Health Canada

Request for Information

HC1000202407

COTS Solution: Workflow and Data Management System for Tobacco Control Inspections and Reporting

Canada

Health Canada
Healthy Environments and Consumer Safety Branch
269 Laurier Avenue West
Ottawa, Ontario, K1A 0K9

RFI Title: *Workflow and Data Management System for Tobacco Control Inspections and Reporting*

Purpose:

To determine which software providers have Commercial-off-the-Shelf (COTS) solutions that meet, or can be configured to meet, the requirements for one or more of the business activities of the National Tobacco Control Program, and the level of functionality available in these products.

See Detailed Description, Sections A to J, below.

Note to Potential Respondents:

This is not a bid solicitation and a contract will not result.

Potential respondents are advised that any information submitted to the government in response to this Request for Information may be used by the government in the development of a subsequent Request for Proposal (RFP).

The issuance of this Request for Information does not create an obligation for Canada to issue a subsequent RFP.

It should also be noted that no agreement to do business with any respondent will result from this specific enquiry.

Closing Date:

Responses to this Request for Information will be accepted at any time until July 20, 2018 at 12:00 EDT.

Contact:

All enquiries and responses related to this Request for Information shall be directed to the contact identified in Section I of the Detailed Description, below.

Detailed Description

A) Background and Context

The Tobacco Control Directorate (TCD) requires an integrated Information Management-Information Technology (IM-IT) solution which effectively supports national and regional program activities authorized under the *Tobacco and Vaping Products Act* (TVPA), the *Canada Consumer Product Safety Act* (CCPSA – consequential amendment in 2018– specifically, as applied to vaping-related products and liquids and cigarette ignition propensity) and the *Food and Drugs Act* (FDA – consequential amendment in 2018, specifically, as applied to vaping-related products and liquids).

Specifically, three broad classes of business activities are targeted:

1. *Compliance and Enforcement (C&E)*

   C&E activities include:

   - Inspections
     - Inspections are conducted by tobacco control inspectors under the authority of the appropriate federal legislation to verify compliance with the requirements of said legislation. The planning, tracking and documentation of these activities are carried out at both the regional and national level. These activities include both cyclical (pre-planned) and reactionary activities (e.g. in response to complaints and observed non-compliances of regulated parties).
     - When non-compliances are observed, possible enforcement actions, ranging from warning letters to prosecution are considered based on a variety of factors including compliance history, severity of the non-compliance, etc. Any and all non-compliances and enforcement actions must be documented, tracked and referenced against specific legislation sections, along with any necessary management approvals and related activities including a subsequent inspection of the regulated parties.
   - Investigations
     - Investigations are separate and distinct from inspections and are carried out by tobacco control inspectors under the authority of the Criminal Code of Canada. The purpose of an investigation is to determine penal liability of the regulated party with respect to non-compliance with the appropriate federal legislation sections.
     - When non-compliances are found following an investigation, possible enforcement actions include the preparation of a prosecution brief for consideration by the appropriate judicial authorities. All information related to enforcement actions must be documented.
   - Compliance Promotion
     - Inspectors, when interacting with regulated parties, provide targeted and specific information to inform and encourage compliance with the applicable federal legislation. In addition to the documentation of time, date and information shared, any and all feedback and relevant information regarding the regulated parties is collected and documented.

- Compliance promotion information is also shared/distributed via other modes of communication, including mail, public notices, advertising in trade publications, e-mail, websites, etc. These Compliance Promotion Activities must be documented and tracked against specific legislation sections.
- Compliance promotion activities never include any enforcement actions.

- Laboratory Analyses
  - In the context of an inspection or investigation, samples or exhibits may be collected and submitted for laboratory analysis. All information related to the planning, collection, submission and results of laboratory analyses along with the chain of custody must be documented.

2. *Industry Reports Processing*

- Under the authority of the TVPA, regulated parties are required to submit appropriate information in a specified form and manner to Health Canada. These submissions are referred to as "Industry Reports" and include information such as brand names, sales data, product ingredients, etc.
- This information will be required to be submitted electronically in prescribed form and manner on a specified date.
- The process will identify late, absent, and incomplete industry submissions.

3. *Business Intelligence and Data Analytics*,

   Business intelligence and data analytics activities encompass the ability to analyse, summarize, and disseminate data received and/or collected through C&E activities and other relevant research and surveillance activities. Business Intelligence activities inform evidence-based decision-making for policy and regulatory development, resource allocation for C&E activities and information for the general public.

B) Requirements

TCD requires a solution to support the following business requirements:

1) Receive and store industry data submissions as required under the revised Tobacco Reporting Regulations and the future Vaping Products Reporting Regulations;
2) Manage submission processing workflow;
3) Identify late, absent and incomplete reports and other relevant data, based on cyclical reporting requirements;
4) Generate documents related to missing or otherwise deficient reports;
5) Manage the TVPA national and regional compliance and enforcement activities, including:
   a. Planning and documenting inspections and outcomes;
   b. Planning and documenting compliance promotion activities;
   c. Documenting investigations;
   d. Documenting sample acquisition and analyses;
   e. Generating inspection documents including warning letters, tickets, sampling receipts, etc.;
   f. Referring activities between regions;

6) Off-line functionality;
7) Business intelligence gathering and reporting, based on data and meta-data related to industry reports and regional compliance and enforcement activities;
8) The documentation of laboratory analyses of product samples and exhibits;
9) The publication of program data for public dissemination and transparency;
10) Compliance with record keeping and information disposition best practices.

C) Nature of Request for Information

This is not a bid solicitation. This RFI will not result in the award of any Contract. As a result, potential suppliers of any goods or services described in this RFI should not reserve stock or facilities, nor allocate resources, as a result of any information contained in this RFI. Nor will this RFI result in the creation of any source list. Therefore, whether or not any potential supplier responds to this RFI will not preclude that supplier from participating in any future procurement. Also, the procurement of any of the goods and services described in this RFI will not necessarily follow this RFI. This RFI is simply intended to solicit feedback from industry with respect to the matters described in this RFI.

D) Nature and Format of Responses Requested

Respondents are requested to provide their comments, concerns and, where applicable, alternative recommendations regarding how the requirements or objectives described in this RFI could be satisfied. Respondents should explain any assumptions they make in their responses. Respondents may use the template attached for their responses in Annex A.

E) Response Costs

Canada will not reimburse any respondent for expenses incurred in responding to this RFI.

F) Treatment of Responses

1. **Use of Responses**: Responses will not be evaluated. However, the responses received may be used by Canada to develop or modify procurement strategies. All responses received on or before the RFI closing date will be reviewed. Responses received after the RFI closing date may, at Canada's discretion, be reviewed.

2. **Review Team**: A review team may review the responses. Canada reserves the right to hire any independent consultant, or use any Government resources that it considers necessary to review any response. Not all members of the review team will necessarily review all responses.

3. **Confidentiality**: Respondents should mark any portions of their response that they consider proprietary or confidential. Canada will handle the responses in accordance with the *Access to Information Act*.

4. **Follow-up Activity**: Canada may request to meet with each Respondent upon request (one-on-one meeting). Following the closing date, the TCD may follow up individually with Respondents. Canada may request that the Respondent provide an overview of the

functionalities of the proposed solution and deliver a demonstration of commercial products so that Canada may obtain a better understanding of the Solution. During any such demonstration, Canada may interact with the Respondent to ask questions in order to gain a better understanding of the capabilities of the proposed solution.

5. **Documentation or any other information** of the proposed Solution, tool suite, or supporting third party applications is welcome.

G) Specific Questions to Industry

We are prioritizing products that meet as many of our requirements as possible, and recognize that all requirements may not be met by a single product.

In order to demonstrate that their product can meet the business requirements identified in Section B, respondents are requested to answer the following questions, with assumptions clearly defined, where applicable. If a specific functionality is not supported by your product please indicate it in your response.

Compliance and Enforcement (C&E) Activities

1. How does your product support, or how can it be configured to support, workflow and process management? For example:
    i. Tracking activity assignments/referrals and approvals, including automatic assignments where applicable under specified business rules.
    ii. Planning and documenting inspection, investigation, compliance promotion and enforcement activities.
    iii. Documenting outcome of inspections and investigations per legislative section.
    iv. Capturing additional information associated with enforcement actions, such as details regarding laboratory analyses, warrants, tickets and prosecution briefs.
    v. Linking activities with establishments, products and other activities.
    vi. Allowing users to view and add comments on activities and other data entered into system.
    vii. Audit history of all changes/transactions.
2. How does your product support, or how can it be configured to support, off-line use, i.e. no internet connection? For example, partial/full offline support of C&E activity documentation, transparent mode switching, automatic data synching, etc.

Industry Reports Processing Activities

3. How does your product support, or how can it be configured to support, electronic submission, storage, and processing of industry data? For example, online portal, input validation rules, submission timeliness assessment, etc.

Common Criteria

4. How does your product support, or how can it be configured to support, Business Intelligence, data analytics and reporting? For example, internal reporting and analysis, data extraction for public transparency, ad-hoc and pre-defined reports, etc.

5. How does your product support, or how can it be configured to support, user management? For example, roles, permissions, separation of internal and external user types, active/inactive users, etc.
6. How does your product support, or how can it be configured to support, document creation, distribution and management? For example:
    i. Storing, searching, and viewing documents in various formats (e.g. images, text, etc.).
    ii. Associating documents with an activity.
    iii. Generating of correspondences (e.g., email) notifications and templated documents for different actors in the system (internal and external user roles).
    iv. Supporting integration with other document management tools.
7. How does your product support, or how can it be configured to support, interoperability with other systems? For example, user authentication (eg. SSO, secure gateway, etc.), open RESTful APIs, standardized file formats, etc.
8. How would your product be deployed and are there any options? In particular, are you proposing to provide the Solution as a service (SaaS) or as a product that the Government of Canada will host? If SaaS, do you have a Canadian data centre that is, or can be, approved for Protected B data security? If you require third party hosting, which third party cloud provider will be used?
9. How does your product support, or how can it be configured to support, bilingual (French and English) operation?
10. What is the level of Web Content Accessibility Guidelines (WCAG) compliance of your product?
11. How flexible and user configurable is your product? For example, can users add or change activities, roles, processes, system parameters, etc.?
12. What are the supported technologies used by your product? (Development Language, Application Server, Database, and Operating system, etc.)

The above list is not intended to limit Respondents' submissions but rather to provide a framework for the Tobacco Control Directorate (TCD) to evaluate whether competition exists to meet the TCD's requirements, and whether TCD should be seeking a single- or multi-product solution. Respondents are encouraged to provide any additional information or innovative equipment and/or services and brochures, not specifically outlined elsewhere in this Request for Information.

H) Format of Responses

1. **Cover Page**: If the response includes multiple volumes, Respondents are requested to indicate on the front cover page of each volume: the title of the response, the RFI number, the volume number and the full legal name of the Respondent. If there is only one volume, a cover page is not required.

2. **Title Page(s)**: The first page of each volume of the response, after the cover page, should be the title page, which should contain:

    a) the title of the Respondent's response and the volume number;

b) the name and address of the Respondent;
c) the name, address, email and telephone number of the Respondent's contact;
d) the date; and,
e) the RFI number.

3. **Corporate Profile:** Each Respondent should provide a brief description of the Company background. For example, this can include expertise, related products, current (in production) clients or clients' references, URLs, partners, product roadmap, or history of development of the product.

4. **Numbering System**: Respondents are requested to prepare their response using a numbering system corresponding to the questions in this RFI. All references to descriptive material, technical manuals and brochures included as part of the response should be referenced accordingly. Respondents may use the template provided for their responses (see Annex A).

5. **Response to be sent electronically**: Canada requests that respondents submit their responses electronically by e-mail to the contact defined in section I. Should your response exceed 20MB in size, hard copy or digital media submissions are to be submitted at the address provided in section I of this RFI.

I) Enquiries

Because this is not a bid solicitation, Canada will not necessarily respond to enquiries in writing or by circulating answers to all potential suppliers. However, respondents with questions regarding this RFI may direct their enquiries to the contact below:

Enquiries, responses and electronic submissions:

Stephanie Cleroux
Senior Contracts and Procurement Officer
stephanie.cleroux@canada.ca
613-941-2082

Hard Copy Response Submission Address:

Health Canada Bid Receiving Unit
Federal Records Centre Building
161 Goldenrod Driveway (Loading Dock)
Ottawa, Ontario, K1A 0K9

J) Submission of Responses

1. **Time and Place for Submission of Responses**: Respondents should email their response to the contact defined in section I.

2. **Responsibility for Timely Delivery**: Each Respondent is solely responsible for ensuring its response is delivered on time to the contact defined in section I.

3. **Identification of Response**: Each Respondent should ensure that its name and return address is provided and that the RFI number and the closing date appear legibly in the subject line of the e-mail.

ANNEX A-Response Template

The questions below are not intended to limit Respondents' submissions but rather to provide a framework for the Tobacco Control Directorate (TCD) to evaluate whether competition exists to meet the TCD's requirements. Respondents are encouraged to provide any additional information or innovative equipment and/or services and brochures, not specifically outlined elsewhere in this Request for Information. The template is provided for convenience but is not mandatory.

Corporate Profile	
i)	Full Corporate Name
ii)	Full Address of head office
iii)	Full address of the sale and service office closest to Ottawa, Canada and number of employees at that office. As well please provide the location of other sale and service offices in Canada.
iv)	Full address of any implementation partners with offices in Canada, if applicable
v)	Total number of worldwide employees
vi)	Name of products. For each component product you are proposing, please provide the year that the product was first made commercially available and the year of the latest physical or software change
vii)	Provide a brief description of the Company background. For example, this can include expertise, related products, current (in production) clients or clients' references, URLs, partners, product roadmap, or history of development of the product
Specific Questions to Industry: Compliance and Enforcement (C&E) Activities	
1)	How does your product support, or how can it be configured to support, workflow and process management? For example: i. Tracking activity assignments/referrals and approvals, including automatic assignments where applicable under specified business rules. ii. Planning and documenting inspection, investigation, compliance promotion and enforcement activities. iii. Documenting outcome of inspections and investigations per legislative section. iv. Capturing additional information associated with enforcement actions, such as details regarding laboratory analyses, warrants, tickets and prosecution briefs. v. Linking activities with establishments, products and other activities.

	vi. Allowing users to view and add comments on activities and other data entered into system. vii. Audit history of all changes/transactions.
2)	How does your product support, or how can it be configured to support, off-line use, i.e. no internet connection? For example, partial/full offline support of C&E activity documentation, transparent mode switching, automatic data synching, etc.
Specific Questions to Industry: Industry Reports Processing Activities	
3)	How does your product support, or how can it be configured to support, electronic submission, storage, and processing of industry data? For example, online portal, input validation rules, submission timeliness assessment, etc.
Specific Questions to Industry: Common Criteria	
4)	How does your product support, or how can it be configured to support, Business Intelligence, data analytics and reporting? For example, internal reporting and analysis, data extraction for public transparency, ad-hoc and pre-defined reports, etc.
5)	How does your product support, or how can it be configured to support, user management? For example, roles, permissions, separation of internal and external user types, active/inactive users, etc.
6)	How does your product support, or how can it be configured to support, document creation, distribution and management? For example: i. Storing, searching, and viewing documents in various formats (e.g. images, text, etc.). ii. Associating documents with an activity. iii. Generating of correspondences (e.g., email) notifications and template documents for different actors in the system (internal and external user roles). iv. Supporting integration with other document management tools.
7)	How does your product support, or how can it be configured to support, interoperability with other systems? For example, user authentication (eg. SSO, secure gateway, etc.), open RESTful APIs, standardized file formats, etc.
8)	How would your product be deployed and are there any options? In particular, are you proposing to provide the Solution as a service (SaaS) or as a product that the Government of Canada will host? If SaaS, do you have a Canadian data centre that is, or can be, approved for Protected B data security? If you require third party hosting, which third party cloud provider will be used?

9)	How does your product support, or how can it be configured to support, bilingual (French and English) operation?
10)	What is the level of Web Content Accessibility Guidelines (WCAG) compliance of your product?
11)	How flexible and user configurable is your product? For example, can users add or change activities, roles, processes, system parameters, etc.?
12)	What are the supported technologies used by your product? (Development Language, Application Server, Database, and Operating system, etc.)