

Joint Action 2015

Call for Tender for Test Laboratories

Product Activity - Soothers and Soother Holders

1. Background

PROSAFE is an international non-governmental organisation established in 1991 by market surveillance officers from various countries throughout Europe. Its main aim is to contribute to the safety of products and services by promoting best practices in market surveillance. Since 2006, PROSAFE has established itself as the organising and coordinating body for Joint Market Surveillance Actions in Europe. PROSAFE's official name is "Stichting PROSAFE". It is a foundation under Dutch law.

PROSAFE's main task is to coordinate Joint Actions. Each Joint Action comprises a number of activities that target specific product groups, and a number of related activities aimed at developing methods and best practices.

PROSAFE is coordinating the Joint Market Surveillance Action 2015. The Action started in May 2016 and will end in June 2018. One of the product-specific activities in the Joint Action is addressing Soothers and Soother Holders.

The Joint Action identifies a number of roles and responsibilities:

- A Project Leader for the Joint Action has been appointed. He is responsible for the performance, reporting and coordination of the Activity Leaders;
- A Member State representative, Sarah Jacques, has been selected as Activity Leader responsible for carrying out the Activity Soothers and Soother Holders;
- An external consultant, Rebecca Morrison, has been appointed as Activity Coordinator responsible for the daily coordination of the Activity for Soothers and Soother Holders;
- PROSAFE's Executive Director is responsible for the general and financial management of the Joint Action;
- The financial and project administration is handled by the PROSAFE Office.

2. The scope of the tender

An important part of the Joint Action is the testing of a number of Soothers and Soother Holders. Within this Joint Action, Soothers are defined as a product that satisfies the non-nutritive sucking needs also to pacify children - they are designed to be in the mouths of babies and children for long periods. Soother Holders encompasses all products that are intended to connect a soother for babies and young children with any other product.

The agreement foresees the testing of a number of Soothers & Soother Holders according to the test methods contained within EN1400:2013 + A1:2014, EN12586:2007 + A1:2011 and EN12686:200 (or a later version of this standard should it be published prior to testing), plus some additional tests as specified - detailed requirements can be found within Appendix 1.

The purpose of the testing is to check Soothers and Soother Holders against the standards above, plus some additional tests designed for Soother Holders.

The task comprises the following services:

- Testing around 250 samples - approximately 100 Soothers and 150 Soother Holders. The precise number of samples may deviate from this budget value. It will be determined by the Activity Leader and the Activity Coordinator during the course of the Action. Testing of further samples might be requested by individual Member States outside the financial scheme of the Action.
- To deliver at least one test report for each sample supplied, that will aid Market Surveillance Authorities in risk assessing the respective sample.

- The Activity will ask the laboratory to participate in one or more project meetings, in order to explain test methods and test results to the Member States.
- The Activity will ask the laboratory to host a 2 day project meeting for the representatives from the sampling Member States, once testing is completed.

The samples will be provided by Market Surveillance Authorities in the following 13 Member States: Belgium, Bulgaria, Cyprus, Denmark, Germany (x2), Greece, Iceland, Lithuania, Latvia, Malta, the Netherlands and Romania.

The Member States will provide the required number of items of each sample (per standard to be investigated) for the examination and testing.

All items will be sent to the laboratory directly from the Member States. They will be accompanied by a list that identifies the items/samples, the Joint Action, the submitting Member State and specific requirements for the testing, if any.

The testing is provisionally planned to start 01 April 2017 and end 30 June 2017. This timeline may change.

It is emphasised that PROSAFE may decide to assign the testing to more than one laboratory.

3. Requirements, tenderer

The main requirements for undertaking the assignment are:

- Ability to carry out the tests required, with an accreditation according to ISO17025, EN1400:2013 + A1:2104, EN 12868:2000 and EN 12586:2007 + A1:2011 or similar for the required standards and tests.
- Full independence from manufacturers, importers or other economic operators in the market for Soothers and Soother Holders.
- Excellent active and passive knowledge of the English language. Preferably good knowledge of other official European languages.

The following management requirements apply:

- It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the respective requirements of the tender specifications.
- The laboratory shall have managerial and technical personnel who have the authority and resources needed to carry out their duties.
- The laboratory shall provide adequate supervision of testing and calibration staff by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results.
- The laboratory shall establish and maintain procedures for the review of requests. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that the laboratory has the capability and resources to meet the requirements.
- Any differences between the request and the contract shall be resolved before any work commences.
- The Activity Coordinator shall be informed immediately of any deviation from the contract.
- The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records.
- The laboratory shall have procedures to protect and backup records stored electronically and to prevent unauthorized access to or amendment of these records.

The following requirements regarding the technical skills apply:

- The laboratory management shall ensure the competence of all who operate specific equipment, perform test and/or calibrations, evaluate results, and sign test reports and certificates. When using staff undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified based on appropriate education, training, experience and/or demonstrated skills, as required.
- Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.
- All equipment used for tests and/or calibrations, including equipment for subsidiary measurements having a significant effect on the accuracy or validity of the result of the test, calibration or sampling, shall be calibrated before being put into service.
- The laboratory shall have due experience in the field of testing.

- The laboratory shall have experience in performing tests related to Soothers & Soother Holders according to the standards mentioned and in interpreting test results and classification issues.

The following requirements apply to subcontracting:

- PROSAFE does not accept that the selected laboratory further subcontracts the testing services.
- If the need to subcontract becomes apparent only after the work has been commissioned, the laboratory must ask for PROSAFE's Executive Director's permission before such a decision is adopted.

4. Requirements, quotation

The tenderer is requested to quote prices for the following services in line with the detailed specifications shown in Appendix 1:

- 1) Testing compliance of the product with the safety requirements in the above standards and PROSAFE protocol for the testing of Soother Holders (see Appendix 1 for full details). The quote must be per test, per sample.
- 2) Producing test reports (in English) with the findings from 1) above. The test reports must indicate the measured value for each property, not only "failed/passed". The quote must be per sample. See Appendix 1 for more details.
- 3) Producing an overview table with the findings from 1) above for all received samples that also indicates the degree of risk associated with any failures.
- 4) Please note, if any sample supplied shows "suspicious" aspects (defective design or manufacture) we may decide to test these aspects, in addition to the tests agreed.

The tenderer must quote all prices including VAT. PROSAFE is not able to recover VAT and does not accept the reverse charge method.

The tenderer must explain where the testing will take place (which country). For practical reasons, PROSAFE will only in exceptional cases engage with laboratories where the testing is going to take place outside the EU/EEA countries.

The tenderer must describe his qualifications and experience in line with the above-mentioned requirements. i.e. experience of testing Soothers & Soother Holders.

5. Deadline

Quotations shall be sent to the offices of PROSAFE Secretariat in hardcopy (Avenue des Arts/Kunstlaan 41, 2nd floor, B-1040 Brussels, Belgium) and via email to info@prosafa.org.

The email shall be copied to the Activity Coordinator, Rebecca Morrison (r.morrison@prosafa.org) and Activity Leader, Sarah Jacques (Sarah.Jacques@economie.fgov.be).

Quotations shall be received at PROSAFE no later than 12noon on Friday 23 December 2016 (Time Zone: GMT +1 hour). Quotations received after the deadline will be rejected.

6. Selection process

The selection will be based on the following criteria:

- The tenderer's ability to carry out the specific tests.
- The tenderer's experience with testing of Soothers and Soother Holders.
- The tenderer's formal qualifications (e.g. accreditation(s)).
- Price including VAT in Euros.
- Delivery time.
- Terms of delivery.
- The tenderer's ability to supply additional services to the Joint Action.
- The tenderer's ability to serve individual Member States with testing of Soothers and Soother Holders outside the Joint Action.
- PROSAFE's general impression of the tenderer's ability to undertake the job.

The selection will follow a 2-stage process. First, one or more laboratories will be shortlisted based on the received tenders. Second, a meeting may be arranged between representatives from the Joint Action and representatives from the shortlisted laboratory(-ies) in their premises to allow a more thorough discussion of the assignment.

The tenderer is invited to provide additional information to ease PROSAFE's evaluation of the services being offered, the prices and other aspects related to the selection criteria as mentioned above.

7. Further information

The contract will be signed under Dutch legislation.

Further information regarding the task and the selection procedure can be obtained from the Activity Coordinator at the address:

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With best regards,



Nicolaas Olie
Executive Director