

I-Ispra: Phase III — Prevalidation of the 3 methods subdivided into 3 lots: lot 1 - Direct Peptide Reactivity Assay (DPRA); lot 2 - Myeloid U937 Skin Sensitisation Test (MUSST); lot 3 - human Cell Line Activation Test (hCLAT)

2009/S 166-239612

CONTRACT NOTICE

Services

SECTION I: CONTRACTING AUTHORITY

I.1) NAME, ADDRESSES AND CONTACT POINT(S):

European Commission, Joint Research Centre — Institute for Health and Consumer Protection, MSU TP 582, via E. Fermi 2749, Attn: Ms Giuliana Talamona, I-21027 Ispra VA. E-mail: JRC-IHCP-PROCUREMENT@ec.europa.eu. Fax +39 0332789434.

Internet address(es):

General address of the contracting authority: <http://web.jrc.ec.europa.eu/callsfortender/>.

Further information can be obtained at: As in above-mentioned contact point(s).

Specifications and additional documents (including documents for competitive dialogue and a dynamic purchasing system) can be obtained at: As in above-mentioned contact point(s).

Tenders or requests to participate must be sent to: As in above-mentioned contact point(s).

I.2) TYPE OF THE CONTRACTING AUTHORITY AND MAIN ACTIVITY OR ACTIVITIES:

European institution/agency or international organisation.

Other: Research.

The contracting authority is purchasing on behalf of other contracting authorities: no.

SECTION II: OBJECT OF THE CONTRACT

II.1) DESCRIPTION

II.1.1) Title attributed to the contract by the contracting authority:

Phase III — Prevalidation of the 3 methods subdivided into 3 lots: lot 1 - Direct Peptide Reactivity Assay (DPRA); lot 2 - Myeloid U937 Skin Sensitisation Test (MUSST); lot 3 - human Cell Line Activation Test (hCLAT).

II.1.2) Type of contract and location of works, place of delivery or of performance:

Services.

Service category: No 08.

Main place of performance: Contractor's premises.

II.1.3) The notice involves:

A public contract.

II.1.4) Information on framework agreement:

II.1.5) Short description of the contract or purchase(s):

The aim of this call is to select the laboratories that will participate in the initial phase (prevalidation) of a project whose aim is to deliver validated alternative methods/strategies for skin sensitisation testing to be used by chemical and cosmetic industries for the safety assessment of products. The selected laboratories will work in close contact with multinational companies as well as the European Commission Joint Research Centre for the initial assessment of 3 of those tests involving flow cytometry and HPLC methods. The laboratories participating in the study will have to test coded chemicals by adhering to a defined protocol/procedure.

II.1.6) **Common procurement vocabulary (CPV):**
73110000, 73111000.

II.1.7) **Contract covered by the Government Procurement Agreement (GPA):**
No.

II.1.8) **Division into lots:**
Yes.
Tenders should be submitted for: one or more lots.

II.1.9) **Variants will be accepted:**
No.

II.2) **QUANTITY OR SCOPE OF THE CONTRACT**

II.2.1) **Total quantity or scope:**
The aim of this call is to select the laboratories that will participate in the initial phase (prevalidation) of a project whose aim is to deliver validated alternative methods/strategies for skin sensitisation testing to be used by chemical and cosmetic industries for the safety assessment of products. The selected laboratories will work in close contact with multinational companies as well as the European Commission Joint Research Centre for the initial assessment of 3 of those tests involving flow cytometry and HPLC methods. The laboratories participating in the study will have to test coded chemicals by adhering to a defined protocol/procedure.
The object of the present call, divided into 3 lots, is the prevalidation of the following 3 methods:
lot 1: direct peptide reactivity assay (DPRA);
lot 2: myeloid U937 skin sensitisation test (MUSST);
lot 3: human cell line activation test (hCLAT).
Estimated value excluding VAT: 136 000 EUR.

II.2.2) **Options:**
No.

II.3) **DURATION OF THE CONTRACT OR TIME-LIMIT FOR COMPLETION:**
Duration in months: 13 (from the award of the contract).

INFORMATION ABOUT LOTS

LOT NO 1

TITLE: Phase III — prevalidation of the direct peptide reactivity assay (DPRA)

- 1) **SHORT DESCRIPTION:**
The objective of this contract is to assess the reproducibility and preliminary predictive capacity of the direct peptide reactivity assay (DPRA) partial replacement test method for the identification of potential skin-sensitising chemicals. The contractor will participate in this study together with other laboratories.
- 2) **COMMON PROCUREMENT VOCABULARY (CPV):**
73110000, 73111000.
- 3) **QUANTITY OR SCOPE:**
The objective of this contract is to assess the reproducibility and preliminary predictive capacity of the direct peptide reactivity assay (DPRA) partial replacement test method for the identification of potential skin-sensitising chemicals. The contractor will participate in this study together with other laboratories.
Estimated cost excluding VAT: 16 000 EUR.
- 4) **INDICATION ABOUT DIFFERENT DATE FOR DURATION OF CONTRACT OR STARTING/COMPLETION:**
Duration in months: 13 (from the award of the contract).

5) **ADDITIONAL INFORMATION ABOUT LOTS:**

LOT NO 2

TITLE: Phase III — prevalidation of the myeloid U937 skin sensitisation test (MUSST)

1) **SHORT DESCRIPTION:**

The objective of this contract is to assess the reproducibility and preliminary predictive capacity of the myeloid U937 skin sensitisation test (MUSST) partial replacement test method for the identification of potential skin-sensitising chemicals. The contractor will participate in this study together with other laboratories.

2) **COMMON PROCUREMENT VOCABULARY (CPV):**

73110000, 73111000.

3) **QUANTITY OR SCOPE:**

The objective of this contract is to assess the reproducibility and preliminary predictive capacity of the myeloid U937 skin sensitisation test (MUSST) partial replacement test method for the identification of potential skin-sensitising chemicals. The contractor will participate in this study together with other laboratories.

Estimated cost excluding VAT: 60 000 EUR.

4) **INDICATION ABOUT DIFFERENT DATE FOR DURATION OF CONTRACT OR STARTING/COMPLETION:**

Duration in months: 13 (from the award of the contract).

5) **ADDITIONAL INFORMATION ABOUT LOTS:**

LOT NO 3

TITLE: Phase III — prevalidation of the human cell line activation test (hCLAT)

1) **SHORT DESCRIPTION:**

The objective of this contract is to assess the reproducibility and preliminary predictive capacity of the human cell line activation test (hCLAT) partial replacement test method for the identification of potential skin-sensitising chemicals. The contractor will participate in this study together with other laboratories.

2) **COMMON PROCUREMENT VOCABULARY (CPV):**

73110000, 73111000.

3) **QUANTITY OR SCOPE:**

The objective of this contract is to assess the reproducibility and preliminary predictive capacity of the human cell line activation test (hCLAT) partial replacement test method for the identification of potential skin-sensitising chemicals. The contractor will participate in this study together with other laboratories.

Estimated cost excluding VAT: 60 000 EUR.

4) **INDICATION ABOUT DIFFERENT DATE FOR DURATION OF CONTRACT OR STARTING/COMPLETION:**

Duration in months: 13 (from the award of the contract).

5) **ADDITIONAL INFORMATION ABOUT LOTS:**

SECTION III: LEGAL, ECONOMIC, FINANCIAL AND TECHNICAL INFORMATION

III.1) **CONDITIONS RELATING TO THE CONTRACT**

III.1.1) **Deposits and guarantees required:**

As specified in tender documents.

III.1.2) **Main financing conditions and payment arrangements and/or reference to the relevant provisions regulating them:**

As specified in tender documents.

III.1.3) **Legal form to be taken by the group of economic operators to whom the contract is to be awarded:**

Tenders may be submitted by groups of economic operators that, if awarded the contract, may be requested to assume a legal form by incorporation, partnership or otherwise which will enable them to contract as a single entity. A group of economic operators, however, must identify the main contractor, the sole responsible towards the Commission, which will interface between the Commission and the economic operators. Each member of the group must fulfil the condition for participation mentioned in point III.2 of this publication.

III.1.4) **Other particular conditions to which the performance of the contract is subject:**

No.

III.2) **CONDITIONS FOR PARTICIPATION**

III.2.1) **Personal situation of economic operators, including requirements relating to enrolment on professional or trade registers:**

Information and formalities necessary for evaluating if requirements are met: Tenderers will not be eligible to take part in this contract award procedure if they are in any of the exclusion situations listed in Articles 93 and 94 of Council Regulation (EC, Euratom) No 1605/2002 of 25.6.2002 (OJ L 248 of 16.9.2002) as amended by Commission Regulation (EC, Euratom) No 1995/2006 of 13.12.2006 (OJ L 390 of 30.12.2006).

The tenderer to whom the contract is to be awarded must also furnish the documents stipulated in Article 134(1)(3) of Commission Regulation (EC, Euratom) No 2342/2002 of 23.12.2002 (OJ L 357 of 31.12.2002), as amended by Commission Regulation (EC, Euratom) No 1261/2005 of 20.7.2005 (OJ L 201 of 2.8.2005), by Commission Regulation (EC, Euratom) No 1248/2006 of 7.8.2006 (OJ L 227 of 19.8.2006) and by Commission Regulation (EC, Euratom) No 478/2007 of 23.4.2007 (OJ L 111 of 28.4.2007).

Any tenderer or candidate shall prove that he is authorised to perform the contract under national law, as evidenced by inclusion in a trade or professional register, or a sworn declaration or certificate, membership of a specific organisation, express authorisation, or entry in the VAT register.

III.2.2) **Economic and financial capacity:**

Information and formalities necessary for evaluating if requirements are met: (a) the balance sheets or extracts from balance sheets for the last 2 years for which accounts have been closed, where publication of the balance sheet is required under the company law of the country in which the economic operator is established; (b) a statement of overall turnover and turnover concerning the services covered by the contract during the last 3 financial years.

III.2.3) **Technical capacity:**

Information and formalities necessary for evaluating if requirements are met:

a) a list of principal similar services delivered in the past 3 years, with the sums, dates, recipients public or private;

b) a statement concerning the quality assurance system in place (e.g. GLP certification or equivalent) or compliance to the requirements of GLP in terms of documentation, traceability and accountability (in the spirit of GLP);

c) a description of the technical equipment to be employed by the tenderers for performing the study, including evidence that they own and have access on their site to the main equipment involved in the study (HPLC for lot 1, cell culture facilities and flow cytometry for lots 2 and 3);

d) proof of the educational and professional qualifications (i.e. CVs) of the technicians/personnel appointed to conduct and monitor the study, with emphasis on their experience on the techniques involved in the studies (at least 2 years' experience);

e) a statement concerning the capacity of the tenderer to safely receive, store and manipulate coded chemicals.

III.2.4) **Reserved contracts:**

No.

III.3) CONDITIONS SPECIFIC TO SERVICES CONTRACTS

III.3.1) Execution of the service is reserved to a particular profession:

No.

III.3.2) Legal entities should indicate the names and professional qualifications of the staff responsible for the execution of the service:

Yes.

SECTION IV: PROCEDURE

IV.1) TYPE OF PROCEDURE

IV.1.1) Type of procedure:

Open.

IV.1.2) Limitations on the number of operators who will be invited to tender or to participate:

IV.1.3) Reduction of the number of operators during the negotiation or dialogue:

IV.2) AWARD CRITERIA

IV.2.1) Award criteria:

The most economically advantageous tender in terms of the criteria stated in the specifications, in the invitation to tender or to negotiate or in the descriptive document.

IV.2.2) An electronic auction will be used:

No.

IV.3) ADMINISTRATIVE INFORMATION

IV.3.1) File reference number attributed by the contracting authority:

IHCP/2009/II/03/53/OC.

IV.3.2) Previous publication(s) concerning the same contract:

No.

IV.3.3) Conditions for obtaining specifications and additional documents or descriptive document:

Time limit for receipt of requests for documents or for accessing documents: 13.10.2009.

Payable documents: no.

IV.3.4) Time-limit for receipt of tenders or requests to participate:

13.10.2009.

IV.3.5) Date of dispatch of invitations to tender or to participate to selected candidates:

IV.3.6) Language(s) in which tenders or requests to participate may be drawn up:

Spanish. Danish. German. Greek. English. French. Italian. Dutch. Portuguese. Finnish. Swedish. Czech.

Estonian. Hungarian. Lithuanian. Latvian. Maltese. Polish. Slovak. Slovenian. Irish. Bulgarian. Romanian.

IV.3.7) Minimum time frame during which the tenderer must maintain the tender:

Duration in month(s): 6 (from the date stated for receipt of tender).

IV.3.8) Conditions for opening tenders:

Date: 20.10.2009 - 14:30.

Place: JRC-ISPRA, via E. Fermi 2749, 21027 Ispra VA, ITALY — ext. building, room 7.

Persons authorised to be present at the opening of tenders: yes.

Please, provide to JRC-IHCP-PROCUREMENT@ec.europa.eu the name of people attending the opening session, within and not later than 13.10.2009.

SECTION VI: COMPLEMENTARY INFORMATION

VI.1) THIS IS A RECURRENT PROCUREMENT:

No.

VI.2) **CONTRACT RELATED TO A PROJECT AND/OR PROGRAMME FINANCED BY EU FUNDS:**

No.

VI.3) **ADDITIONAL INFORMATION:**

The tender documentation has to be downloaded from the following website: <http://web.jrc.ec.europa.eu/callsfortender>

Please be informed that a 'Answers-question.doc' will be regularly updated during the procedure. It is the responsibility of the candidates to check regularly updates and modifications during the tendering period.

VI.4) **PROCEDURES FOR APPEAL**

VI.4.1) **Body responsible for appeal procedures:**

Court of First Instance of the European Communities, rue du Fort Niedergrünwald, L-2625 Luxembourg. E-mail: CFI.Registry@curia.europa.eu. Tel. +352 4303-1. URL: <http://curia.europa.eu>. Fax +352 4303-2100.

VI.4.2) **Lodging of appeals:**

Precise information on deadline(s) for lodging appeals: Within 2 months of the notification to plaintiff, or in absence thereof, of the day on which it came to knowledge.

VI.4.3) **Service from which information about the lodging of appeals may be obtained:**

Court of First Instance of the European Communities, rue du Fort Niedergrünwald, L-2625 Luxembourg. E-mail: CFI.Registry@curia.europa.eu. Tel. +352 4303-1. URL: <http://curia.europa.eu>. Fax +352 4303-2100.

VI.5) **DATE OF DISPATCH OF THIS NOTICE:**

19.8.2009.