



**EUROPEAN COMMISSION**  
CONSUMERS, HEALTH AND FOOD EXECUTIVE AGENCY

Director

Luxembourg,  
Chafea Ares (2014)

**Biomedical Research Foundation,  
Academy of Athens**

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15344 Athens,  
GREECE**

**REGISTERED MAIL and e-mail:**

**Subject: Request for Specific Services No EAHC/2013/Health/12 for the implementation of Framework Contracts No EAHC/2013/Health/23 concerning the development of an EU common reporting format for submission of data on ingredients contained in tobacco and related products and disclosure of the collected data to the public**

**Ref.: Your offer Ares no. 177576, 177606, and 177655 of 24/01/2014**

Dear Sir/Madam,

We are pleased to inform you that your tender has been selected for the award of the above framework contract.

Your offer has obtained 77 points under the award criteria (technical quality points) and the financial offer was assessed as compliant with the criteria indicated in the tender specifications.

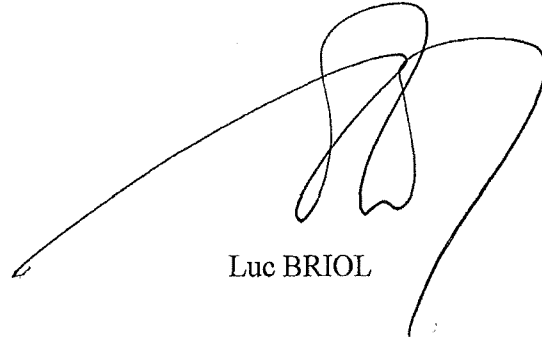
Please refer to the table in Annex for more information about your points received per award criterion and pertinent comments.

This letter informing you of the award of the contract does not constitute a commitment on the part of the Consumers, Health and Food Executive Agency. As the contracting authority, we may, until such time as the contract is signed, either abandon or cancel the procurement procedure without this entitling you to any compensation.

A letter has also been sent today to the unsuccessful tenderer, explaining the grounds for the rejection of his bid and informing him that he may obtain additional information from us, including the characteristics and relative advantages of your bid.

Implementation of the contract may not start before the contract is signed.

Yours faithfully,

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the left.

Luc BRIOL

Annex

**Summary of the assessment of the award criteria:  
EUREST**

	Assessment	Points
<p><b>Criterion 1:</b> Understanding of the services and general approach to the work to be performed. Conformity of the CV(s) of the expert(s) proposed to the skills required, as described in the Request for Specific Services</p>	<p>The offer demonstrates very good understanding of the services to be provided under the specific request for services. The description of the tasks to be implemented is very comprehensive including an exhaustive introduction as well as well-developed methodology to be applied for each of tasks.</p> <p>The CVs are on line with the requirements of the specific request for services. The team count on very senior experts as advisors which may however mean that they contribute to a lesser extent in day to day work.</p>	17/20
<p><b>Criterion 2:</b> Proposed methodology and tools</p>	<p>Both the methodology and the tools are very extensively described and developed in the offer, including: a clear description of the activities to be implemented under each WP; a clear identification of the products to be objects of the study (with an especial emphasis on e-smoking); and justified choices, when requested. Efforts have been also made to provide inputs other than the ones included in the ToR.</p> <p><b>- Work package 1:</b></p> <p>The offer presents a comprehensive range of tools to assess experience with current reporting formats in the EU and elsewhere. The method proposed is very well described, especially as far as the <i>review of the literature, existing formats and international experience</i> is concerned.</p> <p>All the tools are clearly developed, including concrete proposals of possible qualitative questions for the questionnaires, a motivated list of persons/groups to be interviewed and a detailed explanation on the literature review.</p> <p>In this regard, some interesting elements comprise: to look at electronic reporting systems already existing in</p>	<p>Work package 1: 8/10</p> <p>Work package 2: 17/20</p> <p>Work package 3: 8/15</p> <p>Work package 4: 14/15</p> <p><b>Total</b> <b>47/60</b></p>

other areas (i.e. pharmaceutical, toxicological, chemical and risk assessment); other consumer product standards (food and beverages); industry patents and design documents, and patent submissions.

Moreover the EU experience will be confronted with practices in US, Canada, Brazil and Australia, and depending on the results of the "snowball effect" method, best practices from other countries might be included, which is a plus.

However, some concerns are that:

- the questionnaire will be only sent to limited number of Member States,
- the offer refers to EMTOC as a "format" , while this is rather a platform for data submission and access management,
- the SME's should be explicitly included in the sample,
- timelines for questionnaire development, distribution and assessment seem to be overly ambitious,
- Some of the quality indicators cannot be considered as robust indicators.

#### **- Work Package 2**

All the elements requested in the specific request for services are included, categorised in logical domains and for each of the domains, the key aspects of submitted data are discussed in detail. The proposal seems to take into account of the specific request as well as possible dimensions for further extension of the format in line with market, technical and scientific development.

The tobacco products to be considered in the development of the new reporting format are clearly identified and grouped in 5 domains, focusing on different approaches and possible critical aspects. In this context it is valuable the development of the "*Domain 3: Electronic cigarettes*" (in general and also specifically with regard of smaller manufacturers and importers) and the "*Domain 5: Other forms of tobacco products*", which considers possible inclusion of novel products (the example of a forthcoming modified risk tobacco product under development).

The panel of experts covering broad range of relevant

expertise is proposed and its working method is outlined. However, no concrete names are suggested.

Some tasks and concepts described in section "6.5. *linkage with population use data, sales data, preferences and market share developments*", while possibly interesting, go beyond ToR and seem to be overambitious in the context of this study.

While the new EU reporting format is the key deliverable, the offer does not specify technical parameters of this deliverable which are critical for WP3. In order to ensure a logical and efficient articulation between WP2 and 3, it would have been beneficial to present diagram representation e.g. for modelling the main actors, behaviours and their interactions/dependencies, including sequences of exchange messages for the interoperability between systems. Other business rules could have been explained, ideally applying the terminology defined in the data/terms, dictionary/dictionary, describing unambiguously each item, its mandatory status, its format, and the nomenclature used.

**- Work package 3:**

All methodological steps and elements are described. The "semi functional IT solution" seems, in principle, to follow the requirements of the request for services, and the ownership of the final product will belong to the EU in line with the framework contract provisions. However, certain technical parameters are not explicitly acknowledged. In this sense the implementation will require a close step-by-step monitoring ensuring full compatibility of the outcomes with the required specification.

A complete Use Case document should have been included within the deliverables, and the considered fee mechanism should have been better developed, in order to ensure the feasibility and the sustainability of the IT tool. On the basis of the offer it is not possible to assess whether sufficient IT/programming capacities have been foreseen for such complex task.

**- Work package 4:**

Cost-benefit assessment is well described and considers all relevant impact and stakeholders. The methodology is

	adequately outlined including links with previous WP's.	
<b>Criterion 3:</b> Approach proposed for the management of the work	<p>For each WP, a comprehensive scenario is described, including the tasks to be carried out and the detailed methodologies. Team members involved in each WP are identified and a timeline frame, risk assessment and certain contingency measures are included per WP. The intermediate deliverables are listed and several quality indicators and quality control mechanism are also set up per WP.</p> <p>However, some of the contingency measures identified in the risk assessment and contingency measures might not be effective in mitigating the risks (i.e. low interview compliance) especially in view of the overall duration of the study.</p> <p>Whereas the members of the management team are clearly identified, their roles are set up in a rather generic way: their involvement in the project is a key factor in order to ensure the smooth execution of planned activities. In this context the role of the "experts coordinator" is essential to ensure the internal communication and monitoring of the work developed by the scientific team. It is going to be a challenge to coordinate so many experts in such a short period. This is seen as the main risk of the offer: however, this has not been included in the risk analysis.</p> <p>Regarding the Scientific team, the allocation of man-days does not sound consistently made according to the tasks assigned:</p> <ul style="list-style-type: none"> <li>- The offer exhaustively reflects requirements of ToR and in some aspects goes even further. In this regard the execution of the tasks will require a lot of day-to-day work. However, only limited number of man-days are devoted to team members with sound technical background and specific practical experience. On the other hand less than 10 man-days is attributed to multiple subcontractors whose involvement does not seem to be essential for the core tasks (beyond their advisory role).</li> <li>- Man-days are spread among a large number of team members and there is no breakdown of working days per WP. Considering the limited</li> </ul>	13/20

	<p>number of man-days allocated to most team members, it is questionable whether this is sufficient for their involvement in multiple WP's. The issue can be aggravated by geographical and institutional dispersion of the team requiring intensive coordination and frequent teleconferences.</p> <p>Having said that, some concrete examples of the described concerns are:</p> <ul style="list-style-type: none"> <li>- Mr . are not allocated in any WP despite the fact that they are going to work 10 and 25 days respectively. However, on a basis of their expertise descriptions, it seems that they could be involved in WP4.</li> <li>- Mr will be involved on WP 2, 3 and 4, being presumably the key person for WP3. However, the 35 man days are allocated to him might not be adequate to cover all the tasks.</li> <li>- Mr , the "experts coordinator" is allocated only 10 man-days, which does not seem to be enough for such essential and demanding task. <u>The mechanism to ensure the coordination of such a big team should have clearly been assessed in the offer.</u></li> </ul>	
<p><b>Overall assessment:</b></p>		<p><b>77/100</b></p>

