7 The Technical Bid shall be opened by SHEFEXIL or by its authorized representative at the time, place and date specified by SHEFEXIL.
- 14.8 To facilitate evaluation of the Technical Bids, SHEFEXIL shall be entitled to seek the assistance of the Director of the Indian Institute of Toxicological Research (IITR) and also request for clarifications and documents from any Bidder regarding the Technical Bid submitted by it.

## **15. EVALUATION AND COMPARISON OF RESPONSIVE BIDS:**

- 15.1 SHEFEXIL shall evaluate in detail and compare the Bids which are responsive.

### **15.2 Mode of Selection**

- (i) A committee formed by SHEFEXIL will open the Technical Bids and evaluate the bids in the context of the requirements laid out, based upon which short-listing shall be done. SHEFEXIL reserves the right to reject the bid/s not conforming to the requirements contained in this Bid Document.
- (ii) If required, SHEFEXIL may invite the Bidders for a presentation for which formal communication shall be sent to all the participants qualifying the first step mentioned above.

## **16. Preliminary Evaluation**

- 16.1 Prior to evaluation of the Technical Bid, SHEFEXIL shall determine whether each bid is responsive to the requirements of the Bid Document. A Technical Bid shall be considered responsive only if :-

- (a) It is received by the bid due date including any extension thereof provided by SHEFEXIL;
  - (b) It is signed, sealed and marked as stipulated in this Bid Document;
  - (c) It is accompanied with the Bid Security as specified in this Bid Document;
  - (d) It contains all documents/information required to be submitted as part of the Technical Bid including those contained in Clause 4.2 hereof;
  - (e) It contains all the information (complete in all respects) as requested in this Bid Document;
  - (f) It contains experience certificates evidencing compliance with the points mentioned in Clause 2.1 hereof;
  - (g) It does not contain any condition or qualification; and
  - (h) It is not otherwise non-responsive in terms hereof.
- 16.2 SHEFEXIL reserves the right to reject any bid which is non-responsive and no request for alteration, modification, substitution or withdrawal shall be entertained by SHEFEXIL in respect of such bid.
- 16.3 The Bidders adjudged as responsive in terms of this Bid Document and fulfilling the eligibility criteria contained in this Bid Document shall be declared as the qualifying Bidders.

## 17. **Financial Bids**

- 17.1 The Financial bids of only the technically qualified Bidders shall be opened by SHEFEXIL. The technically qualified Bidder quoting the lowest financial bid shall be declared as the Selected Bidder.

## 18. **Bid Prices:**

- 18.1 The Bidder shall give the total composite price in Indian Rupees as per format contained in **Appendix V**.
- 18.2 The prices quoted by the Bidder shall remain fixed during the entire period of contract and shall not be subject to variation on any account. A bid submitted with an adjustable price quotation will be treated as non-responsive and rejected.
- 18.3 “Discount”, if any offered by the Bidders shall not be considered unless they are specifically indicated in the price schedule. Bidders desiring to offer discount shall therefore modify their offers suitably while quoting and shall quote clear charges net of such discount.
- 18.4 The price quoted shall be inclusive of levies and taxes except Goods and Services Tax (GST).

## **19. Modification of Bids**

- 19.1 The Bidder may modify or withdraw his bid after submission provided that the written notice of the modification or withdrawal is received by SHEFEXIL prescribed for submission of bids.
- 19.2 The Bidder's modification or withdrawal notice shall be prepared, sealed, marked and dispatched as required in the case of bid submission in accordance with the provisions of this Bid Document. A withdrawal notice may also be sent by TELEX/FAX but followed by a signed confirmation copy, post marked not later than the deadline for submission of bids.
- 19.3 No Bid shall be modified subsequent to the deadline for submission of bids.

## **20. CONTACTING SHEFEXIL**

- 20.1 No Bidder shall try to influence SHEFEXIL on any matter relating to its Bid, from the time of the Bid opening till the time the contract is awarded.
- 20.2 Any effort by a Bidder to influence SHEFEXIL in the SHEFEXIL's Bid evaluation, Bid comparison or contract award decision shall result in the rejection of the Bid.

## **21. AWARD OF CONTRACT**

SHEFEXIL shall consider placement of work order on the Bidder whose offer has been found technically, acceptable and financially lowest.

## **22. SHEFEXIL's RIGHT TO ACCEPT ANY BID AND TO REJECT ANY OR ALL THE BIDS**

SHEFEXIL reserves the right to accept or reject any Bid, and to annul the Bidding process and reject all Bids, at any time prior to award of contract without assigning any reason whatsoever and without thereby incurring any liability to the effected Bidder or Bidders on the grounds for SHEFEXIL's action.

## **23. ISSUE OF WORK ORDER OR LETTER OF INTENT (LOI)**

The issue of a work order or LOI shall constitute the intention of SHEFEXIL to enter into the Contract with the Bidder. The Bidder shall within 15 days of receipt of the work order, give his acceptance along with performance security by way of Bank Guarantee in the form contained in **Appendix VI** of this Bid Document.

## **24. SIGNING OF CONTRACT**

The issue of Work Order shall constitute the award of Contract to the Bidder. Upon the Bidder furnishing performance security, SHEFEXIL shall discharge the Bid security furnished by the Bidder.

## **25. ANNULMENT OF AWARD**

Failure of the Selected Bidder to comply with the requirement of Clause 23 shall constitute sufficient ground for the annulment of the award and forfeiture of the Bid Security in which event SHEFEXIL may make the award to any other Bidder at the discretion of SHEFEXIL or call for new Bids.

## **26. SUB-CONTRACTS**

The Selected Bidder shall not be entitled to assign or subcontract the work contained in this Bid Document or the Work Order.

## **27. TIME PERIOD OF WORK**

The Bidder shall undertake the work in terms of the Scope of Work contained in Section IV of this Bid Document and shall complete the same within \_\_\_\_ years from the date of issuance of the Work Order. The duration of work may be varied by SHEFEXIL anytime during the period of Contract.

## **28. BIDDER TO FOLLOW GUIDELINES OF THE CENTRAL VIGILANCE COMMISSION (CVC)**

The Bidders shall follow the terms and conditions stipulated by the relevant guidelines and circulars of the Central Vigilance Commission (CVC) while submitting their bids.

Chairman,  
SHEFEXIL, Kolkata

## APPENDIX – I

### COVERING LETTER

Tender No. 1/SHEFEXIL / SHELLAC / 2017-18

**The Chairman,  
SHEFEXIL,  
Vanijya Bhavan, ITFC,  
1/1, Wood Street, 2<sup>nd</sup> Floor,  
Kolkata - 700016**

Dear Sir,

Having examined the conditions of contract and specifications including addenda Nos....., we, undersigned, offer to provide services in conformity with said conditions of contract and specifications for sum of Rs.....(Rs. Only) or such other sums as may be ascertained in accordance with the schedule of prices attached herewith and made part of this bid.

We undertake, if our bid is accepted, to complete services as specified in the contract within the specified time frame.

If our bid is accepted, we will obtain the guarantees of a Scheduled Bank for a sum not exceeding 10% of the contract sum for the due performance of the contract.

We agree to abide by this bid for a period of 180 days from the date fixed for bid opening and it shall remain binding upon us and may be accepted at any time before the expiration of that period. Until a formal Work order of contract is prepared and executed, this bid together with your written acceptance thereof in your notification of award shall constitute a binding contract between us.

Bid submitted by us is properly sealed and prepared so as to prevent any subsequent alteration and replacement.

This is also to certify that we are not related to SHEFEXIL in anyway.

We understand that you are not bound to accept the lowest or any bid, you may receive.  
Dated this ..... day of ..... 2017.

Signature of  
In capacity of  
Duly authorized to sign the bid for and on behalf of .....  
Witness .....  
Address .....  
Signature .....

**APPENDIX - II**  
**INFORMATION TO BE GIVEN BY THE BIDDER**

| <b>Sl.No.</b> | <b>Particulars</b>                                                                                                                                                              | <b>Description</b> |
|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| 01            | Name &Address of the Bidder with Phone Nos.                                                                                                                                     |                    |
|               | a) Registered Office                                                                                                                                                            |                    |
|               | b) Administrative Office                                                                                                                                                        |                    |
| 02            | Nature of constitution of Bidder (Whether individual, Partnership, firm or company registered under Companies Act) Enclose Certificate, MOU, AOA, Partnership Deeds, etc.)      |                    |
| 03            | Name and address of the Proprietor / Partner/ Director                                                                                                                          |                    |
| 04            | Name of authorised signatory of Bidder with Phone no                                                                                                                            |                    |
| 05            | Other place of business with full address                                                                                                                                       |                    |
| 06            | Details of Registrations                                                                                                                                                        |                    |
|               | a) Goods and Services Tax (GST)                                                                                                                                                 |                    |
|               | b) Income tax                                                                                                                                                                   |                    |
|               | c)Central Excise                                                                                                                                                                |                    |
|               | d) Income Tax PAN number                                                                                                                                                        |                    |
| 07            | Last three year's annual Turnover as per Balance Sheet (enclose a certificate certified by a Chartered Accountant together with copies of Balance sheet for the relevant years. |                    |

|    | Financial Year                 | Turnover<br>( in lakh) | Profit/Loss<br>( in lakhs) |
|----|--------------------------------|------------------------|----------------------------|
|    | 2016-17                        |                        |                            |
|    | 2015-16                        |                        |                            |
|    | 2014-15                        |                        |                            |
|    |                                |                        |                            |
| 08 | Any other relevant information |                        |                            |

**Name of the Firm/Company (with Seal) :**

**Signature of Authorized Signatory/Bidder :**

**Name of the Authorized Signatory/Bidder :**

**Address :**

**Phone No. :**

**Fax No. :**

**Date :**

*Note : Bidders should provide photocopies of documents evidencing the information submitted.*

### **APPENDIX - III**

#### **Application Form**

#### **(Technical Bid)**

(To be submitted in a sealed cover along with Technical Bid)

| Sl.No. | Particulars                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Description                             |
|--------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| 1.     | <p>Details of previous experience in conducting Toxicity Studies</p> <p>(Please enclose documentary evidence in the form of copy of COMPLETION CERTIFICATES of assignments undertaken.)</p> <p>Please note COMPLETION CERTIFICATES only shall be acceptable. Only in those cases where assignment is still continuing that we can accept work order/Award letter.</p> <p>Please mention Year, Name of the Project, Name of the client, One para about the type of project, year of completion.</p> | (Use Format – 1)                        |
| 2.     | Briefly provide the Test Facility – Infrastructure Specifications/Capabilities and other Technical Resources available to support “export shipment of natural products” and their safety qualifications/assessments.                                                                                                                                                                                                                                                                               | Attach separate sheet for the write up. |
| 3.     | Detailed list of Accreditation and Regulatory Compliance Certificates from various National and International Institutions (as applicable).                                                                                                                                                                                                                                                                                                                                                        | (Use Format – 3)                        |
| 4.     | Detailed list of Additional Services Offered to Support/as extension of Toxicology Studies.                                                                                                                                                                                                                                                                                                                                                                                                        | (Use Format – 4)                        |
| 5.     | Previous experience in dealing with EU/EFSA requirements (Please mention Year, name of the Project, Client, One paragraph about the type of project, year of completion)                                                                                                                                                                                                                                                                                                                           | (Use Format – 2)                        |
| 6.     | Previous experience in dealing with Shellac or similar                                                                                                                                                                                                                                                                                                                                                                                                                                             | (Use Format –                           |

|    |                                                                                                                                                                                                                        |                                                              |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
|    | natural products used as food additives<br><br>(Please mention Year, Name of the Project, Client, One Para about the type of project, year of completion)                                                              | 2)                                                           |
| 7. | No. of team members, on the payrolls their qualifications<br>(write numbers in the opposite column and attach separate sheet for their experience and qualifications.)                                                 | Total<br>a):<br>b):<br>c):<br>d): Others<br>(Use Format – 5) |
| 8. | No. and names of Government/Multilateral/International organisations associated with during last 5 years alongwith the name of the assignments handled, Value of the project and project area/s (please attach a list) | (Use Format – 6)                                             |
| 9. | Details of Earnest Money Deposit (EMD) : ` 50,000/- (DD NO. ....dated.....drawn on SHEFEXIL.                                                                                                                           |                                                              |

Name of the Firm (with Seal) :

Signature of Authorised Signatory :

Name of the Authorised Signatory :

Phone No. :

Fax No. :

Date :

---

### **Format – 1**

Detail of previous experience in conducting Toxicity Studies

| Sl.No. | Year | Name and Value of the Project | Type of the Client | Product/s covered<br>(Scope of the Projects) | Project in brief (In one para) |
|--------|------|-------------------------------|--------------------|----------------------------------------------|--------------------------------|
|        |      |                               |                    |                                              |                                |
|        |      |                               |                    |                                              |                                |
|        |      |                               |                    |                                              |                                |

### **Format – 2**

Detail of previous experience of issues related to Shellac/food additive items

| Sl.No. | Duration/Year of completion | Name and Value of the Project | Client | Product/s covered<br>(Scope of the Projects) | Project in brief (In one para) |
|--------|-----------------------------|-------------------------------|--------|----------------------------------------------|--------------------------------|
|        |                             |                               |        |                                              |                                |
|        |                             |                               |        |                                              |                                |
|        |                             |                               |        |                                              |                                |

### **Format – 3**

Detailed list of Accreditation and Regulatory Compliance Certificates from various  
National and International Institutions

| Sl.No. | Name of the Accreditation/Certification | Name of the Issuing Authority | Date of Issuance and validity period | Scope |
|--------|-----------------------------------------|-------------------------------|--------------------------------------|-------|
|        |                                         |                               |                                      |       |
|        |                                         |                               |                                      |       |
|        |                                         |                               |                                      |       |

### **Format – 4**

Detailed list of Additional Services Offered to Support/as extension  
of Toxicology Studies

| Sl.No. | Name of the Additional Services Offered | Product/s covered (Scope of the Projects) | Project in brief (In one para) |
|--------|-----------------------------------------|-------------------------------------------|--------------------------------|
|        |                                         |                                           |                                |
|        |                                         |                                           |                                |
|        |                                         |                                           |                                |

Format – 5

Detailed List of Technical Team/Scientific Team Members Involved in the Various Toxicology Studies/Projects and their Technical Experience and Qualifications

| Sl.No. | Name of the Technical/Scientific Team Member | Education Qualifications | Years of Experience | List of Previous Organisations | Areas of Expertise (In one para) |
|--------|----------------------------------------------|--------------------------|---------------------|--------------------------------|----------------------------------|
|        |                                              |                          |                     |                                |                                  |
|        |                                              |                          |                     |                                |                                  |
|        |                                              |                          |                     |                                |                                  |

Format – 6

No. and names of Government/Multinational/International Organisations Associated with  
during the last 5 years

| Sl.No. | Duration/Year of completion | Name of the Project | Client Details | Area | Value of the Project |
|--------|-----------------------------|---------------------|----------------|------|----------------------|
|        |                             |                     |                |      |                      |
|        |                             |                     |                |      |                      |
|        |                             |                     |                |      |                      |

#### **APPENDIX - IV**

##### **Performa of Letter of Authorization for Attending Bid Opening**

Subject : Authorisation for attending Bid opening

Following persons are hereby authorised to attend the bid opening for the tender mentioned above on behalf of \_\_\_\_\_ (Bidder) in order of preference given below.

| Order of preference | Name | Specimen Signature |
|---------------------|------|--------------------|
|---------------------|------|--------------------|

---

I

II

Alternate Representative \_\_\_\_\_

Signature of Bidder

or

Officer authorized to sign the bid on behalf of the Bidder.

Note :

1. Maximum of two representatives will be permitted to attend bid opening.
2. Permission for entry to the hall, where the bids are to be opened, may be refused in case the authorization as prescribed above is not received.

**APPENDIX - V**

**PRICE SCHEDULE**

**(Financial Bid)**

| Sl. | Description of Work                               | Amount (in `) per sample                 |
|-----|---------------------------------------------------|------------------------------------------|
| 1   | Toxicity Study for Shellac (E904) for<br>SHEFEXIL | In figures ._____<br><br>In words Rupees |

Signature of the Bidder along with seal.

**Notes:**

1. Rates are quoted as inclusive of all levies, cess, prevailing taxes, except for GST which will be charged as applicable.

## **APPENDIX - VI**

### **PERFORMANCE SECURITY BOND FORM**

THIS DEED OF GUARANTEE MADE THIS ..... DAY OF ..... between Shellac & Forest Products Export Promotion Council sponsored by the Deptt. of Commerce, Govt. of India and having its Head Office at Vanijya Bhavan, International Trade Facilitation Centre, 1/1 Wood Street, 2nd Floor, Kolkata 700016 (hereinafter called SHEFEXIL) (which expression shall unless excluded by or repugnant to the context include its successors and assignees) of one part and ..... (hereinafter called the "Bank") (Which expression shall unless excluded by or repugnant to the context include its successors and assignees) of the other part.

WHERE SHEFEXIL accepted the tender of M/s ..... (hereinafter called the Firm) to provide services the SHEFEXIL ..... as per contract No..... Dated .....(hereinafter referred to as the said contract.

AND WHEREAS the said contract provides that Firm shall furnish Bank Guarantee to the extent of ten percent of the value of the contract as and by way of security for the due observance and performance of terms and conditions of the contract.

AND WHEREAS at the request of the Firm the Bank agreed to execute these presents.

NOW THE DEED WITNESSED AND IT IS HEREBY AND DECLARED BY AND between the parties hereto as follows:

1. The Bank hereby irrevocably and unconditionally guarantees to SHEFEXIL that the Firm shall render all necessary and efficient services which may be required to be rendered by the Firm in connection with and/ or for the performance of the said contract and further guarantees that the services which shall be supplied by the Firm under the said contract shall be actually performing the work required of it to the satisfaction of SHEFEXIL. In the event of the firm failing or neglecting to render necessary services as foresaid and/or in the event of the services failing to give satisfactory performance, the Bank shall of ..... against any loss or damage that may be caused to or suffered by SHEFEXIL by reason of any breach by the Firm of any of the aforesaid terms and conditions and the Bank further undertake to pay SHEFEXIL, such sum not exceeding ..... on demand and without DEMUR in the event of the Firm's failure to perform and discharge the aforesaid several duties and obligations on his part to be observed and performed under the said contract and/or deficiencies and defects on the satisfactory performance of the services.

2. The decision of SHEFEXIL as to whether the Firm failed to or neglected to perform or discharge his duties and obligation as aforesaid and/or whether the services are free from deficiencies and defects are capable of performing the work required and as to the amount payable to SHEFEXIL by the Bank herein shall be final and binding on the Bank.

3. The liability of the Bank under this Guarantee shall be as of Principal Debtor.

4. The Guarantee herein contained shall remain in full force and effect during the period that would be taken for performance of the aforesaid terms of the said contract and it shall continue to be enforceable 6 months after the services have been taken over, all the dues of SHEFEXIL under or by working of the said contract have been fully paid and it is certified by SHEFEXIL that the terms and conditions of the said contract have been fully and properly carried out by the said Firm and a No Demand Certificate submitted to this effect by the Firm.

5. The Bank further agrees that the Guarantee herein contained shall remain in full force and effect for a period of 24 months from the date hereof and also that the extension of the Guarantee will be provided for by the Bank for such period beyond the said period of 24 months as SHEFEXIL may feel necessary in this behalf provided further that if any claim accrues against the Bank before the expiry of the said period of 24 months or an extension thereof the same shall be enforceable against the bank notwithstanding the fact the same is enforced after the said period of 24 months or any extension thereof.

6. The Guarantee herein contained shall not be affected by any change in the constitution of the Firm or the Bank and shall be a continuing one.

7. SHEFEXIL has fullest liberty, without affecting the Guarantee to postpone for any time and from time to time, any of the powers exercisable by it against the Firm and either reinforce or forbear any of the terms & condition of the said contract and Bank shall not be released from its liability under this Guarantee by any exercise by SHEFEXIL of the liberty with reference to the matter referred aforesaid or by reasons of time being given to the Firm or any other forbearance, act or the omission on the part of SHEFEXIL or any indulgence by SHEFEXIL to the Firm or any other matter or thing whatsoever which under the law relating to sureties shall but for this provision have the effect of so releasing of from its such liability.

8. The Bank undertake not to revoke this Guarantee during its currency except with the previous consent of SHEFEXIL in writing.

9. NOTWITHSTANDING anything contained herein before, our liability under this guarantee is restricted to ..... (in words) ..... Our guarantee shall remain in force till (period to be mentioned). Unless a demand in writing for a claim under this guarantee is lodged with us on or before (date should be mentioned) all your rights under this guarantee shall be forfeited and shall be released and discharged from all liabilities thereunder.

IN WITNESS WHEREOF the parties have executed these presents the day and year therein above-written.

Signed and Delivered by the Attorney for Signed and Delivered by the Attorney for on behalf of the Bank in the presence and on the behalf of Bank in the presence

of :

of:

1. \_\_\_\_\_

1. \_\_\_\_\_

2. \_\_\_\_\_

2. \_\_\_\_\_

### **SECTION III**

#### **GENERAL CONDITIONS OF CONTRACT**

##### **1 APPLICATION:**

The General Conditions shall apply to the contract between SHEFEXIL and the Selected Bidder for the procurement of services in terms of the Bid Document for appointment of GLP Accredited Laboratory for Conducting Toxicity Study for Shellac.

##### **2 STANDARDS:**

The services provided under the contract shall conform to the requirements prescribed in the Bid Document.

##### **3 PATENT RIGHTS:**

The Selected Bidder shall indemnify SHEFEXIL against all third party claims of infringement of Patent, trademark or industrial design rights arising from use of the services or any part thereof.

##### **4 PERFORMANCE SECURITY:**

4.1 The Selected Bidder shall furnish performance security to SHEFEXIL for an amount of 10% of contract value within 15 days of the Selected Bidder's receipt of the Work Order.

4.2 The performance security shall be payable to SHEFEXIL as security for any loss resulting from the Selected Bidder's failure to complete its obligations under the Contract.

4.3 The performance Security Bond shall be in the form of bank guarantee issued by a Scheduled Bank and in the format provided in Appendix VI of the Bid Document.

4.4 The performance Security Bond will be discharged by SHEFEXIL after completion of the Selected Bidder's performance obligations under the Contract and Bid Document.

##### **5. SERVICE DELIVERY:**

5.1 Delivery of the services and documents shall be made by the Selected Bidder in accordance with the terms specified by SHEFEXIL in the Bid Document.

5.2 The Delivery of the services and documents shall commence immediately on acceptance of Work order and be valid for the period as required for completion of the Scope of Work.

## **6. PAYMENT TERMS:**

Payment for the services will be effected in mutually agreed periodic manner after getting the bills certified by SHEFEXIL.

## **7. PRICES:**

- 7a) Prices charged by the Selected Bidder for Services delivered and services performed under the Contract shall not be higher than the prices quoted by the Selected Bidder in its bid.
  - b) In case of revision of statutory levies / taxes during the finalisation period of the tender, SHEFEXIL reserves the right to ask for reduction in the prices.
  - c) Tax Deducted at Source (TDS) would be deducted from the payment released to the Selected Bidder from time to time as per prevailing rates applicable from time to time.
- ii) Price once fixed will remain valid for the period of delivery of services.

## **8. TIME PERIOD OF WORK:**

The work will be awarded initially for a period of \_\_ years within the Selected Bidder. The duration may be varied by the Chairman of SHEFEXIL from time to time during the period of Contract at its sole discretion.

## **9. FORFEITURE OF PERFORMANCE SECURITY :**

Forfeiture of Performance Deposit: Security amount in full or part may be forfeited in the following cases:

- 1. When the terms and conditions of contract is breached by the Selected Bidder.
- 2. When the Selected Bidder fails to provide services satisfactorily.
- 3. When contract is being terminated due to non-performance of the Selected Bidder.
- 4. Notice of reasonable time will be given in case of forfeiture of Performance Deposit. The decision of SHEFEXIL in this regard shall be final.

## **10. FORCE MAJEURE:**

If at any time, during the continuance of this contract, the performance in whole or in part by the Selected Bidder or any obligation under this contract shall be prevented or delayed by reason of any war, or hostility, acts of the public enemy, civil commotion, sabotage, fires, floods, explosions, epidemics, quarantine restrictions, or Acts of God provided notice of happenings, of any such eventuality is given by the Selected Bidder to SHEFEXIL within 7 days from the date of occurrence thereof, SHEFEXIL shall not by any reason of such event be

entitled to terminate this contract and delivery under the contract shall be resumed as soon as practicable after such event may come to an end or cease to exist, and the decision of SHEFEXIL as to whether the delivery has been so resumed or not shall be final and conclusive, provided further that if the performance, in whole or part of any obligation under this contract is prevented or delayed by reason of any such event for a period exceeding 60 days SHEFEXIL may, at its option, terminate the contract.

## **11. TERMINATION FOR DEFAULT**

11.1 SHEFEXIL may, without prejudice to any other remedy for breach of contract, by written notice of default, sent to the Selected Bidder terminate this contract in whole or in part after giving \_\_ days notice in writing.

- (a) If the Firm fails to deliver any or all of the services within the time period(s) specified in the Contract or any extension thereof granted by SHEFEXIL.
- (b) If the Firm fails to perform any other obligation(s) under Contract or commits a breach of the provisions hereof and does not rectify the same within 15 days of notice given by SHEFEXIL; and

11.2 In event SHEFEXIL terminates the contract in whole or in part, pursuant to Para 11.1 SHEFEXIL may procure, upon such terms and in such manner, as it deems appropriate, services similar to those undelivered and the Firm shall be liable to SHEFEXIL for any excess cost for such similar services. However, the Firm shall continue performance of the contract to the extent not terminated.

## **12. TERMINATION FOR INSOLVENCY**

SHEFEXIL may at any time terminate the contract by giving written notice to the Firm, without compensation to Firm, if the Firm becomes bankrupt or otherwise insolvent as declared by the competent court provided that such termination will not prejudice or affect any right or action or remedy which has accrued thereafter to SHEFEXIL.

## **13. ARBITRATION**

13.1 All disputes and differences between SHEFEXIL and the Selected Bidder regarding the work to be undertaken by the Successful Bidder and the construction and interpretation of any of the terms and conditions herein contained or in any way concerning these presents, shall be resolved amicably between SHEFEXIL and the Selected Bidder within 30 (thirty) days from the date of the dispute.

- 13.2 Failing amicable settlement, the disputes or differences shall be referred to arbitration in terms of the Arbitration and Conciliation Act, 1996 and any statutory modifications or reenactments thereof. The arbitral panel shall consist of three arbitrators, one arbitrator each to be appointed by SHEFEXIL and the Selected Bidder respectively and the Third Arbitrator to be appointed by the two arbitrators so appointed.
- 13.3 The place of arbitration shall be Kolkata and the arbitration proceedings shall be conducted in English.

#### **14 JURISDICTION**

The Courts in Kolkata alone shall have the jurisdiction to try all disputes arising out of this agreement.

## SECTION IV

### SPECIAL CONDITIONS OF CONTRACT

The special conditions of the contract shall supplement the “**Instructions to the Bidders**” as contained in Section II and “**General Conditions of the Contract**” as contained in Section III and wherever there is a conflict, the provisions herein shall prevail over those in Section II and Section III.

1. Date fixed for opening of Bids is, if subsequently, declared as holiday by SHEFEXIL, the revised schedule will be notified. However, in absence of such notification, the bids will be opened on the next working day, time and venue remaining unaltered.
2. In case where the document of Bid security is not submitted in the manner prescribed the bid SHALL NOT BE OPENED AND THE BID SHALL BE REJECTED AND RETURNED TO THE BIDDER UN OPENED.
3. SHEFEXIL reserves the right to disqualify such Bidders who have a record of not meeting contractual obligations against earlier contracts entered into with SHEFEXIL.
4. SHEFEXIL reserves the right to blacklist the Bidder for a suitable period in case he fails to honour his Bid with sufficient grounds.
5. SHEFEXIL reserves the rights to counter offer price(s) against price(s) quoted by any Bidder.
6. Any clarification issued by SHEFEXIL in response to query raised by prospective Bidders shall form an integral part of Bid documents and it may amount to amendment of relevant clauses of the Bid documents.
7. The Selected Bidder shall provide services as mentioned in Schedule of requirement in the Tender document.

#### 8. EXPERIENCE:

The Selected Bidder shall be an Indian Analytical Institution /Laboratories etc. meeting the following eligibility criterion:

- (i) The Bidder should be the owner of a Laboratory for carrying out the entire Scope of Study specified in Section V of the Bid Document having Good Laboratory Practice (GLP) certification for undertaking the entire Scope of Study contained in Section V of the Bid Document. The Bidder shall under no circumstances outsource the work assigned to it.
- (ii) A minimum annual turnover of Rs.500 lakhs during the last three years.
- (iii) A minimum of 10 years experience in undertaking chemical analysis and in conducting toxicity studies on food products especially natural products used as food additives including Shellac. Preference shall be given to those who have experience in dealing with quality requirements for export shipments of natural products.
- (iv) Availability of requisite subject matter manpower. The Bidder should have at least 2 experienced toxicologists/board certified pathologists having \_\_\_ years experience in their in house team.

- (v) The Bidder should have access and availability of certified and quality animals.
- (vi) Any Bidder involved in the Shellac and Lac based industry directly or indirectly through group company/joint venture company/sister company or any combination thereof shall not be eligible.
- (vii) Previous experience in dealing with European Union (EU)/European Food Safety Authority (EFSA).

## **SECTION- V**

### **SCOPE AND DESCRIPTION OF WORK**

#### **1. Aims and Objectives of the Survey**

- 1.1 To regain the EU market. The survey shall be aimed at evaluation of Shellac (E904) to be used/permitted as food additives in the EU inter-alia to reinstate and grow the contribution of Shellac Exports to EU.
- 1.2 To make a study of Toxicity of Food grade Shellac ( E 904 ) to establish the suitability of Shellac as a safe food additive for the entire EU.
- 1.3 To do a baseline study of Toxicity of Food grade Shellac ( E 904 ) in order to compare the status in future

#### **2. Scope of the Study**

The assignment offered would cover the following on Shellac ( E 904 ) meant for exports into EU as per the call made by European Food Safety Authority (EFSA) on 01.08.2012.

- a sub-chronic 90-day repeated toxicity in rats in accordance with the OECD Test Guideline 408<sup>3</sup>, limited to do se-range finding.
- for the end point genotoxicity an *invitro* micro nucleus test.
- a combined chronic toxicity/carcinogenicity study in rats following the OECD Test Guideline 453 as specified in the previous public call for data.
- a two-generation reproductive toxicity study in rats in accordance with OECD Test Guideline 416, is considered acceptable provided that it is accompanied by the prenatal developmental toxicity study (OECD Test Guideline 414), as specified in the previous public call for data.

The content of shellac (E 904) in the test preparation should be clearly specified. It should also be indicated whether the material tested is in accordance with the specifications for shellac (E 904) as defined in Directive 2008/84/EC. The tests should be carried out according to the principles of Good Laboratory Practice (GLP) described in Directives 2004/9/EC and 2004/10/EC and accompanied by a statement of GLP compliance.

3. The successful bidder would conduct the Study in-house and will not be permitted to outsource the Study under any circumstances.
  1. The successful bidder has to share the Reports with SHEFEXIL and also allow third party inspection and/or supervision of its work by an entity appointed by SHEFEXIL having technical and professional experience in the relevant field such as IITR, Lucknow etc. and the successful bidder shall follow all instructions, terms and specifications indicated by such entity appointed by SHEFEXIL in conducting its studies from time to time.

## **EUROPEAN FOOD SAFETY AUTHORITY**

### **Call for scientific data on shellac (E 904)**

Published: 1 August 2012

Deadline: 1 December 2012

#### **Background**

In February 2012 the European Food Safety Authority (EFSA) launched a second public call for scientific data on the food additive shellac (E 904)<sup>1</sup>. The call for data was launched due to the limit outcome of a previous public call for data launched in November 2009 on miscellaneous waxes permitted as food additives in the EU<sup>2</sup>.

The second public call for data ended in June 2012 and limited toxicological data on shellac (E 904) were provided which would not enable EFSA to conclude on the safety of its use as a food additive. However, interested parties have provided information to EFSA that they are willing to commission new studies to generate the missing data needed for the risk assessment.

In order to ensure an effective re-evaluation of shellac (E 904), it is important that EFSA acquires from interested parties commitment to commission the studies listed below which are deemed needed for the re-evaluation of shellac (E 904).

#### **Overall objective**

The purpose of this call for data is to offer all interested parties and stakeholders the opportunity to provide commitment to commission new studies as outlined in more detail below.

Interested parties and stakeholders should provide by 1 December 2012 information that they have commissioned the relevant studies with supporting evidence as well as the detailed protocols and timelines of the studies. Based on the commissioned studies EFSA will set a final deadline for the submission of these data which will be communicated to the parties commissioning the studies and published on EFSA's website.

In case no commitment to generate the sought data through new studies would have been provided to EFSA by 1 December 2012, EFSA will base its re-evaluation of shellac (E 904) on the information available at that date.

## Information sought

EFSA kindly asks governments, interested organisations, universities, research institutions, companies and other interested parties to submit the data as mentioned below on shellac (E 904) and with reference to the 2001 guidance of the Scientific Committee on Food on submissions for food additive evaluations<sup>4</sup>.

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<sup>1</sup>EFSA call for scientific data on shellac {E 904},

<http://www.efsa.europa.eu/en/dataclosed/call/120215b.htm>

<sup>2</sup> Call for scientific data on miscellaneous waxes permitted as food additives In the EU.

<http://www.efsa.europa.eu/en/dataclosed/call/ans091123b.pdf>

In the absence of evidence from the ADME studies (unfeasible, due to the fact that shellac is a complex mixture of chemicals and that no specific marker compound has been identified that could be used to this end) the ANS Panel have concluded that it cannot be assumed that absorption of shellac (E 904) is negligible and therefore the following studies should be commissioned:

- a sub-chronic 90-day repeated toxicity in rats in accordance with the OECD Test Guideline 408<sup>3</sup>, limited to dose-range finding.
- for the endpoint genotoxicity an *in vitro* micronucleus test.
- a combined chronic toxicity/carcinogenicity study in rats following the OECD Test Guideline 453<sup>4</sup> as specified in the previous public call for data.
- a two-generation reproductive toxicity study in rats in accordance with OECD Test Guideline 416<sup>5</sup>, is considered acceptable provided that it is accompanied by the prenatal developmental toxicity study (OECD Test Guideline 414<sup>6</sup>), as specified in the previous public call for data.

The content of shellac (E 904) in the test preparation should be clearly specified. It should also be indicated whether the material tested is in accordance with the specifications for shellac (E 904) as defined in Directive 2008/84/EC<sup>7</sup>. The tests should be carried out according to the principles of Good Laboratory Practice (GLP) described in Directives 2004/9/EC<sup>8</sup> and 2004/10/EC<sup>9</sup> and accompanied by a statement of GLP compliance.

## Process of the call for data

The information that case studies have been commissioned and new data will be generated needs to be submitted to EFSA electronically by **1 December 2012** at the latest.

Based on the timeframe of the commissioned studies the new deadline for submission of these data will be communicated by EFSA to the parties commissioning the studies and generating the data and published on EFSA's website.

The interested parties are invited to contact EFSA for further clarification if required.

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<sup>3</sup>OECD Guidance 408. Repeated dose 90-day oral toxicity study in rodents. <http://www.oecd-doserver1/download/fulltext/9740801e.pdf?expires=1326711176&id=id&accname=freeContent&checksum=OABAF94C984DOEOCSC6BAFCB39BZD1B4>

<sup>4</sup>OECD Guideline 453. Combined chronic toxicity/carcinogenicity studies. <http://www.oecd.org/dataoecd/55/19/41362977.pdf>

<sup>5</sup>OECD Guideline **416**. Two-generation reproduction toxicity. <http://www.oecd-library.org/environment/test-no-416-two-Generation-reproduction-toxicity9789264070868-en>

<sup>6</sup>OECD Guideline 414. Prenatal developmental toxicity study. <http://www.oecd-library.org/environment/test-no-414-prenatal-development-toxicity-study9789264070820-en>

<sup>7</sup>Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners. OJL253, 20.9.2008, p.1.

<sup>8</sup> Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) OJL 50, 20.2.2004, p. 28-43.

<sup>9</sup>Directive 2004/10/EC of The European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances OJL 50, 20.2.2004, p. 28-43.

## **Confidentiality and unpublished data**

Specific issues relating to confidentiality of the data provided should be discussed between the owners and EFSA on the basis of the justifications provided by the data owners. In application of Article 8.4 of Regulation 257/2010, following a proposal from EFSA, the Commission will decide after consulting the interested business operator and/or the other interested parties which information may remain confidential and shall notify EFSA and the Member States accordingly.

## **Correspondence**

Please send all electronic correspondence, including enquiries to:  
[foodadditives@efsa.europa.eu](mailto:foodadditives@efsa.europa.eu)

Hard copies can also be sent to the address below:

FIP Unit, Food Additives  
European Food Safety Authority  
Via Carlo Magno 1/a  
43126 Parma  
Italy