#### ANNEX 1

# ARRANGEMENT RESPECTING THE IMPORT OF HEALTH PRODUCTS, CONSUMER PRODUCTS, COSMETICS, CONTROLLED SUBSTANCES, PRECURSORS, RADIATION EMITTING DEVICES, AND PEST CONTROL PRODUCTS

#### **BETWEEN**

#### THE CANADA BORDER SERVICES AGENCY

Represented by the Director General, Border Programs Directorate, Programs Branch Herein referred to as the CBSA

#### **AND**

#### **HEALTH CANADA**

Represented by the Director General, Health Products and Food Branch Inspectorate

(On behalf of the Directors General for
Compliance, Laboratory Services and Regional Operations Directorate,
Consumer Product Safety Directorate,
Controlled Substances and Tobacco Directorate and
Environmental Radiation Health Sciences Directorate and the Executive File
Lead, Compliance and Enforcement of the Regions and Programs Bureau)
Herein referred to as Health Canada

MAR 2 8 2014

Effective Date

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#### **PURPOSE**

- 1. This Annex constitutes the arrangement between the Canada Border Services Agency (CBSA) and Health Canada's programs, hereinafter sometimes referred to as the "Participants", with respect to the import of Goods under Health Canada's mandate, with the exception of Goods regulated as foods, alcohol and tobacco (see Appendix A). This Annex will outline the Participants' respective roles and responsibilities in relation to the administration and enforcement of Health Canada's Legislation with respect to these Goods. The Participants agree to implement their respective roles and responsibilities through their internal operating policies and procedures. The Participants will consult one another as appropriate in developing these policies and procedures.
- 2. This Annex is appended to the *Umbrella Memorandum of Understanding* (UMOU), dated November 14, 2011, between the Participants.
- 3. The provisions of this Annex should not be interpreted in such a way that would:
  - Hinder best practices already in effect between the Participants;
  - Restrict either Participant's arrangements with other agencies; or
  - Restrict enforcement by each Participant of the legislation for which each is responsible.

#### **ORGANIZATIONAL MANDATES**

- 4. The CBSA has, pursuant to the *Canada Border Services Agency Act*, the responsibility for providing integrated border services that support national security and public safety priorities and facilitate the free flow of persons and goods, including animals and plants that meet all requirements under the program legislation. Under the authority of Section 101 of the *Customs Act*, the CBSA is authorized to detain such goods until satisfied that such goods have been dealt with in accordance with the *Customs Act* or any other Act of Parliament that prohibits, controls, or regulates imports and exports relating to such goods.
- 5. Health Canada's mandate includes the enhancement and protection of the health of Canadians through monitoring health, safety and environmental risks as it relates to import, export, and trans-border movement of regulated products, including drugs, controlled substances, precursors, chemicals, pest control products, medical devices, radiation emitting devices, cosmetics and consumer products.

#### **DESIGNATED OFFICIALS**

6. Pursuant to Paragraph 10 of the UMOU, the following designated officials for the Participants will have general oversight for the administration of this Annex.

Director General, Border Programs Directorate, is the designated official for the Canada Border Services Agency.

191 Laurier Ave West Ottawa, Ontario, K1A 0L8 Phone: (613) 954-6431

Director General, Health Products and Food Branch Inspectorate is the designated official for the Health Products and Food Branch Inspectorate (HPFBI).

250 Lanark Avenue, Ottawa, Ontario, K1A 0K9 Phone: (613) 952-5804

Director General, Consumer Product Safety Directorate is the designated official for the Consumer Product Safety Directorate.

269 Laurier Avenue West Ottawa, Ontario, K1A 0K9 Phone: (613) 957-1422

Director General, Controlled Substances and Tobacco Directorate is the designated official for the Controlled Substances and Tobacco Directorate

150 Tunney's Pasture Driveway Ottawa, Ontario, K1A 0K9 Phone: (613) 941-1977

Director General, Environmental and Radiation Health Sciences Directorate is the designated official for the Environmental and Radiation Health Sciences Directorate.

269 Laurier Avenue West Ottawa, Ontario, K1A 0K9 Phone: (613) 954-3859

Director General, Compliance, Laboratory Services and Regional Operations Directorate is the designated official for the Pest Management Regulatory Agency (PMRA).

2720 Riverside Drive Ottawa, Ontario, K1A 0K9 Phone: (613) 736-3484 Executive File Lead, Compliance and Enforcement, Regions and Programs Bureau is the designated official for the Regions and Programs Bureau (RAPB)

200 Eglantine Driveway Ottawa, Ontario, K1A 0K9 Phone: (613) 954-0690

#### • DEFINITIONS

- 7. The following definitions apply for the purposes of this Annex:
  - "Consumer Product" means a product, including its components, parts or accessories, which may reasonably be expected to be obtained by an individual to be used for non-commercial purposes, including for domestic, recreational and sports purposes, and includes its packaging.
  - "Cosmetic" includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes.
  - "Controlled Substance" means a substance included in Schedule I, II, III, IV or V of the Controlled Drugs and Substances Act. For the purposes of the Controlled Drugs and Substances Act and this Annex,
  - (a) a reference to a controlled substance includes a reference to any substance that contains a controlled substance; and
  - (b) a reference to a controlled substance includes a reference to
    - (i) all synthetic and natural forms of the substance, and
  - (ii) any product that contains or has on it a controlled substance and that is used or intended or designed for use
    - A) in producing the substance, or
    - B) in introducing the substance into a human body
  - "Goods" means goods imported into Canada that are subject to requirements set out in legislation administered by Health Canada and described in Appendix A, but does not include food, tobacco, and alcohol.
  - "Health Products" in this Annex refers to all goods within the Health Products and Food Branch's mandate pursuant to the *Food and Drugs Act* and its associated Regulations with the exception of food.
  - "Health Canada" for the purposes of this Annex, refers to the Health Canada Programs that are collaborating with the CBSA to formalize inter-agency procedures and includes, in alphabetical order: Consumer Product Safety

Directorate; Controlled Substances and Tobacco Directorate; Environmental Radiation Health Sciences Directorate; Compliance, Laboratory Services and Regional Operations Directorate; the Health Products and Food Branch Inspectorate; and which are operationalized by the Regions and Programs Bureau.

- "Health Canada's Legislation" means the enabling legislation for each Program as listed in Appendix A.
- "Pest Control Products" in this Annex refers to all products within the Pest Management Regulatory Agency's mandate, and falling under the definition of "pest control product" in subsection 2(1) of the Pest Control Products Act.
- "Precursor" means a substance included in Schedule VI of the Controlled Drugs and Substances Act.
- "Radiation Emitting Device" means any device that is capable of producing and emitting radiation and, any component of or accessory to the device.
- "Request for Confidential Customs Information" refers to written requests submitted to the Office of Primary Interest of CBSA for historical customs Information and is separate and distinct from information sharing which occurs under the Single Window Initiative as defined under the Written Collaborative Agreements between the Participants.
- "Targets" is the product of the targeting process that alert the appropriate CBSA personnel of an impending suspected risk to public safety and/or national security. For purposes of this Annex, targets include port lookouts.
- "In writing" refers to an agreed upon documented process including but not limited to fax, e-mail, or letter in electronic or hard copy format.

# **GENERAL PRINCIPLES**

8. The Participants will:

- Work cooperatively in fulfilling the terms of this Annex;
- Implement the various understandings set out in this Annex;
- Provide information, advice and guidance concerning their respective legislation, programs, policies and procedures;
- Inform each other within a reasonable time of any new activities or initiatives or of changes in legislation, regulations, operational policies and procedures or practices relating to its programs that may affect the other Participant;
- Exchange information as necessary to evaluate programs or activities, formulate policy and support operational needs;
- Meet formally on a regular basis to inform and to consult; and
- Continue working together to enhance the effectiveness and efficiency of border services relating to the import and in-transit movement of goods under the mandate of Health Canada.

#### **ROLES AND RESPONSIBILITIES**

#### ROLE OF THE CBSA

- 9. The CBSA will assist Health Canada in administering the import requirements of Health Canada's Legislation as they relate to Goods.
- 10. Nothing in this Annex should be construed as altering the CBSA's current role or the division of investigative responsibilities with the RCMP as it pertains to the interdiction of Controlled Substances and Precursors that could lead to a criminal investigation or enforcement actions resulting from a contravention of the *Customs Act*.
- 11. The CBSA may detain Goods under Section 101 of the *Customs Act* when border services officers identify or suspect non-compliance with the requirements of Health Canada's Legislation. In these cases, the CBSA may refer the detained Goods to Health Canada for an admissibility recommendation to verify compliance with the requirements.
- 12. Assessing compliance with the import requirements for the Goods by the CBSA may include:
  - Refusing entry of Goods into Canada following an inadmissible recommendation from Health Canada due to non-compliance with Health Canada's Legislation;

- Targeting Goods which have been identified as posing an increased risk to the health or safety of Canadians, or the environment and have been identified to the CBSA, in accordance with the CBSA Targeting Process described in Appendix C to this Annex;
- Provide reasonable access and assistance for Health Canada to conduct inspections for shipments at the border when required;
- Detain referred Goods until an admissibility recommendation has been provided by Health Canada to the CBSA in writing or until Health Canada seizes the detained Goods in accordance with the section on Service Standards;
- Following an admissibility recommendation from Health Canada, CBSA will make arrangements for the continued detention or disposal of the detained goods, as appropriate in accordance with the section on Refusal of Entry and Disposal of Abandoned/Forfeited Goods.
- 13. The specific activities that the CBSA will undertake for each category of Goods are listed in Appendix B Border Activities.

#### ROLE OF HEALTH CANADA

- 14. With respect to roles and responsibilities for Health Canada:
  - Health Canada is responsible for the administration and compliance/enforcement of Health Canada's Legislation;
  - Health Canada will provide information to enable the CBSA to create Targets for interdiction and detention by the CBSA at time of importation in accordance with the Targeting Process section;
  - Health Canada will provide admissibility recommendations for Goods which have been detained by the CBSA and referred to Health Canada in accordance with the Service Standards section;
  - Health Canada's inspectors may examine, open, and/or sample any Goods detained by the CBSA and may make copies of any record or document related to the detained Goods in accordance with the relevant provisions of Health Canada's Legislation;
  - In accordance with the relevant provisions of Health Canada's Legislation and as set out in the section on Refusal of Entry and Disposal of Abandoned/Forfeited Goods, Health Canada's inspectors may detain, seize, or dispose of Goods that have been detained by the CBSA.
  - Prior to inspecting Goods detained by the CBSA, Health Canada will obtain authorization to access the CBSA facility from the regional CBSA office.

#### PARTNERSHIP ACTION PLAN

- 15. The Participants will develop a Partnership Action Plan within two months from the signing of this Annex. The Partnership Action Plan will outline short, medium and long-term program priorities and activities to be undertaken jointly with respect to the Health Canada programs at the border.
- 16. Priorities for inclusion in the Partnership Action Plan are listed in Appendix I.
- 17. The Partnership Action Plan will be reviewed every two years by the Participants. The Participants may amend the Partnership Action Plan at the time of that review, with the amended plan being approved by the Office of Primary Interest listed in Appendix G.
- 18. If the Participants determine that there is a need to amend the Partnership Action Plan before the end of the two-year period, either Participant may propose amendments for discussion and approval by both the CBSA and Health Canada.
- 19. An annual status report will be prepared by the Participants on the activities outlined in the Partnership Action Plan.
- 20. A committee comprised of one representative from each of the Offices of Primary and Secondary Interest listed in Appendix G to this Annex will co-ordinate the development and updating of the Partnership Action Plan and the drafting of the status report. As required, working groups may be established by the Participants to develop and implement specific activities.

#### INFORMATION SHARING

#### Provision of information under this Annex

21. Information will be shared in a timely manner to ensure the effective, efficient and continuous operations of both Participants. The Participants agree that no Protected Client Information will be provided under this Annex except to the extent authorized by law.

#### Use

22. The Protected Client Information can only be used for compliance verification, enforcement activities, and for any other purpose for which it was provided.

#### **Disclosure**

- 23. The Participants agree that no Protected Client Information (as defined in the UMOU) will be provided under this Annex except to the extent authorized by law. Protected Client Information shared under this Annex will not be disclosed except with the consent of the Participant who provided the information.
- 24. The requirement to obtain the consent of the providing Participant may not apply in all cases. The situations where consent is not required and the associated provisions governing such disclosures will be outlined in Appendix J to this Annex.

## **Requests to share Protected Client Information**

- 25. Where a Participant requests the consent of the other Participant to share Protected Client Information, the Participant receiving the request will respond within two business days. The Participant's response will be to:
  - a) provide consent to release the information;
  - b) request additional time to provide consent, when needed;
  - c) identify missing information needed to provide consent; or
  - d) deny consent, with a written explanation of the reason for the denial. In the instance a request is denied, the appropriate officials from CBSA and Health Canada will seek to review the decision and consider other appropriate options for resolution.
- 26. The Participants agree to track requests for consent, monitor compliance with service standards and jointly review semi-annually. Requests for CBSA consent should be sent to the Office of Primary Interest as listed in Appendix G.

## REQUESTS FOR CONFIDENTIAL CUSTOMS INFORMATION

- 27. Any Requests for Confidential Customs Information will be made in writing using the Importation Information Request Form found in Appendix D, and sent to the Office of Primary Interest, as listed in Appendix G.
- 28. Requests for Confidential Customs Information made under subparagraph 107(5)(c)(i) of the *Customs Act*, will be subject to cost-recovery if the request is approved and forwarded by the CBSA to Statistics Canada for processing. In these situations financial arrangements will be negotiated and settled between Health Canada and Statistics Canada prior to Statistics Canada providing the information.

29. The CBSA may decide not to grant a Request for Confidential Customs Information received from Health Canada. If this occurs, a written explanation will be provided by the CBSA to Health Canada.

#### RISK MANAGEMENT

- 30. The Participants are committed to developing risk management practices and priorities to better concentrate its efforts and decision making activities with respect to the customs processing of travellers and Goods, as well as conveyances, Goods, and cargo. With this in mind, the Participants agree to work to identify high risk Goods and importation activities.
- 31. Health Canada will identify to the CBSA specific importations consisting of goods, importers, product types, and exporters which may pose a risk to health, safety, or the environment.

#### TARGETING PROCESS

- 32. Health Canada will work with the CBSA's National Targeting Centre when requesting a Target, to ensure that the respective requirements of the Participants are met and standard operating procedures are followed and adhered to. Appendix C outlines the process to request a target.
- 33. Health Canada will provide the CBSA with adequate information to enable the CBSA to efficiently target goods that are suspected to pose an unacceptable risk to the health or safety of Canadians or the environment which are prohibited or regulated under Health Canada's Legislation.

#### **ENFORCEMENT**

- 34. Health Canada will be responsible for any enforcement action taken with respect to alleged violations of Health Canada's Legislation relating to Goods, other than refusals of entry.
- 35. The CBSA will be responsible for any enforcement action taken with respect to alleged violations of the *Customs Act*.
- 36. Each Participant will have due regard for the enforcement responsibilities of the other.

37. Enforcement of the Controlled Drugs and Substances Act is the responsibility of law enforcement.

# REFUSAL OF ENTRY AND DISPOSAL OF ABANDONED/FORFEITED GOODS

- 38. Health Canada inspectors have the power, pursuant to respective sections of Health Canada's Legislation, to seize and detain Goods. Where Health Canada seizes Goods that have been detained by the CBSA, Health Canada will be responsible for the disposition of those Goods in accordance with Health Canada's Legislation
- 39. The CBSA may detain Goods at the border and request an admissibility recommendation from Health Canada. Where Health Canada makes a recommendation for refusal of entry, the CBSA will be responsible for notifying the importer of their disposition options following the recommendation.
  - a) If the Goods are abandoned to the Crown, Regional CBSA offices will arrange for disposal of the Goods at Health Canada's expense with thirty (30) days written notice to the appropriate Health Canada Regional Border Centre including the location of the Goods and the estimated costs of their disposition. Alternatively, regional arrangements can be made for Health Canada to arrange for disposal of the abandoned Goods at Health Canada's expense.
  - b) In cases where a notice of compliance with respect to non-compliant pest control products is issued by Health Canada, the CBSA will be provided a copy of the notice of compliance setting out the importer's options and subsequently informed of the importer's proposed actions. Should the disposition options set out in the notice of compliance not be followed, the Regional CBSA offices will arrange for disposal of the pest control products with thirty (30) days written notice to the appropriate Health Canada Regional Border Centre including the location of the pest control products and the estimated costs of their disposition. Alternatively, regional arrangements can be made for Health Canada to arrange for disposal of the non-compliant pest control products. The CBSA will not be responsible for the costs associated with the disposal of non-compliant pest control products.
- 40. Controlled Substances will continue to be disposed of by the RCMP on the CBSA's behalf. CBSA and Health Canada will continue to pursue short and long-term solutions regarding the disposal of Precursors.

#### **TRAINING**

- 41. Health Canada will be responsible for the development and provision of the learning materials and learning activities for CBSA officials that are related to the CBSA's role in the administration of import requirements for Goods.
- 42. Health Canada will be responsible for the costs of learning materials related to the learning activities of CBSA officials at ports of entry.
- 43. The CBSA will provide learning opportunities to Health Canada officials relating to CBSA's roles, responsibilities and processes at ports of entry. CBSA will cover the costs of any related learning materials.
- 44. The Participants will consult to identify training priorities through the Partnership Action Plan to ensure national consistency. This will include negotiation of the scope, frequency, method, means of delivery, and monitoring of effectiveness of learning activities.

#### COMMUNICATION

- 45. For the purposes of executing the requirements of this Annex, the Participants will share Information on import requirements for Goods including, but not limited to, legislative changes, program policies, operational procedures and program specific briefings.
- 46. The Participants agree to provide each other, on an annual basis or when changes occur, with up-to-date information details regarding emergency contacts. Emergency contact information will be listed in Appendix H.
- 47. Each Participant will adhere to its own communications policies, standards, approaches, internal structures and resources with respect to managing communications, as well as external requirements such as the *Privacy Act* and the *Access to Information Act* and standards and procedures of other bodies including Treasury Board policies on communications and federal identity.
- 48. Both Participants will share, in a timely manner, ad hoc and emerging issues that are of direct relevance to joint operations and may require immediate communication with stakeholders or the Canadian public.
- 49. When policies of Health Canada are developed on matters relating to the importation of goods under the mandate of Health Canada, and if the CBSA is

- identified as a key partner, both Participants will meet to discuss strategic planning and establish a list of their stakeholders affected by the new policies.
- 50. In times of emergency response, the Participants will work collaboratively to deliver timely and consistent emergency communications to all stakeholders on matters of direct relevance to joint operations as outlined in this Annex.
- 51. In keeping with timely service to regulated parties, when a public inquiry is received by one of the Participants, it will respond through its own public inquiry mechanisms. Should the receiving Participant be unable to respond to the inquiry unilaterally, that Participant will consult with the other Participant.

# PERFORMANCE MEASUREMENT, MONITORING AND REPORTING

- 52. The Participants agree to monitor and report on the performance of activities outlined in this Annex to allow both Participants to monitor and assess the effectiveness of the Annex.
- 53. The Participants agree to the regular exchange of performance measurement data. With respect to Targets issued by the CBSA on behalf of Health Canada, the CBSA will issue regular monitoring reports recording target activity and exam results to assist Health Canada in assessing the effectiveness of any Target. Health Canada will provide regular statistical reports to the CBSA tracking CBSA referrals to Health Canada for admissibility recommendations and their outcomes. The CBSA will monitor Health Canada refusal recommendations and will advise Health Canada when it discovers Health Canada recommendations that were not followed.
- 54. The Participants will meet semi-annually (or on an as-needed basis) to review the results of monitoring and assess the operation and effectiveness of the Annex.

#### **SERVICE STANDARDS**

Ports of Entry Where There Are Regularly Scheduled On-Site Visits by Health Canada 55. Health Canada commits to regular visits to ports of entry, as listed in Appendix F, where regular on-site inspections are scheduled, with timing and frequency to be negotiated regionally with consideration for factors such as risk and volume.

Ports of Entry Where There Are No Regularly Scheduled On Site Inspections For The Goods.

\_56. When the CBSA makes a referral to Health Canada for an admissibility recommendation, the CBSA will make every reasonable effort to provide the necessary information to enable the recommendation. Such information may include:

# For Commercial and Personal Imports

- a. Name and contact information of the importer/exporter;
- b. Customs documentation and/or declaration;
- c. Description of products & quantity sought to be imported (including market authorization);
- d. List of ingredients (found on the label);
- e. Indication of use (found on the label); and
- f. Name and contact information of Border Services Officer.
- 57. Upon receipt of a referral from the CBSA, Health Canada commits to respond within two business days.
- 58. Health Canada's response will be to:
  - a. provide a recommendation;
  - b. request additional time to make the recommendation; or
  - c. identify missing information needed to make a recommendation, and begin a discussion with CBSA on options to resolve the issue.
- 59. In cases where Health Canada does not respond to a referral from the CBSA within two business days, the CBSA may release the goods in the normal manner. If the CBSA releases good pursuant to this clause, the CBSA will provide the appropriate Health Canada Regional Border Centre with the following customs information: importer name and address, product description, quantity and date of release. Health Canada will initiate follow-up action with the importer directly.

# Requests to share Protected Client Information

60. Where a Participant requests the approval of the other participant to share Protected Client Information, the participant receiving the request will respond within two business days.

#### **FINANCING**

- 61. The Participants will be responsible for all costs, including overtime, of their respective employees in the execution of their duties under this Annex.
- 62. The Participants will negotiate cost-sharing or cost-recovery measures, with respect to new responsibilities, new initiatives, and amendments to legislation that would

result in additional responsibilities and will formalize such measures in an arrangement signed by the responsible designated officials for the Participants.

#### DISPUTE RESOLUTION

- 63. Each Participant intends to make all reasonable efforts, in good faith, to reach a consensus and promptly resolve any dispute arising in relation to matters covered by this Annex. To this effect, the designated officials for this Annex may be contacted to resolve any issues.
- 64. If a dispute cannot be resolved by the designated officials of this Annex, the subject matter will then be forwarded to the designated officials listed for this purpose in the Umbrella MOU for a resolution.

# EFFECTIVE DATE, REVIEW, AMENDMENT AND TERMINATION OF THE ARRANGEMENT

- 65. This Annex will come into effect on the date it is last signed and will remain in effect until terminated by either Participant.
- 66. The Participants intend to review this Annex every five years from the date it comes into effect.
- 67. The Annex and its Appendices can be modified prior to a five-year review with the consent of both Participants.
- 68. Either Participant may terminate this Annex upon 30 days written notice to the other Participant. The Annex may be terminated immediately upon consent of both Participants.
- 69. The CBSA or any one of the Health Canada Programs may terminate their arrangement under this Annex upon 30 days written notice to the Responsible Designated Official but the Annex will remain in effect for the CBSA and the remaining Health Canada Programs until otherwise terminated pursuant to Section 68. The arrangement between the CBSA and any one of the Health Canada Programs under this Annex may be terminated immediately upon consent of both the CBSA and the Health Canada Program.

The English and French versions of this document are equally authentic.

Les versions française et anglaise de ce document ont la même valeur.

Director General
Border Programs Directorate
Programs Branch
Canada Border Services Agency

28 day of March 2014

Director General
Health Products and Food Branch Inspectorate
(on behalf of the Designated Officials as indicated)
Health Canada

& Chypnil L

28 day of March 2014

#### APPENDIX A

#### Canada Consumer Product Safety Act and associated Regulations

• Consumer Products

## Controlled Drugs and Substances Act and associated Regulations

Controlled Substances and Precursors

#### Food and Drugs Act and associated Regulations

- Human Drugs including Prescription, Biologics, Radiopharmaceuticals, and other non-prescription drugs;
- Natural Health Products;
- Veterinary Drugs;
- Blood and Blood Components;
- Cells, Tissues, and Organs,
- Semen for Assisted Conception and Assisted Human Reproductive Products
- Medical Devices:
- Clinical Trial Material including Investigational Drug Products
- Health Products imported under the Program's Special Access Program.
- Cosmetics

# Pest Control Products Act and associated Regulations

• Pest Control Products

#### Radiation Emitting Devices Act and associated Regulations

- Medical and diagnostic equipment, such as mammography, ultrasound, medical X-rays
- Industrial and commercial equipment such as baggage X-ray systems, analytical x-rays and cabinet x-ray devices; and
- Household appliances and equipment such as microwave ovens and tanning equipment

# **APPENDIX B**

# **BORDER ACTIVITIES**

This section further describes activities that the CBSA will perform on behalf of Health Canada for the various categories of goods under the mandate of Health Canada within the Traveller, Commercial and Postal Streams.

Goods	CBSA Role	
Human Drugs	The following requirements apply to importations of Human	
and Natural	Drugs and Natural Health Products:	
Health Products	<ul> <li>commercial shipments of prescription drugs must only be imported by practitioners, drug manufacturers, wholesale druggists, or registered pharmacists;</li> <li>commercial shipments of human drugs must be labelled with a Drug Identification Number (DIN) and Natural Health Products must be labelled with a Natural Product Number (NPN) or Homeopathic Medicines Number (DIN-HM);</li> <li>personal importations of non-prescription human drugs and Natural Health Products must not exceed a 90 day supply.</li> <li>personal importations of prescription drugs must not exceed a 90 day supply and must only be imported by a resident of a foreign country while a visitor in Canada or by Canadians returning from abroad with prescription drugs so as not to interrupt a course of treatment while travelling.</li> </ul>	
	If, over the course of their normal duties, border services officers suspect that any of these requirements have not been met, they will detain the Goods and refer them to the appropriate Health Canada Regional Border Centre for an admissibility recommendation.  Upon receipt of a written target request from Health Canada for human drugs and Natural Health Products suspected of representing a risk to Canadians, the CBSA will action the request and will detain targeted goods at time of importation until an admissibility recommendation to release the goods is obtained by Health Canada.	
Medical Devices, Veterinary Drugs, Blood and Blood Products,	Upon receipt of a written target request from Health Canada for other health products (including medical devices, veterinary drugs, blood and blood products, cells, tissues, organs and semen for assisted conception) suspected of representing a risk to Canadians,	

Cells, Tissues, and Organs, and Semen for the purposes of assisted conception.	the CBSA will action the request and will detain targeted goods at time of importation until an admissibility recommendation to release the goods is obtained by Health Canada.
Prohibited Consumer Products (CCPSA Schedule 2)	When border services officers suspect imported products are prohibited under the Canada Consumer Product Safety Act (CCPSA), they will be detained and the appropriate Health Canada Regional Border Centre will be contacted for an admissibility recommendation.
	Upon receipt of a written target request from Health Canada for Consumer Products listed in Schedule 2 of the CCPSA suspected of representing a risk to Canadians, the CBSA will action the request and will detain targeted goods at time of importation until an admissibility recommendation to release the goods is obtained by Health Canada.
Consumer Products subject to the CCPSA, Cosmetics, or Radiation Emitting Devices	Upon receipt of a written target request from Health Canada for Consumer Products subject to the CCPSA, Cosmetics or Radiation Emitting Devices suspected of representing a risk to Canadians, the CBSA will action the request and will detain targeted goods at time of importation until an admissibility recommendation to release the goods is obtained by Health Canada.
	A border services officer may contact the appropriate Health Canada Regional Border Centre for an admissibility recommendation in the absence of a target when it is suspected that a Consumer Products, Cosmetics or Radiation Emitting Devices may pose a danger to human health or safety.
Controlled Substances and Precursors	Upon receipt of a written target request from Health Canada for Controlled Substances and Precursors suspected of representing a risk to Canadians, the CBSA will action the request and will detain targeted goods at time of importation until an admissibility recommendation to release the goods is obtained by Health Canada.
	Detain Controlled Substances and Precursors targeted by Health Canada for the purpose of ascertaining regulatory compliance where interdiction for a contravention of the <i>Customs Act</i> or for

	the purposes of a criminal investigation is not appropriate. In such cases the appropriate Health Canada Regional Border Centre will be contacted for an admissibility recommendation.
	Note: CBSA procedures and policies related to the detention and seizure of controlled substances and precursor for a contravention of the <i>Customs Act</i> or a potential criminal investigation remain unaffected by this annex.
Pest Control Products	Upon receipt of a written target request from Health Canada for Pest Control Products suspected of representing a risk to Canadians, the CBSA will action the request and will detain targeted goods at time of importation until an admissibility recommendation to release the goods is obtained by Health Canada.

#### APPENDIX C

#### TARGETING PROCESS

Standard Operating Procedures applicable to targeting include:

- a) Preparing Target requests (national, regional or local) using the approved template provided by the CBSA, in both official languages (example below);
- b) Providing accurate and complete information in the request in order to make the Target as effective as possible;
- c) Ensuring any risks to the health and safety of the border services officers (BSO) examining the targeted Goods are noted in the request, if applicable;
- d) Forwarding the completed target request form (for commercial mode) to the CBSA via the CBSA Other Government Department (OGD) Targeting mailbox: OGD Target-Cibles AM@cbsa-asfc.gc.ca, (Monday to Friday 8:00 to 16:00 EST) and the NTC Supervisor mailbox after hours and weekends at: NTC-CNC Supervisors@cbsa-asfc.gc.ca; For the traveller mode, via the National Targeting Centre Intelligence mailbox at: NTC-CNC INTELLIGENCE@cbsa-asfc.gc.ca;
- e) Responding to requests from the CBSA for additional information;
- f) Informing the CBSA of any corrections of changes to the target;
- g) Ensuring that the contact list provided for the respective section is updated and communicated to the CBSA as required;
- h) Advising the CBSA of any target cancellation or extension (one week prior) requests if and when warranted, using the same mailboxes;
- i) Responding in a timely manner to BSO's request when shipment is referred.

In addition to performing its day-to-day targeting operations at the border, the CBSA will provide monthly monitoring reports created by the National Targeting Centre to assist Health Canada in assessing the effectiveness of any target.

# **CBSA TARGETING REQUEST FORM**

# REQUEST FOR TARGET/PORT LOOKOUT DEMANDE D'UN CIBLAGE OU D'UN AVIS DE SURVEILLANCE

# 1. ORIGINATOR OF TARGET/PORT LOOKOUT

AUTEUR DE l'AVIS DE SURVEILLANCE/DE CIBLAGE À LA FRONTIÈRE

Department or Agency / Ministère ou organisme :

Contact Name / Nom de la personne-ressource :

Branch / Direction générale :

Telephone Number / Numéro de téléphone :

2. PRODUCT NAME AND HS CODE:

NOM DU PRODUIT ET CODE SH:

Include specific product name and HS code (if available) / Indiquez le nom du produit et le code SH (si disponible)

3. COUNTRY OF ORIGIN:

PAYS D'ORIGINE:

Target will only hit for goods from the country specified / La cible ne visera que les marchandises provenant du pays indiqué

4. EXPORT INFORMATION:

**INFORMATION SUR LES EXPORTATIONS:** 

Name of exporter, if available / Nom de l'exportateur, si disponible

5. IMPORTER NAME AND BUSINESS NUMBER:

IMPORTATEUR ET NUMÉRO D'ENTREPRISE:

Include BN if available / Indiquez le NE, si disponible;

Ensure correct business name and mailing address is included, and name of contact person if available / Indiquez le nom d'entreprise et l'adresse ainsi que le nom de la personne-ressource, si disponible

# 6. REASON & BACKGROUND FOR THE REQUEST:

RAISON ET MOTIF DE LA DEMANDE :

Keep all details regarding why the goods are being targeted in one official language and then follow by the other official language / Inscrivez tous les détails expliquant pourquoi la marchandise est ciblée en une seule langue officielle, puis dans l'autre langue officielle Put explanations in bullet format / Inscrivez les explications sous forme de liste à puces; Clear and concise information easing the BSO's work — easier to follow means less time spent researching and speeds release / detention process / Les renseignements clairs et concis facilitent le travail des ASF — plus de clarté signifie moins de temps consacré à la recherche et un processus de mainlevée et de rétention plus rapide;

Make sure that contact person can be reached; please provide alternate contact / mobile number / Veillez à ce qu'il soit possible de communiquer avec la personne-ressource; veuillez fournir le nom et le numéro de cellulaire d'une autre personne-ressource.

#### 7. DAMAGE:

PRÉJUDICE:

(The non-compliance causes damage to / L'inobservation de la loi porte préjudice à)

Keep all details concerning what kind of damage the non-compliance could cause in one official language and then follow by the other official language / Inscrivez tous les détails concernant les types de préjudices que la situation de non-conformité peut entraîner en une même langue officielle, puis dans l'autre langue officielle;

Put explanations in bullet format / Inscrivez les explications sous forme de liste à puces; Clear and concise information easing the BSO's work — easier to follow means less time spent researching and speeds release / detention process / Les renseignements clairs et concis facilitent le travail des ASF — plus de clarté signifie moins de temps consacré à la recherche et un processus de mainlevée et de rétention plus rapide.

8. DESCRIBE THE CONSEQUENCES OF THE NON-COMPLIANCE: DÉCRIRE LES CONSÉQUENCES DE L'INOBSERVATION DE LA LOI :

Keep all details in one official language and then follow by the other official language / Inscrivez tous les détails en une même langue officielle, puis dans l'autre langue officielle; Put explanations in bullet format / Inscrivez les explications sous forme de liste à puces; Clear and concise information easing the BSO's work — easier to follow means less time spent researching and speeds release / detention process / Les renseignements clairs et concis facilitent le travail des ASF — plus de clarté signifie moins de temps consacré à la recherche et un processus de mainlevée et de rétention plus rapide.

9. POSSIBLE ENTRY POINT(S) / POINTS D'ENTRÉE POSSIBLES:

Should be « national »/ Doit être « national »

10. CBSA ACTION REQUESTED (e.g., Detain shipments of the product and contact the appropriate Health Canada Regional Border Centre):

MESURES REQUISES DE L'ASFC (p. ex., Retenir les envois du produit et communiquer avec le Centre frontalier régional approprié):

Keep all details regarding what action the BSO is required to take in one official language and then follow by the other official language / Inscrivez tous les détails sur les mesures requises de l'ASFC en une même langue officielle, puis dans l'autre langue officielle;

Put explanations in bullet format / Inscrivez les explications sous forme de liste à puces; Clear and concise information easing the BSO's work — easier to follow means less time spent researching and speeds release / detention process / Les renseignements clairs et concis facilitent le travail des ASF — plus de clarté signifie moins de temps consacré à la recherche et un processus de mainlevée et de rétention plus rapide;

Make sure that contact person can be reached; please provide alternate contact / mobile number / Veillez à ce qu'il soit possible de communiquer avec la personne-ressource; veuillez fournir le nom d'une autre personne-ressource/numéro de cellulaire.

#### 11. EFFECTIVE DATE:

DATE D'ENTRÉE EN VIGUEUR:

Specify/Veuillez préciser

#### 12. EXPIRY DATE:

DATE D'ÉCHÉANCE:

Track expiry date so target can be extended if necessary before it expires / Faites le suivi de la date d'échéance afin qu'elle puisse être prolongée au besoin.

# APPENDIX D

# **Importation Information Request Form**



Canada Border Services Agency Agence des services frontaliers du Canada

# **Request for Confidential Information**

# Requested on behalf of:

(Name of the organization: department/agency, division, branch)

# **Contact Information:**

OGD	CBSA
	Senior Program Officer
	OGD Programs Unit
	Commercial Border Programs Division
	Canada Border Services Agency
	150 Isabella, 5th floor
	Ottawa ON K1A 0L8
	Tel: 613-952-0712
0	Fax: 613-946-1520

#### Purpose

(Please provide detailed description)

# **Legislation / Regulations**

(That validate current request: please quote relevant sections)

# **Requested Information**

# **Commodity:**

Description and HS code(s)

# **Data Elements Required:**

(Examples of data elements required)

- importer name;
- importer address;
- importer mailing address, city, province, postal code (or foreign equivalent);
- exporter (vendor) name;
- exporter address, city, province, postal code;
- amount imported (kg);
- value for tax (\$);
- transaction number;
- date of transaction.

# **Scope of requested data:**

# **Output Preferences:**

Please provide the information requested in electronic format (i.e. MS Excel) on a CD.

Report to be completed by: (estimated date)

## APPENDIX E REGIONAL CONTACT LIST

Centres frontaliers régionaux CENTRE FRONTALIER DE L'ATLANTIQUE Bureau des régions et des programmes 16<sup>e</sup> étage, pièce 1625 1505, rue Barrington Halifax (Nouvelle-Écosse) B3J 3Y6

Téléphone: (800) 267-9675 Télécopieur: (902) 426-6676 Atl.Border-Frontiere@hc-sc.gc.ca

CENTRE FRONTALIER DU QUÉBEC Bureau des régions et des programmes 1001, rue St-Laurent ouest

Longueuil (Québec) J4K 1C7

Téléphone: (450) 928-6262 Télécopieur: (450) 928-4455 QC.Border-Frontiere@hc-sc.gc.ca

CENTRE FRONTALIER DE L'ONTARIO

Bureau des régions et des programmes 2301, avenue Midland Scarborough (Ontario) M1P 4R7

Téléphone: (416) 973-1477 Télécopieur: (416) 954-6057 ON.Border-Frontiere@hc-sc.gc.ca

CENTRE FRONTALIER DU
MANITOBA ET
DE LA SASKATCHEWAN
Bureau des régions et des programmes
510, boulevard Lagimodière
Winnipeg (Manitoba)
R2J 3Y1

Téléphone : (204) 984-7971 Télécopieur : (204) 984-2155

MB SK.Border-Frontieres@hc-sc.gc.ca

Regional Border Centres ATLANTIC BORDER CENTRE Regions and Programs Bureau 16<sup>th</sup> floor, suite 1625 1505 Barrington Street Halifax, Nova Scotia B3J 3Y6 Tel: (800) 267-9675

Fax: (902) 426-6676

Atl.Border-Frontiere@hc-sc.gc.ca

QUÉBEC BORDER CENTRE Regions and Programs Bureau 1001 St-Laurent Street West Longueuil, Québec

J4K 1C7 Tel: (450) 928-6262 Fax: (450) 928-4455

QC.Border-Frontiere@hc-sc.gc.ca

ONTARIO BORDER CENTRE Regions and Programs Bureau

2301 Midland Avenue Scarborough, Ontario M1P 4R7

Tel: (416) 973-1477 Fax: (416) 954-6057

ON.Border-Frontiere@hc-sc.gc.ca

MANITOBA AND SASKATCHEWAN BORDER CENTRE

Regions and Programs Bureau 510 Lagimodière Blvd Winnipeg, Manitoba R2J 3Y1

Tel: (204) 984-7971

Fax: (204) 984-2155

MB SK.Border-Frontieres@hc-sc.gc.ca

CENTRE FRONTALIER DE L'ALBERTA

Bureau des régions et des programmes 10217-106 Street

Edmonton (Alberta)

T5J 1H5

Téléphone: (877) 842-6178 Télécopieur: (877) 842-6179 AB.Border-Frontiere@hc-sc.gc.ca

CENTRE FRONTALIER DE LA COLOMBIE-BRITANNIQUE

Bureau des régions et des programmes 4<sup>e</sup> étage, pièce 400

4595, Canada Way

**Burnaby (Colombie-Britannique)** 

V5G 1J9

Téléphone : (604) 658-8344 Télécopieur : (604) 666-9427

BC-CB.Border-Frontiere@hc-sc.gc.ca

ALBERTA BORDER CENTRE

Regions and Programs Bureau

10217-106 Street Edmonton, Alberta

T5J 1H5

Tel: (877) 842-6178

Fax: (877) 842-6179

AB.Border-Frontiere@hc-sc.gc.ca

**BRITISH COLUMBIA BORDER CENTRE** 

Regions and Programs Bureau Suite 400 - 4595 Canada Way Burnaby, British Columbia

Canada V5G 1J9

Tel: (604) 658-8344 Fax: (604) 666-9427

BC-CB.Border-Frontiere@hc-sc.gc.ca

#### APPENDIX F

# List of ports of entry into Canada that are visited by Health Canada inspectors on a regular basis

\*Note: List does not preclude on-site visits by Health Canada inspectors to other Ports of Entry as required or requested.

#### **British Columbia**

803 - Vancouver CBSA Mail Centre and Casual Refund Centre, Vancouver

821 - Air Cargo, Vancouver International Airport, Richmond

#### Manitoba

504 - Winnipeg Longroom (courier)

510 - Winnipeg James Armstrong Richardson International Airport (courier)

#### Ontario

491 - International Mail Processing Centre, Mississauga

417 - Hamilton International Airport, Hamilton

496 - Interport (FedEx), Toronto

497 - Pearson International Airport, Toronto (Air Cargo)

#### **Quebec**

395 - International Mail Processing Centre Léo-Blanchette and Casual Refund Centre, Montreal

396 – Pierre Elliott Trudeau International Airport (courier), Montreal

# APPENDIX G DESIGNATED OFFICIALS

## Offices of Primary Interest

# For the Canada Border Services Agency:

Other Government Department Programs Unit Commercial Border Programs Division Border Programs Directorate 150 Isabella Street, 5<sup>th</sup> floor Ottawa ON K1A 0L8

Compliance Programs Unit Compliance and Program Management Division Border Programs Directorate 150 Isabella Street, 7th floor Ottawa ON K1A 0L8

## For Health Canada:

Health Products and Food Branch Inspectorate Health Products and Food Branch Health Canada 250 Lanark Avenue Ottawa, ON K1A 0K9

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

Environmental and Radiation Health Sciences Directorate Healthy Environments and Consumer Safety Branch Health Canada 269 Laurier Avenue West Ottawa, ON K1A 0K9 Controlled Substances and Tobacco Directorate
Healthy Environments and Consumer Safety Branch
Health Canada
150 Tunney's Pasture Driveway, Room 1605-618
Main Stats Building
Ottawa, ON K1A 0K9

Compliance, Laboratory Services and Regional Operations Directorate Pest Management Regulatory Agency Health Canada 2720 Riverside Drive Ottawa, ON K1A 0K9

Regional Compliance and Enforcement Directorate Border Lead Regions and Programs Bureau Health Canada 200 Eglantine Driveway Ottawa, ON K1A 0K9

# Offices of Secondary Interest

# For the Canada Border Services Agency:

# **Programs Branch**

Import Programs Unit Commercial Border Programs Division Border Programs Directorate 150 Isabella Street, 4<sup>th</sup> floor Ottawa ON K1A 0L8

Commercial Targeting Policy Unit 191 Laurier Street, 13<sup>th</sup> Floor Ottawa ON K1A 0L8

Single Window Initiative End State Development 250 Tremblay Rd, 5th floor Canada Border Services Agency Ottawa, Ontario, K1A 0L8

# **Operations Branch**

Commercial Operations Unit Port of Entry Operations Division Border Operations Directorate 191 Laurier Avenue West, 12th floor Ottawa ON K1A 0L8

National Targeting Centre 2265 St. Laurent Blvd., 2<sup>nd</sup> Floor Ottawa, ON K1A 0L8

# For Health Canada:

Project Director, Single Window Initiative Health Canada Public Health Agency of Canada Brooke Claxton Bldg. 70 Colombine Driveway Ottawa, ON K1A 0K9

# APPENDIX H Emergency Contacts

# **CBSA**

Border Operations Centre Canada Border Services Agency 2265 St-Laurent Blvd. 1st Floor Ottawa ON K1A 0L8 Telephone (English): 613-960-6001 Telephone (French): 613-960-6002

Fax: 613-957-8599

E-mail: boc-cof@cbsa-asfc.gc.ca

# **Health Canada**

Watch Office / Duty Officer Program Health Portfolio Operations Centre Public Health Agency of Canada 100 Colonnade Road Ottawa, Ontario K1A 0K9 Telephone: 613-952-7940

Secondary # 1-800-545-7661

Fax: 613-952-7942

Email address: hpoc\_cops@phac-aspc.gc.ca

#### **APPENDIX I**

# Partnership Action Plan Priorities

The following topics have been identified as priorities for inclusion (but not limited to) in the Partnership Action Plan to be developed following the signature of this Annex:

- Learning activities;
- Medical devices pilot project;
- Performance data management; and
- Risk management strategy

#### **APPENDIX J**

Provisions for the disclosure of Customs Information

# SITUATIONS THAT DO NOT REQUIRE CONSENT FROM THE CANADA BORDER SERVICES AGENCY

As per Section 24 of the Annex, in the following situations Health Canada does not require the prior consent of the CBSA to disclose customs information as long as the information will be used solely for the specific purposes set out in this Appendix.

1. <u>Information related to imported goods that are deemed inadmissible due to safety, quality, or integrity of the shipment, and pose a risk to the life, health or safety of an individual or to the environment in Canada or any other country.</u>

Paragraph 107(4)(e) of the Customs Act

107(4)(e): An official may provide, allow to be provided or provide access to customs information if the information:

(e) may reasonably be regarded as necessary solely for a purpose relating to the life, health or safety of an individual or to the environment in Canada or any other country;

Paragraph 107(4)(e) allows officials to disclose customs information in order to protect the life, health or safety of an individual or the environment in Canada or any other country.

It is CBSA policy that spontaneous disclosures are permissible in urgent and non-urgent circumstances where an official has reasonable grounds to believe that the life, health or safety of a person or the environment in Canada or in any other country is at risk or in danger. Only relevant customs information, which is lawfully under the control of the official, may be provided under this authority. It is understood that this provision is not intended to allow regular ongoing sharing of information but is intended for case-by-case situations where Health Canada needs to be able to work quickly to warn the Canadian public and work expediently with other parties to mitigate an immediate risk.

# 2. Information related to the investigation of an alleged offence

Paragraph 107(5)(a) of the Customs Act

107(5): An official may provide, allow to be provided or provide access to customs information to the following persons:

(a) a peace officer having jurisdiction to investigate an alleged offence under any Act of Parliament or of the legislature of a province subject to prosecution by indictment, the Attorney General of Canada and the Attorney General of the province in which proceedings in respect of the alleged offence may be taken, if that official believes on reasonable grounds that the information relates to the alleged offence and will be used in the investigation or prosecution of the alleged offence, solely for those purposes This paragraph allows officials to disclose customs information to peace officers for the purposes of investigating an alleged offence subject to prosecution by indictment under any Act of Parliament. The referrals to the peace officer could include alleged hybrid offences.

Customs information may only be provided to police or investigative agencies, including any appropriate official who is enabled to reasonably respond to these circumstances. Officials must document the disclosure of customs information as soon as possible after its release, and notify the CBSA of the disclosure. Notifications will specify the date, the customs information that was disclosed, the name of the peace officer that the information was sent to, and the purpose of the disclosure.

# 3. Information disclosed to foreign regulatory authorities

Subsection 107(8) of the Customs Act

107(8): Customs information may be provided by any person to an official or any other person employed by or representing the government of a foreign state, an international organization established by the governments of states, a community of states, or an institution of any such government or organization, in accordance with an international convention, agreement or other written arrangement between the Government of Canada or an institution of the Government of Canada and the government of the foreign state, the organization, the community or the institution, solely for the purposes set out in that arrangement.

This provision permits Health Canada to disclose customs information with foreign regulatory authorities for which Health Canada has a written agreement or arrangement. An administrative list containing written agreements or arrangements will be provided to the CBSA, and updated to include new written agreements or arrangements on a regular basis. In addition, Health Canada will provide a copy of any new agreement or arrangement to the CBSA. The new agreements or arrangements contained in the administrative list will be considered to immediately satisfy the provision unless and until the CBSA advises Health Canada otherwise. Officials must document the disclosure of customs information as soon as possible after its release.

# 4. Information disclosed to certain persons

Subsection 107(9) of the Customs Act

- 107(9): An official may provide, allow to be provided or provide access to customs information relating to a particular person
  - (a) to that particular person;
  - (b) to a person authorized to transact business under this Act or the Customs Tariff as that particular person's agent, at the request of the particular person and on receipt of such fee, if any, as is prescribed; and
  - (c) with the consent of that particular person, to any other person.

This provision permits Health Canada to provide customs information to a person whom the information directly relates to pursuant to paragraph 107(9)(a). If the latter authorizes another person to gain access to their customs information, Health Canada is permitted to share customs information with the authorized representative pursuant to paragraphs 107(9)(b) or 107 (9)(c). A person can be an individual, customs broker, corporation, importer, or organization.