Tobacco Products Regulations (Plain and Standardized Appearance): SOR/2019-107

Canada Gazette, Part II, Volume 153, Number 9

Registration
SOR/2019-107 April 24, 2019

TOBACCO AND VAPING PRODUCTS ACT

P.C. 2019-380 April 23, 2019

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to sections 7 [a] and 33 [b] of the *Tobacco and Vaping Products Act* [c], makes the annexed *Tobacco Products Regulations (Plain and Standardized Appearance)*.

TABLE OF PROVISIONS

Tobacco Products Regulations (Plain and Standardized Appearance)

General

Interpretation

1 Definitions

Application

2 Tobacco product and package — retail sale

3 Non-application

4 Interior surfaces

Purpose

5 Plain and standardized packaging

6 Product standards and markings

PART 1

Tobacco Product Packaging

General Requirements

Package Contents

7 Primary package

Standardized Physical Design Features

8 Secondary package shape

9 Brand element, colour or information

10 Standardized colour

11 Finish

12 Adhesive substance

13 Texture

14 Features

15 Alphanumeric code

16 Bar code

17 Means of electronic communication

18 Feature to prevent counterfeiting

19 Calibration marks

20 Scent and sound

21 Cut-out window

22 Sticker and tab

23 Lining

24 Overwrap

25 Overwrap — more than one primary package

26 Tear tape

Text Size, Style and Placement

Information

27 Text style and colour

Brand Name

28 Brand name — no colour or filter characteristic

29 Placement

30 Text size and style

31 Manner of display

Manufacturer Information and Declaration of Net Quantity

32 Manufacturer identity and principal place of business

33 Manner of display

34 Net quantity and common name

35 Manner of display

36 Placement

37 Text size and style — net quantity and common name

Leaflets

38 Standardized appearance

Specific Requirements — Cigarette Packages

Standardized Physical Design Features and Type of Package

39 Primary package shape

40 Primary package — requirement

41 Slide and shell package — requirements

42 Dimensions

43 Material

44 Lining

Text Placement

45 Declaration of size of cigarettes

Specific Requirements — Little Cigar Packages

46 Primary package shape

47 Material

48 Lining

Specific Requirements — Cigar Packages

49 Interpretation — primary package

50 Overwrap — cigar

51 Overwrap — primary package

52 Lining

Specific Requirements — Packages that Contain Devices or Parts Used with Devices

53 Interpretation — primary package

54 Primary package shape

55 Overwrap

56 Lining

57 Instructions

Specific Requirements — Packages that Contain Tobacco Products Intended for Use with Devices

58 Primary package shape

59 Lining

Specific Requirements — Packages that Do Not Contain Tobacco Products

60 Plain and standardized appearance

PART 2

Appearance and Dimensions of Tobacco Products

General Requirements

61 Appearance

62 Filter

63 Alphanumeric code

64 Means of electronic communication

Specific Requirements — Cigarettes

65 Size of cigarettes

66 Requirements

67 Ventilation holes

Specific Requirements — Little Cigars

68 Size of little cigars

69 Requirements

Specific Requirements — Cigars

70 Requirements

71 Information on cigar band

72 Adhesive band

Specific Requirements — Other Tobacco Products

73 Tobacco products used with a device

74 Ventilation holes

75 Devices

76 Marking on a device

77 Filters

78 Tubes

79 Paper

80 Bidis

PART 3

Consequential Amendments, Transitional Provisions and Coming into Force

Consequential Amendments

81 Tobacco Products Information Regulations

82 Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)

Transitional Provisions

89 Definition of *transitional period*

90 Cigarette packages — edges

Coming into Force

91 S.C. 2018, c.9

SCHEDULE

SCHEDULE 1

SCHEDULE 2

Tobacco Products Regulations (Plain and Standardized Appearance)

General

Interpretation

Definitions

1 (1) The following definitions apply in these Regulations.

Act means the *Tobacco and Vaping Products Act*. (*Loi*)

carton means a secondary package that contains two or more primary packages. (*cartouche*)

drab brown means the colour known as Pantone 448 C. (*brun terne*)

gray means the colour known as Pantone Cool Gray 2 C. (*gris*)

health warning, in respect of a tobacco product, has the same meaning as in the *Tobacco Products Information Regulations* or the *Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)*, as applicable. (*mise en garde*)

lower slide-flap means, in respect of a slide and shell package, the lower extremity of the slide that can be folded and is concealed by the shell when the package is closed. (*rabat inférieur*)

primary package means any package — other than an overwrap — that is intended for retail sale in Canada and in which a tobacco product is directly placed. (*emballage primaire*)

secondary package means any package — other than an overwrap — that is intended for retail sale in Canada and in which a primary package is placed (*emballage secondaire*)

slide means the sliding portion of a slide and shell package. (*tiroir*)

upper slide-flap means, in respect of a slide and shell package, the upper extremity of the slide that can be folded and is concealed by the shell when the package is closed and that is visible when the package is used in the customary manner to gain access to the tobacco product. (*rabat supérieur*)

Interpretation — common name

(2) In these Regulations, a reference to a common name is a reference to the common name that is shown on a label in accordance with subparagraph 10 of the *Consumer Packaging and Labelling Act*.

Interpretation — declaration of net quantity

(3) In these Regulations, a reference to a declaration of net quantity is a reference to the declaration of net quantity that is contained on a label in accordar with section 4 of the *Consumer Packaging and Labelling Act*.

Interpretation — exterior surface

(4) In these Regulations, a reference to an exterior surface of a package that contains a tobacco product is a reference,

(a) in the case of a package that has a rectangular cuboid shape when it is closed, to the part of the package that forms, as the case may be, the exte surface of the front, back, top, bottom or any of the sides of the package;

(b) in the case of a cylindrical package,

(i) to the part of the package that forms, as the case may be, the exterior surface of the top or bottom of the package when it is closed, and

(ii) to the part of the package that forms, as the case may be, the exterior curved surface that makes up the front or back of the package around i circumference; and

(c) in the case of any other package, to the part of the package that forms, as the case may be, the exterior surface of the front, back, top, bottom or a the sides of the package when it is closed.

Interpretation — overwrap

(5) In these Regulations, a reference to an interior or exterior surface of a package that contains a tobacco product does not include a reference to an overwrap.

Application

Tobacco product and package — retail sale

2 (1) These Regulations apply to every package that contains a tobacco product and that is intended for retail sale in Canada, as well as to every tobacco product that is intended for retail sale in Canada.

Package that does not contain tobacco products

(2) These Regulations also apply to a package that does not contain a tobacco product, if the package is furnished by a manufacturer of a tobacco produ that a tobacco product, primary package or secondary package may be placed in it after the tobacco product, primary package or secondary package is at retail in Canada.

Non-application

3 These Regulations do not apply to a package that contains a tobacco product and that is intended to be distributed to a manufacturer or retailer.

Interior surfaces

4 (1) For greater certainty, a provision of these Regulations that applies to any interior surface of a primary package that contains cigarettes applies to eac surface of the slide of a slide and shell package — including the upper slide-flap and lower slide-flap — with the exception of any surface that forms the exterior surface of the top or bottom of the package when it is closed.

Carton

(2) For greater certainty, a provision of these Regulations that applies to any interior surface of a secondary package applies to each surface of a carton th forms its flaps and that is visible only when the carton is opened.

Purpose

Plain and standardized packaging

5 (1) For the purposes of section 23 of the Act, these Regulations set out the requirements that manufacturers of tobacco products must meet in respect of plain and standardized appearance, shape and content of tobacco product packages.

Information — package

(2) For the purposes of section 15.3 of the Act, these Regulations set out the requirements that manufacturers of tobacco products must meet in respect of manner of displaying information on or in tobacco product packages, including the form and placement of the information.

Product standards and markings

6 For the purposes of sections 5 and 5.3 of the Act, these Regulations also establish standards that manufacturers of tobacco products must meet in respe the plain and standardized appearance and shape of tobacco products and set out requirements that manufacturers must meet in respect of the markings may be displayed on tobacco products.

PART 1

Tobacco Product Packaging

General Requirements

Package Contents

Primary package

7 (1) A primary package may contain only a tobacco product, a lining and a leaflet.

Secondary package

(2) A secondary package may contain only a primary package or other secondary package, as well as any overwrap covering those packages.

Standardized Physical Design Features

Secondary package shape

8 Every secondary package must have a rectangular cuboid shape when it is closed, having six surfaces that meet at right angles and edges that are rigi straight, without any rounding or bevelling.

Brand element, colour or information

9 Except as otherwise provided by or under the Act, any other Act of Parliament or any Act of the legislature of a province, the interior and exterior surface primary package and of a secondary package must not display any brand element or any colour or information.

Standardized colour

10 (1) Except as otherwise provided by these Regulations, every interior and exterior surface of a primary package and of a secondary package must be brown.

Exception — required information

(2) Other colours may be used on the interior and exterior surfaces to display a health warning or other information that is required by or under the Act, an other Act of Parliament or any Act of the legislature of a province in accordance with the requirements imposed by or under that Act, other Act of Parliame Act of the legislature of a province.

Exception — package made of metal or wood

(3) An interior surface of a primary package that is made of metal or wood may be the natural colour of the metal or wood.

Finish

11 Except as otherwise provided by or under the Act, any other Act of Parliament or any Act of the legislature of a province, every interior and exterior surf of a primary package and of a secondary package must have a matte finish.

Adhesive substance

12 Any adhesive substance that is used on an interior or exterior surface of a primary package or of a secondary package or on any lining or overwrap mu transparent and colourless.

Texture

13 (1) Every interior and exterior surface of a primary package and of a secondary package, as well as any overwrap covering the package, must have a smooth texture, without any raised features, embossing, decorative ridges, bulges or other irregularities.

Exception — carton

(2) However, a carton may include a perforated strip for opening that, once torn, may leave serrations on the carton's interior and exterior surfaces.

Features

14 (1) The interior and exterior surfaces of a primary package and of a secondary package, as well as any lining, leaflet and overwrap, must not include a feature that is designed to change the appearance (such as heat-activated ink) or to change the surface area (such as a fold-out panel) of the package, li leaflet or overwrap.

Means of opening

(2) A primary package must be designed in such a manner that it may be opened by only one means when the package is used in the customary manner gain access to the tobacco product.

Inner box

(3) A primary package must not be designed in such a manner that it forms an inner box that can be removed without being damaged.

Alphanumeric code

15 (1) A primary package and a secondary package may display an alphanumeric code that is composed of no more than 10 numeric characters and eith the abbreviation "CA" that represents Canada or one of the following internationally approved alpha codes that represents the province or territory where t product is sold:

(a) in the case of Ontario, "ON";

(b) in the case of Quebec, "QC";

(c) in the case of Nova Scotia, "NS";

(d) in the case of New Brunswick, "NB";

(e) in the case of Manitoba, "MB";

(f) in the case of British Columbia, "BC";

(g) in the case of Prince Edward Island, "PE";

(h) in the case of Saskatchewan, "SK";

(i) in the case of Alberta, "AB";

(j) in the case of Newfoundland and Labrador, "NL";

(k) in the case of Yukon, "YT";

(l) in the case of the Northwest Territories, "NT"; and

(m) in the case of Nunavut, "NU".

Alphanumeric code — manner of display

(2) The alphanumeric code may be displayed on a primary package and a secondary package if it is displayed in such a manner that the code

(a) has a matte finish and is printed in a regular weight and width Lucida Sans Serif font style, without italics, and in black or gray;

(b) is printed only once on the primary package and once on the secondary package, in characters of no more than 8 points; and

(c) in the case of a package that has a rectangular cuboid shape when it is closed, is displayed on only the exterior surface of the top, bottom or any of the sides of the package.

Information — characteristics

(3) The alphanumeric code must not convey any information relating to characteristics of the tobacco product that the package contains or the tobacco product's emissions.

Brand element

(4) The alphanumeric code must not evoke the tobacco product's brand elements.

Bar code

16 (1) A primary package and a secondary package may display a bar code that is rectangular in shape, does not contain any image or design and is no than 40 mm by 20 mm in size.

Bar code — manner of display

(2) The bar code may be displayed on a primary package and a secondary package if it is displayed in such a manner that the code

(a) has a matte finish and is printed in either black and white or in drab brown and white;

(b) is displayed only once on the primary package and once on the secondary package; and

(c) in the case of a package that has a rectangular cuboid shape when it is closed, is displayed on only the exterior surface of the top, bottom or any of the sides of the package.

Means of electronic communication

17 (1) The interior and exterior surfaces of a primary package and of a secondary package, as well as any lining, leaflet and overwrap, must not include a feature that is designed to permit access remotely to any promotion by a means of electronic communication.

Other types of information

(2) The surfaces, lining, leaflet and overwrap may include a feature that is designed to permit access remotely to other types of information by a means of electronic communication if the feature becomes visible only through technological means or meets the requirements imposed by or under the Act, any oth Act of Parliament or any Act of the legislature of a province.

Feature to prevent counterfeiting

18 (1) A feature that is designed to prevent counterfeiting may be displayed on an exterior surface of a primary package or of a secondary package if the feature

(a) is required under an enactment of a foreign government;

(b) is a QR code, DotCode or Data Matrix;

(c) is rectangular in shape and does not contain any image or design;

(d) is no more than 40 mm by 20 mm in size;

(e) has a matte finish and is printed in either black and white or in drab brown and white;

(f) is displayed only once on each package; and

(g) in the case of a package that has a rectangular cuboid shape when it is closed, is displayed on only the exterior surface of the top, bottom or any of the sides of the package.

Definition of *QR code, DotCode* and *Data Matrix*

(2) For the purposes of this section, ***QR code***, ***DotCode*** and ***Data Matrix*** have the same meanings as in Article 21 of the *Commission Implementing Regu (EU) 2018/574 of December 15, 2017 on Technical Standards for the Establishment and Operation of a Traceability System for Tobacco Products*.

Calibration marks

19 Calibration marks that are necessary for the automated manufacturing of a primary package or of a secondary package may be displayed on any of its interior or exterior surfaces, if those marks are not visible when the package is used in the customary manner to gain access to the tobacco product.

Scent and sound

20 (1) The interior and exterior surfaces of a primary package and of a secondary package, as well as any lining, leaflet and overwrap, must not be capab emitting a scent or sound.

Exception — packages made of wood

(2) However, the interior and exterior surfaces of a primary package and of a secondary package that are made of wood may emit the natural scent of the wood.

Cut-out window

21 The interior and exterior surfaces of a primary package and of a secondary package must not include any cut-out window that permits the contents of t package to be visible without opening it.

Sticker and tab

22 (1) Subject to subsections (2) and (5), the interior and exterior surfaces of a primary package and of a secondary package must not include any sticke tab.

Exception — required information

(2) An exterior surface of a primary package and of a secondary package may include an irremovable sticker that displays information required by or und Act, any other Act of Parliament or any Act of the legislature of a province, if the sticker is placed on the package in such a manner that it does not concea obscure any such information on the package.

Sticker — surface

(3) The sticker is deemed to form a part of the surface on which it is placed.

Sticker — requirements

(4) However, only the requirements of sections 9 to 12, subsections 13(1) and 14(1) and sections 17 and 20 apply to the sticker.

Exception — pouch or soft package

(5) An interior and exterior surface of a primary package that is a pouch or a soft package may include a rectangular tab for resealing the package after opening if the tab

(a) does not conceal or obscure any information required by or under the Act, any other Act of Parliament or any Act of the legislature of a province; a

(b) does not display any brand element or any information.

Tab — requirements

(6) Only the requirements of subsection 10(1) and sections 11 and 12, subsections 13(1), 14(1) and 17(1) and section 20 apply to the tab.

Transparent and colourless sticker or tab

(7) Any tab or sticker that covers any information required by or under the Act, any other Act of Parliament or any Act of the legislature of a province must b transparent and colourless.

Lining

23 Except as otherwise provided by these Regulations, any lining that is placed in a primary package must

(a) be white or drab brown;

(b) have a matte finish and no variations in colour tone;

(c) not display any brand element or any information; and

(d) have a smooth texture, without any raised features, embossing, decorative ridges, bulges or other irregularities aside from embossed dots or squa that are required for the automated manufacturing process and that are uniform in size and equidistant.

Overwrap

24 Except as otherwise provided by these Regulations, any overwrap that covers a primary package or secondary package must

(a) mould to the primary package or secondary package that it covers;

(b) be transparent and colourless;

(c) not include any tear tape;

(d) not display any brand element; and

(e) not display any information or features.

Overwrap — more than one primary package

25 If an overwrap covers more than one primary package, the following information and features may be displayed on it:

(a) calibration marks that meet the requirements of section 19;

(b) a bar code, if it is displayed only once on the overwrap, meets the requirements of subsection 16(1) and paragraph 16(2)(a) and is printed directly the overwrap or on a label that meets the requirements of section 11 and subsections 13(1) and 14(1);

(c) a solid black rectangle to cover the bar code on each primary package;

(d) the declaration of net quantity and the common name of the tobacco product, printed in white on a black rectangle, if they are oriented parallel to a the same direction as any information that is displayed on the surface that the overwrap covers; and

(e) a health warning and any other information that is required or authorized by or under the Act, any other Act of Parliament or any Act of the legislatu a province.

Tear tape

26 An overwrap that covers a primary package or secondary package may include a single tear tape that

(a) is made of plastic, is transparent and is either colourless or the colour required by or under an Act of the legislature of a province;

(b) forms a straight line that has a uniform width of no more than 3.5 mm around the package or the width required by or under an Act of the legislatur province;

(c) is parallel to any straight edge of the package and perpendicular to the opening of the package;

(d) is designed in such a manner that the entire overwrap is removed once the tear tape is torn; and

(e) displays only information that is required or authorized by or under the Act, any other Act of Parliament or any Act of the legislature of a province.

Text Size, Style and Placement

Information

Text style and colour

27 (1) Except as otherwise provided by or under the Act, any other Act of Parliament or any Act of the legislature of a province, any text that is displayed o primary package or secondary package, or on any overwrap covering the package, must have a matte finish and be printed in a regular weight and width Lucida Sans Serif font style, without italics, and in gray.

Spacing

(2) The space between every word that forms part of an expression must be no more than 4 mm.

Brand Name

Brand name — no colour or filter characteristic

28 A brand name that is not prohibited by the Act may be displayed in accordance with these Regulations on a primary package and a secondary packag the brand name does not evoke a colour or a characteristic of a filter.

Placement

29 (1) In the case of a primary package or secondary package that has a rectangular cuboid shape when it is closed, the brand name may be displayed o once on each exterior surface of the front, back, top, bottom and sides of the package.

Cylindrical package

(2) Subject to subsection (3), the brand name may be displayed only once on each of the following surfaces of a cylindrical primary package or secondary package:

(a) the exterior surface of the top and bottom of the package; and

(b) the exterior curved surface of the front and back of the package.

Cigar tube

(3) The brand name may be displayed only once on a cigar tube.

Other package

(4) In the case of any other package, the brand name may be displayed only once on each exterior surface of the package.

Text size and style

30 (1) Any brand name that is displayed on a primary package or secondary package must

(a) be printed in alphabetic characters of 14 points; and

(b) form only one line of text.

Capital letter

(2) Only the first letter of each word in the brand name may be a capital letter.

Manner of display

31 (1) If a brand name is displayed on an exterior surface of a primary package or secondary package and a health warning is also displayed on that surface, the brand name must be oriented parallel to and in the same direction as the health warning and must be centered in the area of that surface that remains unoccupied by the health warning and any other information that is required or authorized by or under the Act, any other Act of Parliament or any Act of the legislature of a province.

Other cases

(2) If a brand name is displayed on an exterior surface of a primary package or secondary package, and no health warning is displayed on that surface, the brand name must be

(a) oriented parallel to and in the same direction as any other information that is displayed on that surface and centered in the remaining area of that surface; or

(b) centered on that surface, if no other information is displayed on it.

Exception — cigar tube

(3) Subsections (1) and (2) do not apply to a cigar tube.

Manufacturer Information and Declaration of Net Quantity

Manufacturer identity and principal place of business

32 (1) The manufacturer's identity and principal place of business may be displayed only once on every primary package and secondary package and must be printed in characters of 10 points.

Package — rectangular cuboid shape

(2) In the case of a primary package or secondary package that has a rectangular cuboid shape when it is closed, the manufacturer's identity and principal place of business may be displayed on the exterior surface of only one of the sides of the package.

Manner of display

33 In the case of any package, other than a cylindrical package, the manufacturer's identity and principal place of business must be oriented parallel to and in the same direction as any other information that is displayed on the same exterior surface of the package.

Net quantity and common name

34 (1) The declaration of net quantity and the common name of a tobacco product may be displayed on every primary package and secondary package.

Principal display panel

(2) The declaration of net quantity and the common name of a tobacco product may be displayed only once on each *principal display panel*, as defined in subsection 2(2) of the *Consumer Packaging and Labelling Regulations*.

Manner of display

35 (1) If the declaration of net quantity and the common name of a tobacco product are displayed on an exterior surface of a primary package or of a secondary package and a health warning is also displayed on that surface, the declaration and the common name must be oriented parallel to and in the direction as the health warning.

Other cases

(2) If the declaration of net quantity and the common name of the tobacco product are displayed on an exterior surface of a primary package or of a secor package and no health warning is displayed on that surface, the declaration and the common name must be oriented parallel to and in the same direction any other information that is displayed on that surface.

Placement

36 In the case of a package that has a rectangular cuboid shape when it is closed, the declaration of net quantity and the common name of the tobacco product must be displayed in such a manner that the last letter of that information is 5 mm from the bottom and right edges of the package.

Text size and style — net quantity and common name

37 (1) The declaration of net quantity and the common name of the tobacco product must be printed in characters whose height is no more than the minim height of the numerical quantity in the declaration of net quantity set out in subsection 14(2) of the *Consumer Packaging and Labelling Regulations*.

Definition of *height*

(2) For the purposes of this section, ***height*** has the meaning assigned by subsection 14(1) of the *Consumer Packaging and Labelling Regulations*.

Leaflets

Standardized appearance

38 (1) Except as otherwise provided by or under the Act or any other Act of Parliament, a leaflet must have a matte finish and the text that is displayed on i must be printed in a regular weight and width Lucida Sans Serif font style, without italics, and in either black on a white background or gray on a drab brov background.

Brand name — no colour or filter characteristic

(2) A brand name that is not prohibited by the Act may be displayed on a leaflet in accordance with this section, if the brand name does not evoke a colou characteristic of a filter.

Image

(3) Subject to subsection 17(2), a leaflet must not display any image other than one that warns consumers of the health hazards arising from the use of the tobacco product or that provides instructions for its use.

Risk statement

(4) Any statement respecting a risk arising from the use of the tobacco product may be printed in red.

Specific Requirements — Cigarette Packages

Standardized Physical Design Features and Type of Package

Primary package shape

39 Every primary package that contains cigarettes must have a rectangular cuboid shape when it is closed, having six surfaces that meet at right angles a edges that are rigid and straight, without any rounding or bevelling.

Primary package — requirement

40 A primary package that contains cigarettes must be a slide and shell package with a vertical opening.

Slide and shell package — requirements

41 A slide and shell package must meet the following requirements:

(a) the only way to open it is by using the slide; and

(b) the edges of its upper slide-flap and lower slide-flap must be rigid and straight, without any rounding or bevelling, except at the corners that are concealed by the shell when the package is closed.

Dimensions

42 (1) A slide and shell package that contains regular size cigarettes must have the following dimensions when it is closed:

(a) a height of no less than 72 mm and no more than 77 mm;

(b) a width of no less than 81 mm and no more than 106 mm; and

(c) a depth of no less than 15 mm and no more than 18 mm.

King size cigarettes

(2) A slide and shell package that contains king size cigarettes must have the following dimensions when it is closed:

(a) a height of no less than 84 mm and no more than 89 mm;

(b) a width of no less than 81 mm and no more than 106 mm; and

(c) a depth of no less than 15 mm and no more than 18 mm.

Material

43 (1) Every primary package and secondary package that contains cigarettes must be made of rigid cardboard.

Exception — carton

(2) However, a carton may be made of paper.

Overwrap

(3) An overwrap that meets the requirements of sections 24 to 26 may be used, instead of a carton, to cover two or more primary packages that contain cigarettes.

Lining

44 Any lining that is placed in a primary package that contains cigarettes must

(a) be made of one sheet of silver-coloured foil that is attached to white backing paper and to an interior surface of the package in such a manner that cannot be removed without being damaged; and

(b) meet the requirements of paragraphs 23(b) to (d).

Text Placement

Declaration of size of cigarettes

45 The declaration of the size of cigarettes as regular size or king size may be displayed on the exterior surface of the front and back of a primary packag of a secondary package and it must be printed in alphabetic characters of 10 points, oriented parallel to and in the same direction as the health warning a positioned in such a manner that the first letter of the declaration is 5 mm from the bottom and left edges of the package.

Specific Requirements — Little Cigar Packages

Primary package shape

46 (1) Every primary package that contains little cigars must have a rectangular cuboid shape when it is closed, having six surfaces that meet at right ang and edges that are rigid and straight, without any rounding or bevelling.

Exception — metal package

(2) However, a primary package that is made of metal and contains little cigars — and any carton that contains such a primary package — may have roun or beveled corners.

Material

47 (1) Every primary package that contains little cigars must be made of rigid cardboard or metal.

Secondary package

(2) Every secondary package must be made of rigid cardboard.

Exception — carton

(3) However, a carton may be made of paper.

Overwrap

(4) An overwrap that meets the requirements of sections 24 to 26 may be used, instead of a carton, to cover two or more primary packages that contain lit cigars.

Lining

48 Any lining that is placed in a primary package that contains little cigars must

(a) be made of one sheet of silver-coloured foil that is attached to white backing paper and to an interior surface of the package in such a manner that cannot be removed without being damaged; and

(b) meet the requirements of paragraphs 23(b) to (d).

Specific Requirements — Cigar Packages

Interpretation — primary package

49 Despite these Regulations, a package is considered to be a primary package if it is intended for retail sale in Canada and cigars that are covered by overwraps are directly placed in it.

Overwrap — cigar

50 (1) Any overwrap that covers a cigar must mould to the cigar and meet the requirements of paragraphs 24(b) to (d).

Overwrap — more than one cigar

(2) If an overwrap covers more than one cigar, the information and features referred to in section 25 may be displayed on the overwrap.

Overwrap — primary package

51 An overwrap that meets the requirements of sections 24 to 26 may be used, instead of a carton, to cover two or more primary packages that contain cig

Lining

52 Any lining that is placed in a primary package that contains cigars must

(a) have a smooth texture, without any raised features, embossing, decorative ridges, bulges or other irregularities, unless such features are necessar hold the cigar in place or to remove it from the lining; and

(b) meet the requirements of paragraphs 23(a) to (c).

Specific Requirements — Packages that Contain Devices or Parts Used with Devices

Interpretation — primary package

53 Despite these Regulations, a package is considered to be a primary package if it is intended for retail sale in Canada and a device that is necessary fo use of a tobacco product and that is covered by an overwrap is directly placed in it or a part that may be used with such a device and that is covered by a overwrap is directly placed in it.

Primary package shape

54 Every primary package that contains a device that is necessary for the use of a tobacco product, or a part that may be used with such a device, must h a rectangular cuboid shape when it is closed, having six surfaces that meet at right angles and edges that are rigid and straight, without any rounding or bevelling.

Overwrap

55 (1) Any overwrap that covers a device that is necessary for the use of a tobacco product, or a part that may be used with such a device, must mould to device or part and meet the requirements of paragraphs 24(b) to (d).

Overwrap — more than one device

(2) If an overwrap covers more than one device that is necessary for the use of a tobacco product or more than one part that may be used with such a dev the information and features referred to in section 25 may be displayed on the overwrap.

Lining

56 Any lining that is placed in a primary package that contains a device that is necessary for the use of a tobacco product, or a part that may be used with such a device, must

(a) be made of plastic or rigid cardboard;

(b) have a smooth texture, without any raised features, embossing, decorative ridges, bulges or other irregularities, unless such features are necessar hold the device or part in place or to remove it from the lining; and

(c) meet the requirements of paragraphs 23(a) to (c).

Instructions

57 The exterior surfaces of a primary package and of a secondary package that contains a device that is necessary for the use of a tobacco product, or a that may be used with such a device, may display instructions for the safe handling or storage of the device or part if the instructions

(a) do not contain any promotion, image or design;

(b) are printed in characters of 10 points;

(c) are displayed, in both English and French, only once on the primary package and once on the secondary package;

(d) are displayed only on the exterior surface of any side of the package; and

(e) are oriented parallel to and in the same direction as any other information that is displayed on the same exterior surface of the package.

Specific Requirements — Packages that Contain Tobacco Products Intended for Use with Devices

Primary package shape

58 Every primary package that contains a tobacco product that is made in whole or in part of tobacco and intended for use with a device that is necessary the use of that product must have a rectangular cuboid shape when it is closed, having six surfaces that meet at right angles and edges that are rigid and straight, without any rounding or bevelling.

Lining

59 Any lining that is placed in a primary package that contains a tobacco product that is made in whole or in part of tobacco and intended for use with a device that is necessary for the use of that product must

(a) have a smooth texture, without any raised features, embossing, decorative ridges, bulges or other irregularities, unless such features are necessar hold the product in place or to remove it from the lining; and

(b) meet the requirements of paragraphs 23(a) to (c).

Specific Requirements — Packages that Do Not Contain Tobacco Products

Plain and standardized appearance

60 (1) If a manufacturer of a tobacco product furnishes a package so that a tobacco product may be directly placed in it after the product's retail sale in Canada, the package must meet the requirements of these Regulations that apply to a primary package that contains the tobacco product, other than the requirements of subsection 14(3) and sections 23 and 32 to 37.

Bag

(2) Despite subsection (1), if a manufacturer of a tobacco product furnishes a bag so that a tobacco product, primary package or secondary package ma placed in it after the tobacco product, primary package or secondary package is sold at retail in Canada, the bag must meet the requirements of

(a) section 9;

(b) subsections 10(1) and (2);

(c) sections 11 and 12;

(d) subsection 13(1);

(e) subsection 14(1);

(f) section 15;

(g) subsection16(1) and paragraph 16(2)(a);

(h) sections 17 to 19;

(i) sections 20 and 21;

(j) subsections 22(1) to (4) and (7);

(k) sections 27 and 28;

(l) subsection 29(4);

(m) section 30; and

(n) subsection 31(2).

PART 2

Appearance and Dimensions of Tobacco Products

General Requirements

Appearance

61 Subject to section 62, every tobacco product that is made of tobacco that is rolled in paper or in a wrapper composed of reconstituted tobacco must h smooth texture, without any raised features, embossing, decorative ridges, bulges or other irregularities.

Filter

62 A filter may have holes or recesses that are not visible.

Alphanumeric code

63 (1) A tobacco product may display an alphanumeric code if the code

(a) is printed only once on the tobacco product, in characters of no more than 8 points;

(b) meets the requirements of subsection 15(1) and paragraph 15(2)(a); and

(c) in the case of cigarettes, little cigars, cigars and tobacco products that are made in whole or in part of tobacco, rolled in paper and intended for us

with a device, is oriented parallel to and displayed no more than 38 mm from the end of the product that is not designed to be lit or heated.

Exception — cigars

(2) Despite paragraph (1)(a), instead of being printed on a cigar, the alphanumeric code may be printed on a cigar band that meets the requirements of subsection 71(4) if the code is displayed only once on the band and is printed in characters of no more than 10 points.

Information

(3) The alphanumeric code must not convey any information relating to characteristics of the tobacco product or its emissions.

Brand element

(4) The alphanumeric code must not evoke the tobacco product's brand elements.

Means of electronic communication

64 (1) A tobacco product must not include any feature that is designed to permit access remotely to any promotion by a means of electronic communicati

Other types of information

(2) The tobacco product may include a feature that is designed to permit access remotely to other types of information by a means of electronic communi if the feature becomes visible only through technological means or meets the requirements imposed by or under the Act, any other Act of Parliament or an of the legislature of a province.

Specific Requirements — Cigarettes

Size of cigarettes

65 Cigarettes must have a diameter of no less than 7.65 mm and no more than 8.0 mm and must be

(a) no less than 70.0 mm and no more than 73.0 mm in length, in the case of regular size cigarettes; and

(b) no less than 82.0 mm and no more than 85.0 mm in length, in the case of king size cigarettes.

Requirements

66 A cigarette must meet the following requirements:

(a) the part of its filter, if any, that is visible under normal conditions of use must be white;

(b) the paper that it is made of must be white and have a matte finish; and

(c) its tipping paper must have a matte finish and be white or imitate a cork pattern.

Ventilation holes

67 Despite section 61, the paper that a cigarette is made of, including any tipping paper, may have ventilation holes that do not form any word, image or design.

Specific Requirements — Little Cigars

Size of little cigars

68 Little cigars must have a diameter of no less than 7.0 mm and no more than 8.5 mm.

Requirements

69 A little cigar must meet the following requirements:

(a) its mouthpiece or tip must have a matte finish and be white or drab brown;

(b) the part of its filter, if any, that is visible under normal conditions of use must be white; and

(c) its tipping paper must have a matte finish and be white or drab brown, or imitate a cork pattern.

Specific Requirements — Cigars

Requirements

70 A cigar must meet the following requirements:

(a) any mouthpiece or tip must have a matte finish and be white or drab brown; and

(b) any tipping paper must have a matte finish and be drab brown.

Information on cigar band

71 (1) The following information may be displayed on a cigar if it is displayed on a band that is fitted around the circumference of the cigar and meets the requirements of this section:

(a) a brand name that is not prohibited by the Act, if the brand name does not evoke a colour or a characteristic of a filter;

(b) the manufacturer's identity and principal place of business; and

(c) the name of the country in which the cigar was manufactured.

Requirements — information

(2) The information referred to in subsection (1) may be displayed only once on the band and must

(a) have a matte finish and be printed in a regular weight and width Lucida Sans Serif font style, in characters of no more than 10 points, without italics in gray; and

(b) be displayed horizontally along the length of the band such that the text runs around the circumference of the cigar.

Bar code

(3) A bar code may be displayed only once on the band and must meet the requirements of subsection 16(1) and paragraph 16(2)(a).

Requirements — cigar band

(4) The band must be drab brown and have a matte finish and smooth texture, without any raised features, embossing, decorative ridges, bulges or other irregularities.

Adhesive band

72 (1) The band referred to in section 71 may be placed over another band that does not meet the requirements of these Regulations if it completely cover other band and is attached to it by adhesive and in such a manner that it cannot be removed without the other band being damaged.

Non-compliant band

(2) A band need not meet the requirements of these Regulations if it is completely covered, in accordance with subsection (1), by the band referred to in section 71.

Specific Requirements — Other Tobacco Products

Tobacco products used with a device

73 (1) The requirements of section 66 apply to a tobacco product that is made in whole or in part of tobacco, rolled in paper and intended for use with a device.

Tobacco products not rolled in paper

(2) A tobacco product that is made in whole or in part of tobacco and intended for use with a device but that is not rolled in paper must have a matte finish be drab brown.

Ventilation holes

74 Despite section 61, any paper in which a tobacco product that is intended for use with a device is rolled, including any tipping paper, may have ventilat holes that do not form any word, image or design.

Devices

75 Except as otherwise provided by or under the Act, any other Act of Parliament or any Act of the legislature of a province, the surfaces of a device that is necessary for the use of a tobacco product and of the parts that may be used with the device need not be the natural colour of the materials of which they made.

Marking on a device

76 (1) Except as otherwise provided by or under the Act, any other Act of Parliament or any Act of the legislature of a province, a marking that is not a promotion may be displayed on a device that is necessary for the use of a tobacco product and on a part that may be used with the device.

Exception — brand name

(2) However, a brand name that is not prohibited by the Act may be displayed on a device and on a part that may be used with the device if the brand nar does not evoke a colour or a characteristic of a filter.

Filters

77 The part of a filter that is visible when the filter is used with a tobacco product under normal conditions of use must be white.

Tubes

78 The requirements of paragraphs 66(a) to (c) apply to a tube that is intended for use with a tobacco product.

Paper

79 (1) Any paper — other than tipping paper — that is intended for use with a tobacco product must have a matte finish and be white.

Ventilation holes

(2) Despite section 61, the paper may have ventilation holes that do not form any word, image or design.

Bidis

80 Any thread around the circumference of a bidi must be black.

PART 3

Consequential Amendments, Transitional Provisions and Coming into Force

Consequential Amendments

Tobacco Products Information Regulations

81 Subsection 13(2) of the *Tobacco Products Information Regulations* [1] is repealed.

Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)

82 (1) Paragraph (a) of the definition *top edge* in section 1 of the *Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)* [2] is repea

(2) Paragraph (b) of the definition *top edge* in section 1 of the Regulations is replaced by the following:

(b) in respect of a package, the edge that is in the horizontal plane and that forms the upper limit of the package when the package is used in the customary manner to gain access to the tobacco product; and

83 Section 12 of the Regulations is replaced by the following:

Display areas

12 Health warnings must be displayed in respect of each type of package set out in column 1 of Schedule 1 on the display areas set out in column 2.

84 Subsections 13(2) to (5) of the Regulations are repealed.

85 Section 17 of the Regulations is replaced by the following:

Display areas

17 A toxic emissions statement must be displayed in respect of each type of package set out in column 1 of Schedule 2 on the display areas set out in column 2.

86 Subsections 18(5) to (7) of the Regulations are replaced by the following:

Space occupied

(5) For the purposes of subsections (2) to (4), the toxic emissions statement must completely occupy the portion of the display area.

87 Section 23 of the Regulations is replaced by the following:

Leaflet

23 Subject to section 22, a health information message must be displayed on a leaflet inserted in the package except in the case of cartons.

88 Schedules 1 and 2 of the Regulations are replaced by the Schedules 1 and 2 set out in the schedule to these Regulations.

Transitional Provisions

Definition of *transitional period*

89 (1) For the purposes of this section, *transitional period* means

(a) in respect of all tobacco products and packages that contain tobacco products, including little cigars but no other cigars or packages tha contain other cigars, the period beginning on the day on which these Regulations come into force and ending on the 90th day after that day;

(b) in respect of cigars and packages that contain cigars, other than little cigars, the period beginning on the day on which these Regulations come into force and ending on the 180th day after that day.

Tobacco product or package

(2) During the transitional period, a retailer may sell a package that contains tobacco products or a tobacco product that does not meet the requirements of these Regulations.

Package or bag

(3) During the transitional period, a retailer may furnish a package or bag referred to in section 60 that does not meet the requirements of these Regulations.

Cigarette packages — edges

90 (1) Despite these Regulations, until the second anniversary of the day on which subsection 11(2) of *An Act to amend the Tobacco Act and the smokers' Health Act and to make consequential amendments to other Acts*, chapter 9 of the Statutes of Canada, 2018, comes into force, a primar package that contains cigarettes may have edges that are rounded and beveled and not rigid and straight.

Retailers

(2) Despite subsection (1), a retailer may continue to sell a primary package or a secondary package that contains cigarettes and whose edges ar rounded and beveled and not rigid and straight until the day that, in the 27th month after the month in which subsection 11(2) of *An Act to amend Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other Acts*, chapter 9 of the Statutes of Canada, 2018, comes into force, has the same calendar number as the day on which that subsection comes into force or, if that 27th month has no day with that number, the last day of that 27th month.

Coming into Force

S.C. 2018, c.9

91 (1) Subject to subsections (2) and (3), these Regulations come into force on the day on which subsection 11(2) of *An Act to amend the Tobacc and the Non-smokers' Health Act and to make consequential amendments to other Acts*, chapter 9 of the Statutes of Canada, 2018, comes into fo

First anniversary

(2) These Regulations come into force, in respect of cigars and packages that contain cigars, other than little cigars, on the first anniversary of th day on which subsection 11(2) of *An Act to amend the Tobacco Act and the Non-smokers' Health Act and to make consequential amendments to other Acts*, chapter 9 of the Statutes of Canada, 2018, comes into force.

Second anniversary

(3) The following provisions come into force on the second anniversary of the day on which subsection 11(2) of the *Act to amend the Tobacco Ac and the Non-smokers' Health Act and to make consequential amendments to other Acts*, chapter 9 of the Statutes of Canada, 2018, comes into fo

(a) sections 40 to 42; and

(b) sections 61 and 62, in respect of tobacco products that are made in whole or in part of tobacco and intended for use with a device.

SCHEDULE

(Section 88)

SCHEDULE 1

(Section 12 and subsection 14(3))

DISPLAY AREAS FOR HEALTH WARNINGS

Item	Column 1 Type of Package	Column 2 Display Areas
1	Slide and shell package	The two largest sides of the package
2	Slide and shell package with a lateral slide	The two largest sides of the package
3	Box that is not a carton	If the two largest sides, excluding the top and bottom of the package, have a total surface area greater than the surface area of t top, the two largest sides If the two largest sides, excluding the top and bottom of the package, have a total surface area less than or equal to the surface a of the top, the top
4	Carton	The two largest sides of the package are the two primary display areas and the next two largest remaining sides are the two secondary display areas

SCHEDULE 2

(Section 17)

DISPLAY AREAS FOR TOXIC EMISSIONS STATEMENTS

Item	Column 1 Type of Package	Column 2 Display Areas
1	Slide and shell package	A side, other than that on which a health warning is displayed, excluding the top and bottom of the package
2	Slide and shell package with a lateral slide	A side, other than that on which a health warning is displayed, excluding the top and bottom of the package
3	Box that is not a carton	If the health warnings are displayed on sides other than the top of the package, one of the largest remaining sides, excluding the bott If the health warning is displayed on the top of the package, one of the largest remaining sides, excluding the bottom
4	Carton	The remaining sides, other than the sides on which the health warnings are displayed

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations or the Order.*)

Executive summary

Issues: Tobacco use is the leading preventable cause of illness and premature death in Canada. Eighty-six percent of smokers smoke their first cigaret before the age of 18. Youth are particularly vulnerable to both nicotine addiction and the promotion of tobacco products. Rates of tobacco use have not declined meaningfully in the past several years, and tobacco use among youth and young adults remains unacceptably high. Measures aimed at reducing the appeal of tobacco packages and the products they contain are expected to help further reduce inducements to tobacco use. These measures, in association with other tobacco control measures, will contribute to preventing youth and others from tobacco initiation and their consequer dependence on tobacco products.

Description: The *Tobacco Products Regulations (Plain and Standardized Appearance)* [the Regulations], made pursuant to paragraphs 7(a) and 33(a) the *Tobacco and Vaping Products Act* (the Act), include measures that standardize the appearance of tobacco product packages, as well as the appearance of the tobacco products themselves, including the information on tobacco packages and tobacco products. The Regulations also make consequential amendments to the *Tobacco Products Information Regulations* (TPIR) and the *Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)* [TPLR]. In addition, the *Order Amending Schedule 1 to the Tobacco and Vaping Products Act (Colouring Agents)* aligns the restrictions on the use of colouring agents with the requirements set out in the Regulations.

Cost-benefit statement: The Regulations will impose a variety of costs on the tobacco industry and the Government of Canada. The cost-benefit analy (CBA) estimates that the total monetized costs associated with the Regulations would range from $138.4 million to $195.9 million (present value [PV]). T analysis suggests that relatively small effects on smoking initiation and cessation rates over the next 30 years — in the order of a 0.03% increase in the annual rate of cessation and a 0.03% decline in initiation rates — would be sufficient to produce public health benefits equivalent to or greater than the estimated monetized costs.

"One-for-One" Rule and small business lens: The "One-for-One" Rule does not apply, as there is no change in administrative costs to business; however, the small business lens applies. A flexible option that would allow packages to remain on the market for an additional six months was considered, which would amount to a $1,900 saving to small business manufacturers; however, the original proposal has been retained since the flexibl option would undermine the purpose of the Regulations without greatly reducing small business costs. Health Canada will undertake targeted complian promotion to facilitate the transition for all small businesses (manufacturers and retailers).

Domestic and international coordination and cooperation: Plain packaging is supported by the World Health Organization Framework Convention o Tobacco Control (FCTC), to which Canada is a party. Guidelines adopted in 2010 for the implementation of articles 11 and 13 of the FCTC recommend that parties consider introducing plain packaging measures. Country-specific plain packaging action is emerging across the globe, with measures implemented in 6 countries: Australia (2012); the United Kingdom (2017); France (2017); and Ireland, Norway and New Zealand (2018). Hungary, Slovenia and Uruguay have announced implementation dates by 2020. Over 18 other countries have announced their intention to introduce plain packaging measures.

Background

Tobacco use is the leading preventable cause of premature death in Canada, [3] having a role in causing over 40 diseases and other serious negative heal outcomes. [4] In 2012, there were over 45 000 Canadian deaths attributable to smoking, and the Canadian economy incurred $6.5 billion in direct health ca costs and $16.2 billion in combined health and economic costs. [5]

In response to the substantial and pressing concern of tobacco-related death and disease, Parliament adopted the Act, which replaced the *Tobacco Act*, regulate the manufacture, sale, labelling and promotion of tobacco products and vaping products. This legislation protects all Canadians, with a particular emphasis on youth, from the inducements of tobacco use, the consequent dependence on them and the health hazards of using tobacco products. The A

also sets out the authorities under which the Regulations are made.

The Government of Canada addresses the public health problem of tobacco use through its federal tobacco strategy, which was introduced as the Federa Tobacco Control Strategy (FTCS) in 2001 and replaced by Canada's Tobacco Strategy (CTS) in 2018. CTS focuses on helping Canadians quit using tobac protecting youth and non-tobacco users from nicotine addiction, strengthening the foundations in science, surveillance and partnerships and working with national and regional Indigenous organizations. It is estimated that changes in cigarette initiation and cessation rates from 1999–2015 reduced the excess deaths attributable to cigarette smoking by an estimated 31 700 deaths, which totals approximately $330 billion * (PV) in total health benefits. [6] This is the result of comprehensive, ongoing and collaborative efforts under the FTCS, along with tobacco control strategies from other federal, provincial and municip partners.

According to the World Health Organization (WHO), Canada has already implemented most of the internationally recognized tobacco control measures. [7] Some of Canada's key accomplishments under the FTCS include the following:

- In 2009, Parliament amended the Act to ban appealing additives, including flavours in cigarettes and little cigars, to further protect youth from marke tactics aimed at them.
- In 2011, the *Promotion of Tobacco Products and Accessories Regulations (Prohibited Terms)* came into effect, prohibiting the use of the terms "light" "mild" in the promotion of tobacco products, including on the packaging.
- In 2012, the TPLR came into effect, increasing the size of health warnings (HWs) to 75% of the front and back of cigarette and little cigar packages, a with including a toll-free quit line number and web address in the warnings.

Although these measures have helped reduce tobacco use in Canada, there are still 5.3 million tobacco users in Canada. In 2017 alone, approximately 91 Canadians became daily smokers. [8] Most tobacco use begins during adolescence. Eighty-six percent of adult daily smokers in Canada (age 25 and olde began by the age of 18. [9] In 2016–2017, students in grades 7 to 12 (secondary 1 to secondary 5 in Quebec) reported the average age for smoking a cigarette for the first time was 13.6 years. [10] Young persons are particularly sensitive to the dependence-causing effects of nicotine in tobacco and report symptoms of dependence even at low levels of cigarette consumption. [11] Furthermore, they are disproportionately at risk of taking up and developing lon term dependence to tobacco. Rates of tobacco use for youth and young adults remain unacceptably high, suggesting that more needs to be done to prot youth and young adults from inducements to use tobacco, the dependence that can result and the health hazards of using tobacco products.

The appearance of tobacco packages and products has been shown to be an inducement to tobacco use among youth and young adults. Among others, 2012 report by the U.S. Surgeon General concluded that "tobacco companies have changed the packaging and design of their products to increase their appeal to adolescents and young adults." [12] Promotional effects of tobacco packages and products may be particularly effective on impressionable adolescents and young adults, as this is when brand loyalty and smoking behaviour are beginning to be established. [13] Given the strength of nicotine addiction and the severe health consequences that can result from tobacco use, it is imperative that additional measures be taken to prevent tobacco initi and use, particularly among young persons.

The Government of Canada has undertaken new initiatives to further reduce tobacco use and tobacco-related death and disease. This includes a ban on menthol flavoured tobacco products, a new regulatory approach under the authorities of the Act to regulate vaping products and the addition of new provi in the Act to support the implementation of measures to standardize the appearance of tobacco product packaging and tobacco products.

Branding, packaging and product design as promotional tools

Under the Act, promotion by means of tobacco product packaging has only been subject to specific prohibitions (e.g. false, misleading or deceptive prom and promotion of prohibited additives on packaging). Therefore, packaging is one of the few remaining channels available for the promotion of tobacco products in Canada and the only promotional outlet for reaching youth.

Some provisions of the Act, which will come into force by order in council at the same time as the Regulations, will further restrict promotion of tobacco products by means of packaging and by the appearance of products themselves. Once the provisions are in force, the promotion of tobacco products by means of packaging and markings on tobacco products will be prohibited except to the extent that they are expressly permitted by law or by regulation. T Regulations will standardize the appearance of tobacco packages and the products they contain to limit their promotional effect and to better protect Canadians, and especially young people, from inducements to tobacco use.

Branding

The definition of "brand element" under the Act "includes a brand name, trade-mark, trade name, distinguishing guise, logo, graphic arrangement, design slogan that is reasonably associated with, or that evokes, a product, a service or a brand of product or service, but does not include a colour." Product branding is an important aspect of marketing, as characteristics associated with a brand can trigger an emotional connection with the consumer, which ca dictate which brand of product they choose and whether or not they remain loyal to that particular brand. [14] Distinct product brand personalities can distinguish products from each other and also target specific consumers who share those traits or wish to share those traits. [15] Tobacco products are ofte referred to as "badge products," in that they have a high degree of social visibility when being used and the users endorse the product while making a statement about themselves. [16]

Tobacco companies are aware of this, [17], [18] with one company stating that "to serve as a badge, a product/brand must be something of which the consu feels they want to utilize as a statement about themselves." [19] The brand imagery has two roles: (1) it provides the user with a sense of self; and (2) it prov an identity when seen by others (image). The second function is particularly important among youth and young adults. [20]

Numerous studies, including those conducted by the tobacco industry, demonstrate that tobacco packaging and the products they contain are extensively used to promote tobacco products and the brand image. Some tobacco industry documents have suggested that packaging alone could be enough to promote brand imagery. [21]

Research has found that tobacco companies continue to use aspects of the package, such as specific branding elements, colour, typography and packag format to promote tobacco products in a manner that renders them particularly attractive to youth. [22], [23], [24], [25] Young adult smokers associate cigarette branding with positive personal characteristics, social identity and status. [26]

Packaging

Tobacco packages are a unique marketing tool in that they also have a high degree of social visibility because they are frequently on display (e.g. each tir cigarette is taken out of the package or each time the package is shared with others). They are carried around by the user until all the cigarettes are consu [27] and have been referred to as the "silent salesman" [28] because of their inherent and portable promotional power. Research demonstrates that standard cigarette packages to a single package shape, size and opening could minimize the ability for cigarette packages to be used as a promotional tool. [29], [3 [31], [32]

Tobacco companies have conducted considerable market research on all aspects of packaging (e.g. colour, size, shape and opening) to increase their ap to various target groups, such as women (young women in particular), youth and young adults. It has been shown that novel packaging used by tobacco companies make their products more appealing to youth [33] and influence perceptions of risk that tobacco use presents among consumers. [34], [35] Such packages are also associated with a greater number of positive attributes, including glamour, slimness and attractiveness, compared to brands without descriptors and "plain" packages. [36], [37] For example, to target young women, slim and thin cigarette packages, often referred to as "purse packs," were designed to be easier to carry in one's purse. These slimmer packages have been found to increase the attractiveness of packages and the cigarettes the contain are more likely to be perceived as milder and less harmful. [38] Packages with novel openings and shapes are often perceived as being more contemporary and modern, and packages with rounded or "beveled" edges, or with octagonal shapes, convey stylishness, elegance and class. [39] In addition, package appeal and attractiveness are directly correlated to the ability of the package design to distract from the HWs [40], [41] and to increase product purchase and trial intentions. [42]

Studies show that package design, brand imagery and colours can also impact consumer perception of the risks of the use of tobacco products and their characteristics, such as product strength. [43], [44] Characteristics such as package shape and opening style affect smokers' perception of the product, [45] and novel package shapes (e.g. octagonal) and openings are associated with positive brand imagery and are particularly appealing to youth and young adults. [46] Furthermore, smokers associate tobacco products in smaller shaped packages with reduced health risks. [47], [48]

Tobacco product packages can also be designed in such a way as to distract attention from HWs and have an impact on HW salience. Studies indicate th brand imagery displayed on branded tobacco packages has the ability to diffuse the impact of HWs. [49], [50], [51], [52], [53] For example, novel package shapes reduce the visibility of HWs [54], [55] Distractions can also be accomplished by incorporating the colours of the HWs into the package design, causir the message to blend with the package and reducing its saliency. [56] It was also noted that super slim packages were found to undermine the HWs displa on the package. [57]

Tobacco products that are in packages that have lighter shades of colour and more white space are perceived as having a lower strength and causing les harm. [58], [59], [60], [61] Packages with darker colours were perceived to be more "harmful to health" and their products "harder to quit," in contrast to packages with lighter colours. [62] Similarly, a study in France observed that package colour has a significant impact on beliefs about the health risks of tobacco products and their content, concluding that plain packages were associated with fewer false beliefs. [63] Evidence from Australia following the implementation of plain packaging suggests that the use of colour names on tobacco packages can also convey false beliefs about the harms of tobacco products. Despite standardization of the package colour, the incorporation of colour names into brand variant descriptors may have continued to reinforce beliefs that some variants are less harmful than others among smokers. [64] Tobacco manufacturers have also begun to use filter characteristics, such as "F Refreshing Crushball," in their brand names to help differentiate their brands. [65] Brand names were being used not only to convey the technology of a filte such as a "taste flow filter," but also to convey a characteristic of a filter, such as the presence of menthol, through names like "Ice Blast," for example.

Tobacco packages currently available on the market are designed to be appealing and target certain Canadian market segments. For instance, pink and pastel colours for tobacco packages target young women. [66] Studies show that these colours evoke positive qualities, such as freshness, cleanliness, pur health and intelligence. [67] Such studies also show that the tobacco product package can be used to evoke positive characteristics, such as glamour, bea femininity, masculinity and fun, with the tobacco product it contains. [68] Advances in printing technologies have also allowed for branding elements on the outer film and tear tape of the package, along with the use of holograms on the tobacco package, [69] both of which can make the product more appealing Tobacco industry documents indicate that the tobacco package can be used to comfort smokers and ease or alleviate the feelings of guilt and social rejec in connection with their tobacco use. [70]

Product design

Like the package, tobacco products can also be designed in a format that is more appealing to their target demographic. For instance, the appearance of cigarette is used to communicate brand attributes and imagery that appeal to the smoker [71], [72], [73], [74] and like the package, functions as a badge produ in that it has a high degree of social visibility and is carried around until it is consumed. [75] A cigarette's appearance has the potential to influence smokers non-smokers as well as generate significant interest in the product, particularly among youth and young adults. [76], [77] The appearance of a cigarette has been shown to strongly influence smoking initiation. [78] Documents from the tobacco industry suggest that the appearance of cigarettes has been modifie appeal to specific segments of the population, including both young adults and women, [79] ultimately increasing sales and market share. [80], [81] An examp of such a modification to the appearance of cigarettes is the use of floral and satin tipping paper to target females. [82] Variations in the tobacco product dimensions also contribute to conveying misconceptions about the product's health effects and characteristics (such as strength). For example, studies sh that slim diameter cigarettes often convey a weaker or milder taste and the false belief that they are less harmful. [83]

What is meant by plain and standardized packaging

The expression “plain and standardized packaging” refers to packages without any distinctive or attractive features, which are similar in appearance and c same ordinary colour. Plain packaging is supported by the FCTC, which Canada has ratified and which came into force in 2005. Guidelines adopted in 20 the implementation of articles 11 and 13 of the Convention recommend that Parties consider introducing plain packaging measures, with a recommended practice to apply such measures to all tobacco products.

In 2012, Australia became the first country in the world to introduce plain packaging, followed by the United Kingdom (2017), France (2017), and Ireland, Norway and New Zealand (2018). Hungary, Slovenia and Uruguay have announced implementation dates by 2020. At least 18 other countries have annou their intention to introduce plain packaging measures, including Belgium, Botswana, Chile, Finland, The Gambia, Georgia, Kenya, Malaysia, Mauritius, Nep Romania, Singapore, South Africa, Sri Lanka, Taiwan, Thailand, Turkey and Saudi Arabia.

Studies show that plain packaging measures reduce the promotional effect of packages and tobacco products themselves. [84], [85] Removing the brand image from tobacco packages makes the packages less appealing. [86] Independent studies, spanning at least two decades and multiple countries, have unequivocally demonstrated that plain packaging is perceived as less attractive and less appealing, particularly among youth and young adults. [87]

In preparation for plain packaging regulations in Australia, a qualitative study was conducted to test a number of different colours to determine their level c appeal. The dark, drab brown colour package was considered to be the least appealing package overall and the least likely to induce tobacco use; the package more likely to contain lower quality cigarettes; the package posing the highest harm to health; the package containing harder to quit products; ar the package containing cigarettes that users would be less likely to consider smoking. [88] To date, a dark, drab brown (Pantone 448C) is the package colc selected by all countries that have implemented plain packaging measures for tobacco products. Health Canada also commissioned public opinion research (2016–17) that confirmed that the Canadian population findings were consistent with those for Australia, whereby Pantone 448C, a dark, drab brc was considered to be an unappealing colour. [89]

Studies have also shown that plain packaging measures contribute to the public’s awareness of the health risks of tobacco use by increasing the salience graphic HWs that are required on packaging. Some studies indicate that HWs were more noticeable and effective when displayed on plain packages whe compared to branded packages. [90], [91], [92], [93]

Standardizing the appearance of tobacco products by mandating the colour of the paper and of the permitted inscriptions on them helps reduce the appe the tobacco product and minimizes the opportunity for the product appearance to mislead consumers about the harms of tobacco use. [94], [95] Results fror the public opinion research (2016–17) varied in terms of preference for colours; however, there was a strong indication that any new colour on a tobacco product would be seen as novel and would generate curiosity (e.g. a yellow cigarette). [96] On the other hand, there was a clear finding that removing bran from the cigarette stick would decrease the appeal of cigarettes. [97], [‡]

Issues

Tobacco use is the leading preventable cause of illness and premature death in Canada. Preventing initiation of tobacco use by young persons and others one of the most effective means of reducing nicotine addiction, tobacco use and the associated health risks.

Rates of tobacco use have not declined meaningfully in the past several years, and tobacco use among youth and young adults remains unacceptably hig Numerous studies, including those conducted by the tobacco industry, demonstrate that tobacco packaging and the products they contain are designed t make them attractive to particular segments of the population, such as youth and young adults. More needs to be done to lower tobacco use rates, espec for the youth and young adult segment of the population.

Objectives

Reducing the appeal of tobacco packages and the products they contain will reduce inducements to tobacco use. The Regulations, in association with otl tobacco control measures under CTS, aim to prevent youth and others from tobacco initiation, from developing an addiction to nicotine and from the consequent health hazards of tobacco use.

The Regulations will directly support two of the four tobacco-related objectives of the Act:

(1) To protect young persons and others from inducements to use tobacco products and the consequent dependence on them; and

(2) To prevent the public from being deceived or misled with respect to the health hazards of using tobacco products.

The Regulations, in association with other tobacco control measures under CTS, are expected to contribute to these objectives.

Description

In order to achieve the objectives outlined above, Health Canada is introducing the new Regulations, including consequential amendments to the TPIR an TPLR, and an order amending Schedule 1 to the Act with respect to colouring agents.

The Regulations will standardize the appearance of tobacco packages and products through general requirements applicable to all tobacco products, as as through specific requirements applicable to individual tobacco product types (e.g. tobacco that is rolled in paper or in a wrapper composed of reconsti tobacco). For instance, all tobacco product packages will be of the same drab brown colour, bearing only the permitted text displayed in a standard locati font style, colour and size. The size and shape of cigarette packages will also be standardized. Tobacco products will be plain in their appearance, bearin only the permitted text in the prescribed location, font style, colour and size. The colour of most tobacco products will be prescribed. Cigarette dimensions the diameter of little cigars will also be standardized.

The Regulations will also apply to devices necessary for the use of a product made in whole or in part of tobacco, such as heated tobacco products (HTPs and their packages, as they are defined as “tobacco products” under the Act.

Tobacco Products Regulations (Plain and Standardized Appearance)

The measures for tobacco packages include the following:

- Standardize tobacco product packages' overall appearance (e.g. no embossing, or other distinct visual or tactile features on the exterior or interior surfaces of tobacco product packages);
- Require a single ordinary colour (Pantone 448C — drab brown with a matte finish) on all exterior surfaces of tobacco product packages and all interi surfaces (for materials other than wood and metal);
- Authorize the display of a brand name on the package, in a standard font style (Lucida Sans Serif), size, colour (Pantone Cool Gray 2C) and location except for brand names that are prohibited by the Act or that evoke a colour or characteristic of a filter;
- Require a standard font style (Lucida Sans Serif), size and colour (Pantone Cool Gray 2C) for permitted information displayed on packages (e.g. nan and address of the manufacturer, net quantity and common name of the product, alphanumeric code, barcode and safe handling and storage inform for device packaging);
- Limit package contents to a lining, a leaflet and a tobacco product;
- Standardize the format (slide and shell), shape (rectangular cuboid, no rounded or beveled edges), material and dimensions for cigarette packages;
- Specify requirements for package lining;
- Specify the shape and material requirements for little cigar packages (rectangular cuboid, no rounded or beveled edges);
- Specify the shape (rectangular cuboid, no rounded or beveled edges) for packages containing devices and their parts and packages containing tob products intended for use with these devices;
- Specify the shape for all cartons and other secondary packages (i.e. packages that contain tobacco product packages);
- Require plain and standardized packaging for cigarette cases/bags furnished by a tobacco manufacturer; and
- Authorize the display of an alphanumeric code in a standardized size, font, colour, and placement and of an anti-counterfeiting marking required unc enactment of a foreign government in a standardized size, shape, placement and colour on tobacco packaging.

The measures for the appearance of tobacco products include the following:

- Standardize the appearance by only allowing the use of standard colours (e.g. white or drab brown Pantone 448C with a matte finish) for cigarettes a other tobacco products that can be coloured (including cigarettes, mouthpieces/tips, tubes and a tobacco product that is intended for use with a de
- Allow the display of an alphanumeric code on the tobacco product with a standardized appearance (colour, font style, size and placement) on tobac products (e.g. cigarettes, little cigars, cigars and tobacco products made in whole or in part of tobacco, rolled in paper and intended for use with a device);
- Require a standard colour and prohibit apparent designs (e.g. grooves, holes or recesses) on visible parts of the cigarette (filters, paper, etc.), and fo tobacco products intended for use with devices;
- Require cigarettes to be one of two standard lengths, reflecting regular and king size cigarettes;
- Require a standard diameter for cigarettes and little cigars; and
- Authorize the display of a standardized brand name on cigar bands and devices and their parts.

As a result of these requirements, the Regulations will reduce the inducing effect that a branded package and product may have on the consumer and als prevent current promotional practices known to increase the appeal of tobacco products, such as:

- Packages with rounded or "beveled" edges, or with octagonal shapes;
- Packages with novel openings and shapes;
- Slim and thin cigarette packages;
- Slim diameter cigarettes; and
- Use of colours on packages and products that increase the product's appeal or that may create an erroneous impression with respect to the product health effects or hazards.

Order Amending Schedule 1 to the Tobacco and Vaping Products Act (Colouring Agents)

Schedule 1 to the Act specifies which additives (column 1) can be used in the manufacture of a tobacco product (column 2). The tobacco products listed column 2 exclude products that are manufactured or sold for export.

Item 4 of Schedule 1 to the Act, which allows the use of whitening agents to whiten the paper or filter or colouring agents to imitate a cork pattern on the tip paper of cigarettes, will be amended to include a new list of tobacco products. In addition to cigarettes, the list will now include tubes and tobacco produc rolled in paper and intended for use with a device.

Item 4.1 of Schedule 1 to the Act, which prohibits the use of any colouring agents in blunt wraps, will be amended to also apply to leaf tobacco.

Items 4.2, 4.3 and 4.4 of Schedule 1 to the Act, which allow the use of whitening agents and the use of white and brown or bronze as colouring agents in certain cigars and little cigars, will be amended to replace brown or bronze with Pantone 448C, a drab brown.

Item 4.5 will be new and added to Schedule 1 to the Act and will allow the use of Pantone 448C, a drab brown, as a colouring agent to colour tobacco pro that are made in whole or in part of tobacco and that are intended for use with a device, but that are not rolled in paper.

Item 4.6 will be new and added to Schedule 1 to the Act and will prohibit the use of colouring agents in filters and papers intended for use with a tobacco product, except for whitening agents.

Item 4.7 will be new and added to Schedule 1 to the Act and will prohibit the use of colouring agents in bidis, except for those used to render the thread a a bidi black.

Consequential amendments

There will be consequential amendments to the TPIR and the TPLR as a result of the Regulations. These amendments are meant to repeal provisions that a no longer applicable as a consequence of the Regulations, such as regulatory requirements for package formats that will no longer be permitted (e.g. soft packages for cigarettes).

Coming into force

Certain provisions of the Act, referred to in subsection 11(2) of *An Act to amend the Tobacco Act and the Non-smokers Health Act and to make consequer amendments to other Acts* (An Act to amend the Tobacco Act), and relating to promotion by means of the packaging and the markings on the tobacco products will come into force on a date to be fixed by order in council, which will be 200 days after the day the Order in Council is made. The coming into of the Regulations will be coordinated with that day.

The majority of the provisions of the Regulations will come into force on the day on which subsection 11(2) of An Act to amend the Tobacco Act comes into force, which will be 200 days after the day that the Order is made. However, specific provisions will have a phased implementation timeline to support compliance:

(1) Requirements for cigars and packages that contain cigars will come into force one year after the day on which subsection 11(2) of An Act to amend the Tobacco Act comes into force, that is, one year after the day on which the majority of the provisions of the Regulations come into force.

(2) Certain appearance requirements for tobacco products intended for use with a device will come into force two years after the day on which subsection 11(2) of An Act to amend the Tobacco Act comes into force, that is, two years after the day on which the majority of the provisions of the Regulations come into force.

(3) Certain requirements for cigarette packaging (e.g. slide and shell, package dimensions) will come into force two years after the day on which subsection 11(2) of An Act to amend the Tobacco Act comes into force, that is, two years after the day on which the majority of the provisions of the Regulations come into force.

Retailers of tobacco products will have an additional 90 days after the day on which subsection 11(2) of An Act to amend the Tobacco Act comes into forc comply with the Regulations. However, retailers will have an extra 180 days after the day on which the relevant provisions of the Regulations come into forc comply with requirements for cigars and their packages.

The *Order Amending Schedule 1 to the Tobacco and Vaping Products Act (Colouring Agents)* and the consequential amendments to the TPIR and to the T will come into force 180 days after the day on which subsection 11(2) of An Act to amend the Tobacco Act comes into force. Certain amendments to Schedule 1 applicable to colouring agents used in cigars will come into force one year after the day on which subsection 11(2) of An Act to amend the Tob Act comes into force.

Regulatory and non-regulatory options considered

Status quo

This option would have maintained the existing legislative regime with respect to promotion, including the limited restrictions on tobacco product promotio means of the packaging and of the product's appearance. Tobacco packages and the products they contain would have remained a powerful promotiona vehicle for the tobacco industry. Research has found that the tobacco industry uses packaging to promote product brand elements preferred by youth. [98] Maintaining the status quo would have meant that tobacco products could have continued to be offered in stylish and colourful branded packages and wo have therefore remained appealing to youth and young adults.

Therefore, the status quo was not considered to be an appropriate option.

Regulatory options

(a) Plain and standardized packaging for cigarettes and little cigars and plain branded cigarettes

This option considered adopting measures to standardize the appearance (i.e. colour, permitted text) and shape of cigarette and little cigar packages only which account for 93% of the Canadian tobacco market. Under this option, the size of cigarette packages and the appearance of cigarettes (e.g. prescrib font style, size and colour for brand names; prescribed colour for the paper) would have also been standardized. These measures would have been comparable to those of the United Kingdom in that the measures would have only applied to a subset of tobacco products.

All other tobacco products would have continued to be offered in stylish and colourful branded packages and with features that are known to be appealing youth and others. The cigarettes without branding would have continued to be offered in various sizes, such as slim cigarettes, which have been shown to appealing to females and are often misconceived as being less harmful to health.

Experience has shown that when some tobacco products are exempted from the application of regulatory measures, marketing strategies are adapted to from the exemption. For example, in 2009 when the flavour ban on little cigars was introduced, the weight of many brands of little cigars was increased slig so that the product would no longer fall within the statutory definition of "little cigar" and could continue to be marketed with flavours and packaging appea to youth.

Considering that all tobacco products are addictive and harmful, this option would not have achieved the objectives of reducing inducements to use tobac products and the consequent dependence on them.

(b) Plain and standardized packaging for all tobacco products and plain unbranded cigarettes

This option considered new measures to standardize the appearance and shape of cigarette and little cigar packages as well as the appearance of all oth tobacco product packages. This option would have also included measures to standardize the size of cigarette packages and appearance of cigarettes (e no brand elements; prescribed font style, size and colour for alphanumeric code; prescribed colour for the paper), except for cigarette size/dimensions, si to what is done in Australia.

This option was not considered to be optimal as it would have continued to allow for variations in cigarette sizes (e.g. slim and super slim cigarettes), whic known to be an effective marketing tactic to entice youth, women and others, and often lead to misconceptions with respect to the danger posed by the product to users' health.

(c) Recommended option: Plain and standardized packaging for all tobacco products and plain unbranded cigarettes of a standardized size

Requiring a plain and standardized appearance for all tobacco packages and products is considered the most appropriate option. This option consists of measures to standardize the appearance of all tobacco packages (e.g. a drab brown, Pantone 448C, no distinctive visual or tactile features) and the appearance of tobacco products (e.g. prescribed font style, size and colour for alphanumeric code; prescribed colour for the paper), including specific requirements to standardize the cigarette package type to slide and shell only with a prescribed size, shape and material. The dimensions of cigarettes an diameter of little cigars are also standardized.

This option is recommended as it is more likely to meet the objectives of the Act. This option integrates the Australian approach to plain packaging, with adaptations to take into account the findings of more recent studies, including Canadian studies, as well as feedback from Canadian public consultations from international experience with plain packaging.

Since the introduction of plain packaging internationally, some companies have found ways to circumvent the plain packaging measures and continue to market their products with distinctive branding and features. For example, following the introduction of plain packaging in Australia, package fillers were introduced to allow for slim and super slim size cigarettes to continue to be sold in the new standard package size. The Regulations limit package content lining, a leaflet and a tobacco product and standardize the products themselves, thereby preventing the marketing of slim and super slim cigarettes, or oth novel appealing sizes.

Package shape

Mandating only one package type for cigarettes has the potential to reduce the promotional power of the package [99], [100] and prevent deceptive messag about the risk of smoking based on package size [101], [102] and has been part of all comprehensive plain packaging initiatives internationally. It prevents tobacco manufacturers from differentiating their products based on package type, mitigating their capacity to microsegment the market. The Regulations therefore limit cigarettes to a single package type, slide and shell. Among other features, slide and shell packages generally have a larger surface area tha flip-top packages, meaning the HWs they must display (both text and pictures) are larger in absolute size. In addition, HW labels are less likely to be obsc on slide and shell packages, given that they are opened by a sliding mechanism through the side of the package; in contrast, the opening mechanism for top packages has the potential to split design elements of the HW. The potential for slide and shell packages to carry larger HWs and HWs that are not obscured may enhance the noticeability of the warnings, which is considered a best practice in warning label design and implementation. [103], [104] In addition, health information messages (HIMs) are printed permanently on the slide and shell package; in contrast, HIMs for flip-top packages are printed o loose inserts placed in the package, which can be separated from the package and discarded. The potential for slide and shell packages to retain the HIM with the package may improve their chances of being read. This may be advantageous, as evidence shows that more frequent reading of HIMs is associa with increased confidence to quit, quit attempts, and sustained quitting among smokers. [105]

Restricting package type to slide and shell will contribute to both plain and standardized appearance (PSA) objectives to reduce inducements to use toba products, and to prevent the public from being deceived or misled with respect to the health hazards of using tobacco products.

Brand names

Areas not covered in the Australian plain packaging regulations have allowed industry to innovate and adapt marketing strategies to continue to promote b imagery, variant names and filter technology modifications through the brand names themselves. For example, in Australia, "Dunhill Infinite" is now "Dunhil Infinite White + Taste Flow Filter." The Regulations include measures to prevent this type of practice.

Benefits and costs

Overview of the tobacco industry in Canada

In 2015, manufacturers and importers of the tobacco industry reported sales of tobacco products in Canada — including federal excise duties imposed u the *Excise Act, 2001* — totalling $6.91 billion. This wholesale value is driven primarily by sales of cigarettes, which in 2015 accounted for approximately 93 of the total value. Of these cigarette sales, approximately 42% were imported cigarettes. The remainder of the wholesale market is made up of cigars at 2.5 cigarette tobacco at 2.3%, smokeless tobacco at 1.5%, pipe tobacco at 0.1% and kreteks at 0.02%.

The market for cigars is distinct from the market for cigarettes and other tobacco products. The market for cigars is characterized by a high degree of brar differentiation; 26 companies currently sell more than 2 800 distinct brands (3 450 stock keeping units [SKUs]).

Heated tobacco products only recently started to appear on the market and had yet to be introduced on the Canadian market when Health Canada held consultations on plain and standardized packaging in 2016. For that reason, the impacts of the Regulations on heated tobacco products were not include the cost-benefit analysis. Currently, only the three major cigarette manufacturers in Canada have heated tobacco products. As cigarette sales account for 95% of their wholesale revenue, heated tobacco products would fall within the remainder. Therefore, within their overall adjustment costs, heated tobacco product costs would be relatively small compared to those of cigarettes. It would be highly unlikely that these costs would alter the break-even point in the benefit analysis.

Health Canada commissioned a cost-benefit analysis (CBA) to evaluate the impact of the Regulations. The analysis incorporates information from a variety sources (i.e. direct outreach to tobacco product manufacturers and importers, suppliers, trade associations, advocacy groups, information provided by th Australian and British regulatory authorities, published literature and the information submitted to Health Canada pursuant to the *Tobacco Reporting Regulations*). A copy of the comprehensive CBA is available upon request.

Cost-benefit analysis — Costs

The Regulations will result in costs to industry and the Government of Canada and may have some impact on consumers. The analysis examines the costs these measures over a period of 30 years. The projection of compliance costs over this period takes into account the timing of incremental capital expend and anticipated equipment replacement cycles as well as changes in annual operating costs. In accordance with guidelines published by the Treasury Bo of Canada Secretariat, the analysis calculates the present value of future costs employing a real annual discount rate of 8%. Consistent with the present va calculation, compliance costs were also annualized at a discount rate of 8%. All cost estimates obtained from the literature have been adjusted for inflation are expressed in 2015 Canadian dollars (CAD).

Industry compliance costs

The analysis of compliance costs incorporates information from a variety of sources. For this analysis, information was gathered in the course of direct outr to tobacco product manufacturers and importers, their suppliers and various trade associations or advocacy groups. Information was also provided by Australian and UK regulatory authorities that have implemented similar plain packaging measures.

Representatives from a total of 14 organizations were interviewed, including representatives from the 3 largest tobacco manufacturers that supply Canada which represent over 93% of cigarettes sold in Canada.

The cost to industry analysis includes costs that will be carried by manufacturers and importers, their suppliers and distributors or retailers of tobacco products. Based on the experience of other countries that have implemented plain packaging, there is a possibility that some products could be eliminate from the market if the annual compliance cost exceeds annual revenues. The compliance cost for industry analysis assumes that there will be approximate 10% consolidation of brands for cigarettes and little cigars, 80% consolidation of brands for pipe tobacco and 45–50% consolidation of brands for cigars, smokeless tobacco and cigarette tobacco.

Artwork changes and associated retooling costs

The analysis indicates that the implementation of PSA measures will require replacing the rotogravure cylinders currently used to print brand labels. This w represent a substantial initial investment. In the long run, these initial costs may be offset, at least in part, by factors that reduce printing costs. To estimate net cost to the industry, the analysis compared a 30-year projection of printing costs in the absence of new regulations to a projection of the printing costs industry would incur should PSA measures be required. This analysis of artwork changes took a number of factors into consideration, such as the number cylinders per SKU, the potential consolidation of SKUs, the useful life of print cylinders, and administrative costs.

Artwork and retooling costs of cigarettes, pipe tobacco, smokeless tobacco, cigarette tobacco, kreteks and little cigars are included in this calculation. Du standardization and creation of plain packages, there will be long-term savings for manufacturers. Canadian manufacturers will substantially reduce their c related to the design and redesign of packages or the associated focus group testing and marketing. Long-term savings in printing costs will significantly mitigate and, in some cases, exceed the initial costs associated with the implementation of PSA measures. The estimate across all products ranges from a cost of $2.6 million to a net saving of $11.2 million over 30 years. On an annualized basis, the estimate of net impacts ranges from costs of approximately $120,000 to savings of approximately $1.2 million.

Caveats and limitations: The analysis of savings relative to baseline costs assumes that consolidation of the SKUs available on the Canadian market will translate to an equivalent reduction in the number of SKUs that manufacturers produce for sale worldwide. The estimates of long-term savings in printing c do not take into account the elimination of other premium packaging features that will be prohibited following the implementation of PSA measures. These features include embossing, raised lettering, foil stamping, and other distinct visual or tactile features on the exterior or interior of tobacco product packag Similarly, the analysis does not account for the elimination of costs associated with periodic changes in package design, which manufacturers currently inc whenever they update brand imagery or package artwork. These factors may lead to understated long-term savings and overstated net compliance costs

Format and product — Tobacco manufacturing

In addition to standardizing the artwork on the package exterior and interior, PSA measures will limit cigarettes to only regular and king size and standardiz colour of cigarette paper and filters, as well as filter design. They will also standardize the size, shape, format and related features of the packages in whic cigarettes are sold. Compliance with these standardization requirements will be expected to require investments in new equipment and other changes in

manufacturing operations. None of those consulted provided an estimate of the costs associated with standardizing the appearance of cigarette papers o filters, nor did they suggest that such costs will be substantial. However, they did express some concern with their ability to acquire papers or filters that ar compliant with PSA measures while also satisfying product performance standards or other regulatory specifications.

Cigarette manufacturer expenditures: Information from the three largest cigarette manufacturers that supply the Canadian market suggests that standardiz the appearance and packaging of cigarettes will require investments in new equipment and other changes in their manufacturing operations.

Manufacturers indicate that complying with standardizing the appearance and packaging of cigarettes will require substantial changes in their operations. particular, most of the expenditures will relate to modifying packer equipment (i.e. the machines that assemble loose cigarettes into packages). Modificatic packers, purchased in the form of conversion kits, will be required with the change to standard cuboid packages. One firm also anticipates the purchase c new packing machines and wrapper conversion kits, as well as costs associated with reconfiguring its plant floor.

All three firms indicate that they will need to purchase slide and shell packaging equipment and are concerned about purchasing it in a timely fashion. It is estimated that the capital expenditure for all cigarette manufacturers will be $68.8 million (present value) over 30 years. This figure is equivalent to an annualized cost of $7.4 million associated with cigarette manufacturing. This estimate, provided by these three tobacco manufacturers, was scaled upwar account for the costs that other cigarette manufacturers may incur.

Industry representatives also noted that retooling to comply with standardizing the appearance and packaging of cigarettes will require a substantial amou time. They estimated that acquisition time for cigarette manufacturing equipment will range from 24 to 30 months, and that multiple orders to equipment manufacturers could add delays. It was also noted that time will be needed to install, test, and calibrate equipment sequentially, which will extend the time needed to come into compliance.

Format and product — Packaging suppliers

Packaging expenditures: Standardization of cigarette packaging will also require the companies which provide the packaging to retool machinery. To prod blank packages (prior to printing), cutting and creasing tools are used to crease, shape, fold, perforate and emboss the paperboard. The machinery used this process is tailored to the dimensions and features of the final packaging.

It is estimated that one company supplies over 95% of the packaging for cigarettes sold in Canada and presently, there is considerable variety in the rang packaging on the Canadian market. The PSA measures will narrow this range to one package type: cuboid slide and shell packages for regular and king s cigarettes. Based on the company's market share and its analysis of the investment that it will need to make, it is estimated that packaging firms will incur retooling costs of approximately $30.3 million to $45.4 million (present value) over 30 years. These figures are equivalent to annualized costs of $2.9 millior $4.3 million associated with artwork retooling.

Bottlenecks could also develop in the supply of packaging materials. The primary slide and shell package equipment supplier to the Canadian market indicates that it will require sufficient lead time of 18–22 months to convert its systems to produce compliant packages and meet the demand of cigarette manufacturers that serve the Canadian market.

Caveats and limitations: The analysis of the cost of standardizing the appearance of cigarettes and cigarette packages is subject to a number of limitation Most importantly, the analysis is based on compliance cost estimates provided by representatives of the tobacco industry, which were taken as given. Whi these estimates were reviewed to ensure they are consistent with information on the brands reported under the *Tobacco Reporting Regulations* (TRR), the accuracy of future projections and limitations cannot be verified.

Repackaging of cigars

Most cigars currently sold in Canada are imported; sales of cigars produced domestically account for less than 12% of the market. Nonetheless, for many foreign manufacturers, Canada is a relatively small market and sales in Canada are unlikely to be high enough to justify a substantial investment in redesig their packaging. The industry representatives consulted anticipate that the introduction of PSA measures will lead to a substantial consolidation in the varie cigars available on the Canadian market.

It is estimated that the introduction of PSA measures will lead to a 50% reduction in the number of cigar SKUs available on the Canadian market. The analy assumes that all cigars that remain on the market will be repackaged by Canadian manufacturers or importers to comply with the PSA measures. The toba manufacturers consulted estimated that implementing a repackaging system will cost between $3,300 and $15,000 per SKU. They envisioned this as a on time cost associated with designing and producing compliant packaging, coupled with establishing a facility capable of receiving imported cigars and transferring them to this packaging. The estimated costs range from $5.75 million to $25.9 million (present value) over 30 years, equating to annualized co from $473,000 to $2.1 million associated with cigar repackaging.

Retailers

Under the Regulations, retailers may incur costs to retrain their employees, reconfigure their inventory and reorganize their stockrooms. They may also incu costs associated with an increase in retail transaction time. The analysis estimates the cost to the retail sector to be approximately $28 million over 30 year equating to annualized costs of $2.3 million associated with retailer compliance. The analysis is based exclusively on costs for convenience store retailers, therefore likely underestimates the total impact to all tobacco retailers (i.e. tobacconists and specialty tobacco retailers). The costs of the latter were not quantified as they were not determined to be substantial enough to alter the break-even point in the cost-benefit analysis.

The Canadian Convenience Stores Association (CCSA) volunteered to survey its members on the potential impacts of PSA measures and provided a sumr of the results, which represented over 2 300 of its members.

Training costs: Based on the survey of CCSA members and Australia's post-implementation study of plain packaging, the analysis assumed that 30% of tobacco product retailers in Canada will incur training costs. On average, eight employees per store will require training; the time required for training will average two hours per employee. The analysis values this time at a wage rate of $15.14 per hour and treats these additional training costs as a one-time c carried upon implementation of PSA measures. The estimated present value of the cost for training is approximately $2.2 million.

Inventory and stockroom reconfiguration costs: In addition to training costs, responses to the CCSA survey suggest that approximately 88% of convenienc stores will incur costs to reconfigure inventory and facilitate the identification of different products. It is estimated that staff will require an additional two hou per day to order, receive and stock tobacco products following the implementation of PSA measures. As with training costs, this additional time is valued a $15.14 per hour. The analysis assumes that these costs will be carried at 88% of all retail establishments selling tobacco products and will persist for 30 da following the implementation of PSA measures. The estimated present value of the cost is approximately $24.7 million.

Transaction costs: International evidence regarding the effect of plain packaging on retail transaction times is mixed and highly uncertain. Some studies ha found a slight increase associated with more difficulty differentiating between products, as well as an increase in service errors (e.g. customers receiving t incorrect product). It is estimated that there will be an average increase of 2.59 seconds per transaction in the month following implementation of PSA, with discernable effect thereafter. This is considered the best available estimate and was used to determine the increased cost to retailers, valuing the added ti at the average retail worker wage rate of $15.14 per hour. The analysis assumes that transaction delays will be experienced at all retail stores. The estimate present value of the transaction costs are approximately $965,000.

Stranded inventory costs: Non-compliant inventory at the end of the implementation period is not expected to be a cost for retailers. Unsold tobacco produ remaining at retail at the end of this period, if any, are likely to be returned to the suppliers.

Caveats and limitations: The analysis is directly based on information that CCSA provided in a summary of its members' responses to a survey. The survey findings are reported as provided, and the ability to evaluate the accuracy of this information is limited. As well, the impact of PSA measures on retail transaction times is highly uncertain, as is the duration of the effect on transaction times and inventory/stockroom reconfiguration.

Costs to the Government of Canada

The introduction of PSA measures for tobacco products will require an investment of public sector resources to administer and verify compliance with the Regulations. Health Canada estimates initial implementation costs of approximately $496,000, coupled with annual outreach and compliance and enforcer costs of approximately $499,000. The present value of these costs is approximately $6.6 million. This is equivalent to an annualized cost of approximately $540,000 associated with Government administration.

Potential economic impacts

In addition to imposing direct costs on industry and Government, PSA measures could also affect the supply and demand in the market for tobacco produ

Impacts on manufacturers

The implementation of PSA measures could have a variety of market impacts that would affect the sales, profitability and operations of tobacco product manufacturers and their suppliers.

Impacts on tobacco product prices and sales: The cost of complying with PSA measures could influence the price of tobacco products, which would in tu impact the demand for tobacco products and thus affect sales. The analysis estimates that manufacturers could incur profit losses ranging from about $2.8 million to $5.5 million over 30 years. This equates to annualized costs of $228,000 to $454,000 associated with the loss of profits due to loss of sales f manufacturers.

Employment: Any reduction in the sale of tobacco products stemming from the introduction of PSA measures could have an adverse effect on employmen the tobacco product manufacturing sector. To provide a rough estimate of the potential employment impact, the analysis assumes that such an impact will proportional to projected changes in unit sales of tobacco products. A proportional reduction in the number of individuals employed in Canada's tobacco product manufacturing sector suggests, in the upper-bound case, the loss of approximately one job.

Impacts on retailers

Loss of profits: PSA measures could also affect the profits of tobacco product retailers. The effect of higher prices passed along to the consumer due to manufacturers' increased compliance costs could erode profits by $6,331,733 to $11,993,335 over 30 years. These figures are equivalent to annualized co of $520,770 to $981,982 associated with loss of profits due to loss of sales for retailers. These figures underestimate the costs to retailers as they only repr costs associated with convenience stores and are not reflective of small business tobacconists or specialty stores.

Impacts on consumers

Price increases: To the extent that manufacturers and retailers of tobacco products pass their compliance costs to consumers in the form of higher prices, those who continue to purchase the products will realize a loss in consumer surplus. The potential impact of PSA measures on the price of most tobacco products is relatively modest. As a result, the loss in consumer surplus associated with any increase in prices will also be modest (e.g. less than $3.50 per for a pack-a-day smoker). Price increases were not included in the overall cost calculation in order to avoid double-counting, given that it is already captur within the loss of profits.

Transaction delays: According to retailers, an increase in retail transaction time will also have an adverse effect on consumers. To estimate this cost, the sa assumptions were employed in evaluating impacts on retailers (i.e. a delay of 2.59 seconds per transaction and an effect enduring for 30 days) and valued consumers' time based on an average post-tax wage rate of $19.22 per hour. This approach yields an estimated reduction in consumer surplus of

approximately $1.2 million. To place this figure in context, the estimated impact on a consumer who engaged in 20 transactions during the month following introduction of PSA measures will be a loss in consumer surplus of approximately $0.28.

Impacts on tax revenue

The impacts on tax revenues have not been regarded as economic costs in this analysis based on guidance outlined in the Treasury Board Secretariat's *Canadian Cost-Benefit Analysis Guide*. [106]

Other impacts considered

Potential costs of illicit tobacco control

The Government of Canada recognizes that illicit tobacco has been an issue in Canada and that contraband tobacco undermines key tobacco use reduct interventions. Because of this, illicit tobacco is an ongoing concern for the Government of Canada, and enforcement has been a key component of the FT(and will remain a priority moving forward in CTS.

Public Safety Canada and portfolio agencies including the Royal Canadian Mounted Police, the Canada Revenue Agency and the Canada Border Service Agency are working in close collaboration with Health Canada, the Department of Justice and key stakeholders to tackle illicit tobacco issues. Should ther a rise in illicit tobacco, enforcement authorities would likely need to increase the frequency of retail and supply chain audits following implementation of PS measures. It is difficult to predict the impact, if any, PSA measures will have on illicit tobacco; therefore, the incremental cost of these enforcement activitie remains uncertain.

The Canadian tobacco industry has claimed that illicit levels will increase as a result of PSA measures. Such claims were also made in 2009, when Canad introduced a schedule to restrict flavours in cigarettes, little cigars and blunt wraps, and again in 2011, when Canada increased the size of its HWs on cigarettes and little cigars to 75% of the package. In both these cases, contraband tobacco levels did not increase after the new requirements came into f Academic research on Canada's illicit market suggests that illicit tobacco levels have decreased in recent years. [107] Additionally, between 2010 and 2017 reported sales of legal cigarettes declined at a rate consistent with the decline in smoking prevalence. This suggests that illicit tobacco has not been increasing its share of total cigarette consumption.

The Australian government published a post-implementation review of plain packaging in 2016. This review reveals that there was no change in use of unbranded illicit tobacco. In addition, there was no evidence of increases in use of illicit cigarettes or an increase in purchases of tobacco from informal se after plain packaging measures were introduced in Australia in 2012. [108] As well, prior to the implementation of plain packaging regulations, the U.K. Department of Health conducted a prospective impact analysis and concluded that plain packaging was not likely to substantially increase the size of the market, or the illicit market overall.

Down-trading

Down-trading occurs when tobacco consumers switch from premium brands to value brands (i.e. lower-priced alternative brands). The cigarette market in Canada has exhibited down-trading since 2002, primarily as a result of aggressive pricing strategies by one main company, followed by the others, that evolved into distinct pricing segments. Price segmentation has more or less become a permanent feature of the Canadian cigarette market. Companies ha discount cigarette strategy in place with the objective of attracting young smokers, low-income smokers and smokers who might be thinking of quitting sm for financial reasons. [109], [110] For tobacco products other than cigarettes, down-trading is expected to have a relatively small impact on the manufacturer's profits.

For the Canadian market, despite down-trading, the average revenue per cigarette for companies has continued to rise. In 2016, tobacco companies' reve for cigarettes reported to Health Canada under the TRR reached their highest recorded level, up 32% from 2014 revenues.

Evidence from Australia shows that after plain packaging was implemented, the inflation-adjusted recommended retail prices of all cigarette products from three largest cigarette companies increased by 3.4% on average from 2012 to 2013, with increases greater for premium and mainstream brands. [111]

The potential for down-trading to raise or lower profits for manufacturers and retailers following the implementation of PSA measures was taken into consideration. However, the presence of price segmentation and down-trading, at least in the Canadian experience, is not an indication that average cigar prices and industry revenues will decline. In Canada, the opposite has been true; therefore, down-trading was not included in the analysis.

Benefits

Literature review

A large number of studies have been carried out regarding the effect of tobacco product packaging on the appeal of tobacco products, consumer percep of the health risks of tobacco use and consumers' attitudes toward tobacco use. Research across a variety of disciplines has also explored tobacco plain packaging measures and their effectiveness in helping to reduce the public health burden of tobacco use. Studies indicate that among other things, plain packaging can contribute to

- limiting the promotional effect of tobacco product packaging;
- reducing the appeal of tobacco packages, products and brands;
- increasing the salience of HWs displayed on the packages containing tobacco products;
- reducing misconceptions about the dangers of using the product based on the format or colour of the product or its packaging; and

- helping to change attitudes and beliefs toward tobacco use that foster changes in behaviour, both by discouraging young people from becoming tob users and by encouraging current users to quit.

The Regulations will support CTS and work in tandem with other factors in the environment to reduce inducements to tobacco use. The Regulations are expected to primarily benefit youth and young adults by supporting the prevention of tobacco initiation and the dependence on tobacco products that cou result and continue over a lifetime. PSA measures will also benefit youth, young adults and others by increasing the salience of HWs and reducing the abil tobacco product packages to mislead consumers. The Regulations are expected to have a significant long-term impact on the decline in disease incidenc mortality and disability caused by tobacco use. Long-term economic benefits will be realized in terms of avoided tobacco-related mortality and morbidity a exposure to second-hand smoke.

Sex- and gender-based analysis

Key findings indicate that while tobacco use has declined over the past 15 years, a gender gap still exists. For instance, in 2001, 24% of males and 20% o females reported current cigarette smoking; by 2017, the rate of current cigarette smoking had decreased to 17% among males and 13% among females.

The Regulations are expected to have a positive impact on both genders. PSA measures restricting slim cigarettes, which represent 2.3% of the current cigarette market, are expected to primarily benefit women. Research has indicated that slim and thin cigarette packages increase the attractiveness of packages, particularly among young women, and that slim and super slim cigarettes are more likely to be perceived as milder and less harmful.

Public opinion research in support of the development of these Regulations was inclusive of both genders, and preliminary tobacco package colours teste demonstrated that the drab brown packaging was unattractive to both genders. Similarly, unbranded cigarettes were also found to be unappealing by botl genders.

International findings

The evidence from Australia suggests that plain packaging has an impact on the prevalence of tobacco use and the associated public health burden. It is estimated that the Australian measures implemented in 2012 account for a 0.55 percentage point reduction in smoking prevalence between December 20 and September 2015. This represents approximately 25% of the overall 2.2% decline in smoking prevalence observed over this time. However, it is difficult isolate reliable estimates of the impact of plain packaging based on the prevalence of tobacco use in Australia post-implementation, given that plain packa requirements for tobacco were introduced simultaneously with other measures, including requiring new, larger graphic warning labels, imposing a 25% tobacco excise tax increase and restricting Internet advertising of tobacco products. The simultaneous implementation of these measures restricts assess of their independent impacts. Hence, the 0.55 percentage point reduction in smoking prevalence seen in Australia was not used in the break-even analysis

In 2017, the Australian government posted results from the National Drug Strategy Household Survey (NDSHS) for 2016, which showed there was no signi decrease in smoking rates in Australia between 2013 and 2016. However, there was an increase in the age at which young people began to smoke, up fro 15.9 to 16.3 years, as well as an increase in the proportion of teenagers who had never smoked, from 95% to 98%. [113] These findings indicate that plain packaging, as part of other tobacco control measures recently implemented in Australia, may have had a positive impact with respect to youth smoking in time period.

Quantitative analysis — Break-even analysis for PSA

The past success of the FTCS is a result of a multifaceted and coordinated approach involving many partners, including provinces and territories, municipalities, non-governmental organizations, community agencies and the private sector. Given the variety and number of tobacco control interventions working in tandem under CTS, it is challenging to quantify the benefits of an individual tobacco control measure. For this reason, an estimate of the benefit associated with PSA measures was not developed. Instead, a break-even analysis was performed to calculate the effect that the Regulations would need t have on initiation and cessation rates, in order for PSA measures to provide public health benefits that equal or exceed the estimated costs.

Model description

In order to conduct the break-even analysis, a model was developed to quantify and value the benefits of changes in the prevalence of cigarette use in Canada. Three benefits resulting from changes in the initiation and cessation rates were considered: (1) benefits of reduced tobacco-related mortality, (2) benefits of reduced tobacco-related morbidity, and (3) benefits of reduced second-hand smoke.

Benefits of reduced tobacco-related mortality

A benefit of the Regulations as part of CTS is the likely reduction in deaths attributable to smoking as a result of a decline in smoking prevalence. To estima and value the impacts of changes in cigarette use on tobacco-related mortality, estimates of the relative mortality risk of current and former smokers were drawn from a study by Taylor et al. [114] As the duration of time since quitting increases, the mortality risk faced by a former smoker declines. The estimates annual mortality risk by age, sex and smoking status are adjusted to match the aggregate age- and sex-specific mortality rates reported by the Statistics Canada CANSIM database. [115]

The model estimates the social value of averting premature deaths based on a value of $7.4 million per statistical life (2015 dollars), based on the recommendations of Chestnut and DeCivita. [116] The value of a statistical life (VSL) is an aggregated estimate of the value of small annual mortality risk changes in a population and is based on estimates of individual willingness-to-pay (WTP) to reduce one's own mortality risk by a small amount. These WTP estimates are derived primarily from wage-risk studies of workers across jobs of varying risk levels. The VSL represents the value of one "statistical life," no value of saving a particular individual's life.

Benefits of reduced tobacco-related morbidity

An additional benefit of the Regulations is the likely reduction in illnesses attributable to smoking as a result of a decline in youth uptake. The analysis used cost-of-illness data on tobacco use from *The Costs of Substance Abuse in Canada 2002* by Rehm et al. [117] Cost-of-illness studies measure direct (e.g. medical expenses such as hospital visits and medication) and indirect (e.g. lost wages) costs incurred by affected individuals. It is recognized that tobacco related illnesses generally take several years to manifest themselves; therefore, a latency period of 10 years between smoking initiation and the onset of no fatal health effects was assumed. It was estimated that the annual morbidity costs are about $1,400 per smoker (2015 dollars). This estimate was applied t number of smokers aged 27 and older to estimate the total annual costs of tobacco-related illness each year.

Benefits of reduced second-hand smoke

The model also estimates non-smoker deaths attributable to exposure to second-hand smoke (SHS). The analysis relies on a study by Max et al. [118] that estimates the number of deaths attributable to SHS exposure in the United States based on exposure and cause-of-death data collected in 2006. Calculat yield annual rates of 0.66 adult SHS-attributable deaths per 1 000 smokers and 0.03 infant SHS-attributable deaths per 1 000 female smokers. The model adjusts these parameters dynamically in response to changes in total population, since — all else equal — an increase in total population is likely to increa the number of non-smokers exposed to SHS.

Prospective baseline scenario

A prospective baseline scenario was then developed to estimate the prevalence of cigarette use over the next 30 years. This scenario assumes that future cigarette initiation and cessation rates will hold constant at levels equal to the annual average of the rates derived from the 2009–2013 results of the Canad Student Tobacco, Alcohol and Drugs Survey (CSTADS) and Canadian Tobacco Use Monitoring Survey (CTUMS).

Break-even analysis — Results: The break-even analysis illustrates the effect that PSA measures would need to have on cigarette initiation and cessation r relative to the prospective baseline scenario, over the next 30 years, in order for the PSA measures to provide public health benefits that equal or exceed t estimate of the costs of those measures. Two break-even scenarios were considered.

The first break-even scenario (break-even low) estimates the change in initiation and cessation rates necessary over the next 30 years (2017 through 2046 generate public health benefits with a present value of at least $138.4 million (2015 CAD), the lower-bound cost estimate of the Regulations.

The second break-even scenario (break-even high) estimates the change in initiation and cessation rates necessary over the next 30 years (2017 through 2046) to generate public health benefits with a present value of at least $195.9 million (2015 CAD), the upper-bound cost estimate of the Regulations.

The analysis suggests that both of these break-even points would be achieved if PSA measures proved to have even a minor effect on cigarette initiation a cessation. Specifically,

- a 0.03% increase in the annual rate of smoking cessation and a 0.03% reduction in the annual rate of smoking initiation, relative to the prospective baseline scenario, would yield public health benefits of approximately $198 million (present value), sufficient to exceed the break-even point for the b even high scenario and break-even low scenario.

In order to put the analysis of public health benefits for the two break-even scenarios into perspective, Table 1 provides additional information. The numbe this table are not a prediction of what PSA measures will accomplish. Rather, they illustrate the public health benefits that would be accrued in the event of 0.03% increase in cessation and 0.03% decline in initiation rates for the high- and low-cost scenarios. Since the estimated costs for the Regulations have b calculated, the benefits for the break-even scenario must equal or exceed the costs. Using the model created for this analysis, it can then be determined h much prevalence would need to change from the prospective baseline scenario in order to achieve the benefits that would equal or exceed the costs. Fro the number of statistical lives that would have to be saved over the next 30 years to achieve these benefits can be calculated. For this break-even analysis reduction in the number of excess deaths attributable to cigarette use is 101 fewer deaths over 30 years.

Table 1: Public health benefits of changes in annual smoking initiation and cessation rates: 2017–2046 (2015 CAD, 8% discount rate [**])

Benefit Category	**0.03% increase in cessation and 0.03% decline in initiation rates**
PV of benefits from reduced morbidity ($millions)	$5
PV of benefits from reduced smoking mortality ($millions)	$145
PV of benefits from reduced SHS mortality ($millions)	$48
Total present value of health benefits ($millions)	**$198**
Reduction in excess deaths due to smoking	77
Reduction in excess deaths due to exposure to SHS	24
Total reduction in excess deaths attributable to cigarette smoking	**101**

Notes

** Discount rate: The stream of costs and benefits will usually not occur in the same year, but is spread over 30 years. Discounting allows for the systematic comparison of costs and benefits that occur in different time periods by allowing one to calculate the net present value of PSA measu

It is important to note that the break-even analysis is based on estimates of the costs of complying with PSA measures, government administration costs, consumer transaction costs and lost profits due to reduced sales. Some of these costs may be overestimated given the delay in certain provisions coming force (i.e. the requirement for slide and shell cigarette packaging). Further, the analysis does not take into account other potential costs, such as the costs counteracting the potential rise of counterfeiting operations or down-trading. The impact of these costs, however, would need to be substantial in order to a the fundamental conclusion that small effects on initiation and cessation of tobacco use would be sufficient to produce public health benefits equal to or g than the costs associated with implementing PSA measures.

Accounting statement

Table 2: Summary of costs and break-even information

	Costs Present Value (CAD, 2015)		**Costs Annualized (30 years, 8%)**	
	Lower (millions)	**Upper (millions)**	**Lower**	**Upper**
Direct compliance costs				
Artwork retooling costs	–$11.2	$2.6	–$1,227,000	$116,000
Cigar repackaging cost	$5.8	$25.9	$473,000	$2,128,000
Format and production — Tobacco manufacturing	$68.8	$68.8	$7,439,000	$7,439,000
Format and product — Packaging suppliers	$30.3	$45.4	$2,856,000	$4,284,000
Retailers	$28.0	$28.0	$2,299,000	$2,299,000
Government administrative	$6.6	$6.6	$540,000	$540,000
Potential economic impacts				
Loss of profit due to loss of sales — manufacturer	$2.8	$5.5	$228,322	$454,088
Loss of profit due to loss of sales — retailer	$6.3	$12.0	$520,770	$981,982
Transaction delays for consumer	$1.2	$1.2	$100,766	$100,766
TOTAL COSTS	**$138.4**	**$195.9**	$12,293,717	$17,401,294
Break-even Analysis				

	Lower and Upper End
Benefits needed to break-even (millions $)	$198
Benefit of reduced morbidity (millions $)	$5
Benefit of reduced mortality (millions $)	$145
Benefit of reduced exposure to SHS (millions $)	$48
Reduction in excess deaths due to tobacco smoking for break-even	101
% increase in cessation	0.03%

% decline in initiation rates	0.03%
Qualitative impacts	
Positive impacts	Reduced morbidity and mortality related to tobacco use. Reduced mortality related to exposure to second-hand smoke.
Negative impacts	Reduction in product availability or variety of tobacco products, which will reduce consumer's optior

"One-for-One" Rule

There is no administrative burden expected for businesses due to the Regulations, as there will not be additional reporting requirements. Therefore, the "O for-One" Rule does not apply.

Small business lens

In developing the Regulations, approaches that would balance minimizing regulatory burden to business with protecting young persons and others from inducements to use tobacco products were considered.

The Regulations will allow manufacturers/importers of tobacco products a transition period of at least six months from the publication date to allow the maj of these businesses, if not all, to realign their operations and to deplete or modify any remaining stock that does not comply with the Regulations. An exten timeframe has been permitted for certain measures to facilitate compliance. This transition period will also allow Canada to meet its obligations under the \ Trade Organization (WTO) Technical Barriers to Trade Agreement.

Retailers will have at least an additional three-month transition period for implementation from the date of coming into force during which they will be able t through inventory of non-compliant tobacco products. An extended transition period has been permitted for cigar packaging and products to facilitate compliance.

Flexible option

In 2015, it was estimated that the Regulations would affect 27 small manufacturers. Small manufacturers make up less than 1% (0.15%) of the market shar (based on wholesale values) of all tobacco manufacturers (including importers).

A flexible option, which would have provided manufacturers an additional six months to implement the Regulations, was considered. However, providing a implementation period of more than six months for small businesses to alleviate compliance costs was deemed to be counter-effective to the protection of Canadians.

Table 3 demonstrates the savings for the tobacco manufacturing industry of delaying implementation by an additional six months. The savings for manufacturers that are small businesses would be approximately $1,900. Delaying implementation by more than six months from the publication date is therefore not considered to be part of an effective approach. Allowing branded packages and products from small businesses to remain on the Canadian market any longer than the six-month period would undermine the purpose of this proposal, without greatly reducing small business costs.

Table 3: Small business flexibility analysis (2015 CAD, 8% discount rate)

	Initial Option		**Flexible Option**	
Short description	**6-Month delay for implementation**		**12-Month delay for implementation**	
Number of small businesses impacted	**27**		**27**	
	Costs Annualized (30 years, 8%)	**Costs Present Value (CAD, 2015)**	**Costs Annualized (30 years, 8%)**	**Costs Present Value (CAD, 2015)**
Total costs (all small businesses)	**$2,273**	**$25,593**	**$2,104**	**$23,685**
Average cost per small business	$84	$948	$78	$877
Consideration	Small business costs have been estimated to be $1,900 (2015) greater under a 6-month delay compared with 12 months.		The extension of the delay in implementation from 6 to 12 months would increase the ris youth in Canada becoming life-long smokers. This would compromise the health of Canadians.	

The initial option value combines foregone profits and one-time compliance costs associated with unsold inventory. The reason for including the one-time c in the initial option, but not in the flexible option, is to model the argument that businesses may not have enough time to sell through their inventories in 6 months, but would likely manage to sell them within one year. Foregone profit includes reduced sales due to price increases for cigarettes. Foregone profit were included in the calculation of both options because of the lower level of sales, the only difference being that in the 12-month option, businesses woul carry half the amount of the first year foregone profits, as they would have 6 more months to clear existing stock.

The flexibility analysis is only reflective of the impact on small business tobacco manufacturers, and not retailers, as most of the costs associated with the Regulations are incurred by manufacturers. Further, one-time compliance costs account for the majority of the impact on retailers and these would be incu regardless of the implementation timeline.

Although the flexible option would be the lower-cost option for small business in terms of compliance costs, it would not be the lower-cost option for Canac The avoided cost was considered too low to justify delaying implementation of important public health measures.

Consultation

Consultations with partners

Under CTS, Health Canada collaborates with the Canada Revenue Agency, the Canada Border Services Agency, the Royal Canadian Mounted Police, the Public Health Agency of Canada, Indigenous Services Canada and Public Safety Canada on tobacco control measures. Health Canada consulted with its partners early in the regulatory development process. No major concerns were raised during these consultations.

Consultation document

On May 31, 2016, Health Canada launched a public consultation on plain and standardized packaging to be considered for all tobacco products. A consultation document entitled "Consultation on 'Plain and Standardized Packaging' for Tobacco Products (http://healthycanadians.gc.ca/health-system-systeme-sante/consultations/tobacco-packages-emballages-produits-tabac/document-eng.php)" setting out the proposal under consideration was publish on Health Canada's website and was distributed to members of the tobacco industry, non-governmental organizations (NGOs), governmental organizatior academics, experts and researchers. The document solicited comments on the possible regulatory measures.

Over 58 000 responses were received from members of the general public, representatives of the tobacco industry, retailers, health organizations, other le of government, NGOs and academics. Ninety-two percent of respondents were in support of plain and standardized packaging for tobacco products. The majority of these comments were from the general public, but support also came from NGOs, public health organizations, government and academic researchers. Eight percent of respondents opposed plain and standardized packaging. Industry, retailers and business associations were opposed to plai and standardized packaging, but opposition also came from the general public and academics.

Of those from the general public, NGOs, public health organizations and academics who showed support for plain and standardized packaging, many requested that plain and standardized packaging apply to all tobacco products. They also expressed a desire for plain and standardized packaging to be implemented as soon as possible and suggested limiting cigarette packages to slide and shell format only. They also supported the standardization of bot tobacco product packages and cigarette sizes.

Many of the academics and NGOs who responded presented scientific reviews of available studies in support of plain and standardized packaging. In the consultation document, Health Canada solicited input on potential challenges that might arise in Canada with the implementation of plain and standardize packaging. NGOs and academics included studies and information that countered these concerns. Provincial, territorial and municipal governments provi support for plain and standardized packaging and many commented that plain and standardized packaging would complement strategies already in plac their respective jurisdictions.

Less than 7% of the general public who provided feedback on the consultation opposed plain and standardized packaging and nearly all of those who responded from industry, retailers and business associations opposed plain and standardized packaging. Those who were not in support of plain and standardized packaging raised several concerns. They felt the Government had overstepped its boundaries with such restrictive regulations and was crea a "nanny state." Many also felt that plain and standardized packaging would cause an increase in illicit tobacco, which is already a concern for Canadians They also stated that plain and standardized packaging would not work and stated that there was no scientific evidence to support it. Many felt that plain a standardized packaging would violate domestic and international laws. They stated that plain and standardized packaging violated the *Canadian Charter Rights and Freedoms* and the *Trade-marks Act* and is inconsistent with the World Trade Organization Trade-Related Aspects of Intellectual Property Rights the Technical Barriers to Trade Agreement.

Industry respondents were also concerned about the implementation costs associated with plain and standardized packaging and claimed that changes r to the packaging format would require manufacturing equipment modifications that would be both costly and complex. Many industry respondents also commented on how plain and standardized packaging would negatively affect the Canadian taxpayer and that it would result in lost tax revenues, potentia losses, an increased need for governmental resources and an increased burden for small business owners.

In addition to the consultation, during the development of the cost-benefit analysis, manufacturers expressed concern with the slide and shell requirement indicating that they would need to purchase slide and shell packing equipment, and expressed concern over their ability to acquire this equipment in a tim fashion, estimating that it could take 24 to 30 months (while it would take 12 to 18 months for both flip-top and slide and shell packages). It was further not that multiple orders to the one equipment manufacturer in Canada could add delays to their compliance, and that time would also be needed to install, tes and calibrate equipment sequentially.

The majority of retailers and business associations believed that the implementation of plain and standardized packaging would lead to a number of operational hurdles, such as longer retrieval times at the point of sale resulting from clerks experiencing difficulties distinguishing between brands of cigar Many also conveyed the belief that plain packages would create challenges in inventory control and that additional training costs would be carried by employers. In association with the projected longer retrieval times, some retailers also raised security concerns. No additional evidence has been provide stakeholders so far to support this claim. Manufacturers of pipe tobacco, smokeless tobacco, and cigars and some members of the general public stated pipe tobacco, cigars and smokeless tobacco products should not be included in the scope of the plain and standardized packaging, as they are not direc at youth or young adults.

All comments and concerns were reviewed and taken into consideration while preparing the Regulations.

Face-to-face meetings: In August 2016, Health Canada held face-to-face meetings and teleconferences with stakeholders (NGOs and some tobacco indu representatives). The purpose of these meetings was to provide an overview of the plain and standardized packaging under consideration and to solicit feedback on the proposed measures. Comments and concerns gathered from these meetings, as well as comments received in response to the May 201 consultation document, were included in the summary report.

A full summary of the comments received can be found on the Health Canada website at http://www.healthycanadians.gc.ca/publications/healthy-living-vie saine/tobacco-packages-summary-resume-consultation- emballages-tabac/index-eng.php (http://www.healthycanadians.gc.ca/publications/healthy-living saine/tobacco-packages-summary-resume-consultation-emballages-tabac/index-eng.php).

Response of Health Canada to key stakeholder concerns

Evidence to support the measures: Numerous studies have suggested that plain packaging measures reduce the appeal of tobacco packages and the products they contain, particularly among young people. Australia was the first country to implement plain packaging of tobacco products in 2012. The evidence from Australia suggests that plain packaging does have an impact on the prevalence of tobacco use and the associated public health burden. It estimated that the Australian measures, which included both plain packaging and larger graphic warning labels, implemented in 2012 accounted for a 0.55 percentage point reduction in smoking prevalence between December 2012 and September 2015.

International and domestic law: The Government of Canada has taken the legal concerns raised by those not in support of PSA measures into consideratio There have been no findings, to date, that plain packaging measures are inconsistent with international trade agreements, nor has there been a finding of breach of intellectual property rights in any of the jurisdictions where plain packaging measures have been implemented.

Industry costs: The costs identified by stakeholders during the consultation period have been included in the cost-benefit analysis. The analysis of industry costs is subject to a number of limitations and uncertainties. The estimates provided by industry could not be critically assessed. Overall, the analysis indi that only a very small change in initiation and cessation rates would need to occur for the benefits to outweigh the costs. The transition period for implementation of the PSA measures is consistent with the WTO obligation of a period not less than six months.

Public opinion research

Given that the principal objective of PSA measures is to help protect young persons and other Canadians from inducements to use tobacco products, pub opinion research with Canadian youth and young adults was used in the development of the Regulations. Qualitative and quantitative consumer research conducted on how participants, which included non-smokers and smokers, perceive mock-up PSA tobacco products and packages.

The purpose of this research was to explore Canadians' perceptions and beliefs with respect to aspects of cigarettes (e.g. their size, length and circumfer and colour and branding elements) and cigarette packages (e.g. colour and branding elements), as well as determine whether certain aspects are associ with perceptions of decreased harm or increased attractiveness. This research provided greater insight and understanding of the elements that have the greatest impact in reducing the appeal of tobacco products and their packaging, particularly among young Canadians.

The research consisted of two qualitative phases (focus groups) and one quantitative phase (survey). The conclusions presented below are based on both phases of the focus groups and the quantitative study.

Results indicate that brighter coloured plain packaging, particularly reds, blues and greens, have an impact on the appeal and the ability to attract the atte of Canadians. This was particularly evident among youth and young adults, who in virtually all combinations of brand element colours and HWs tested, consistently provided higher appeal and noticeability scores for brighter coloured packaging. By contrast, the beige and brown colours tested all received lower preference scores for noticeability and appeal. The beige and browns tested were also less likely to make Canadians, particularly youth and young adults, curious about what was in the package. These findings were consistent across the three different HWs tested. In essence, the beige and brown co are less likely to capture the attention of Canadians.

The findings for appeal and noticeability of cigarettes based on size varied. Smokers in the focus groups generally expressed an appeal for a size that resembled their current brand, or expressed an appeal for a size based on specific circumstances (e.g. smaller cigarette size for a work break). Sizes that more common to a regular cigarette were generally less appealing and less likely to make participants curious about them.

For cigarette colour, the findings suggest that all of the coloured cigarettes (i.e. other than white) tested invited curiosity. While the visual appeal scores for coloured cigarettes were lower in comparison to white cigarettes, their unfamiliarity increased interest. White cigarettes, conversely, were considered famili and conveyed a negative connotation about tobacco use to Canadians. They were not appealing to non-smokers. This was particularly evident among you and young adults included in this research.

Finally, results demonstrate that Canadians find cigarettes with branding (i.e. logo, brand name) more noticeable and more appealing than those without branding. This was particularly the case with youth and young adults.

The full report of the findings can be found on the Health Canada website at http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2017/041-16-e/report.pdf (http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2017/041-16-e/report.pdf).

Prepublication in the *Canada Gazette*, Part I

The proposed Regulations were prepublished in the *Canada Gazette*, Part I, on June 23, 2018, followed by a 75-day consultation period that ended on September 6, 2018. Health Canada also undertook a number of technical meetings, at the request of stakeholders, to discuss technical challenges related implementing the regulatory requirements.

A total of 4 452 responses were received during the comment period. Of the responses, 4 295 were received as part of organized campaigns, while 157 w unique (noncampaign) submissions. The 157 submissions were received from various stakeholders including 74 from the general public; 14 from non-governmental organizations (NGOs); 18 from the public health community, including public health organizations, cities, counties, provinces and territories; from academics and researchers; 24 from the tobacco manufacturers and their equipment suppliers; 23 from retailers and business associations; and one an international government. All comments were reviewed and taken into consideration when finalizing the Regulations.

NGOs, the public health community, academics, and many members of the general public voiced their support for the full range of proposed measures, st that the suite of requirements for tobacco packaging and products would make Canada's plain packaging regulations world leading. They believe that PSA measures will reduce the appeal of tobacco products, citing scientific evidence and examples of success from Australia. Members of the general public w supported the proposed measures also cited the importance of government action to reduce the suffering and societal burden caused by tobacco use. M stakeholders stated that applying PSA measures to all tobacco products, including cigars, is important for the effectiveness of the Regulations. They also expressed a desire for the Government of Canada to adopt the proposed Regulations as soon as possible, based on lessons learned from the implementa of packaging requirements in other jurisdictions.

Tobacco manufacturers and their suppliers, business associations, retailers, international organizations and some members of the general public strongly opposed the proposed measures, or their application to specific tobacco products. Tobacco manufacturers stated that existing tobacco control measures which limit the age of access, restrict promotion, and require HWs and HIMs on or in packages, are sufficient. They state that the proposed measures go beyond those passed in both the United Kingdom and Australia. They state that plain packaging has failed to decrease smoking rates elsewhere and questioned the evidence for plain packaging, and in particular, evidence to support an exclusive shift to slide and shell packaging for cigarettes. In their submissions, they claimed that youth are not induced to smoke by product packaging, and that Health Canada's decision to go forward with PSA measure was influenced by the tobacco control lobby and international trends.

In addition, tobacco manufacturers and many business associations stated that displaying their trademarks is an essential liberty and vital for consumer protection against counterfeit tobacco products. Similarly, they indicate that the Government will lose revenue as a result of PSA measures and create a ba to trade. Many retailers and some members of the general public believe that limiting branding limits free consumer choice and that the Government of Ca should not interfere with an adult's choice to smoke. They raised concerns about consumers down-trading to less expensive tobacco products, if price becomes the key factor differentiating products. They also question why the restrictions on tobacco packaging and products go so much further than othe consumer products, such as alcohol and cannabis. Some submissions from the general public proposed alternative measures to PSA, such as eliminating nicotine from cigarettes, eliminating additives, fining underage smoking in public and supporting cessation activities for tobacco users, particularly parents

The Department of Health has noted all support and opposition comments received during this consultation. Many of these comments were expressed du the consultation in 2016 and have been carefully considered during the development of the Regulations. The Government of Canada maintains that these Regulations are an important step forward in protecting Canadians from the health hazards of tobacco use.

The remaining comments received during the consultation were of a technical nature or made suggestions that were considered to be outside the scope o Regulations. Those comments and the Department's responses are described in more detail below.

Application of the Regulations

Scope of the Regulations

Health Canada received considerable feedback opposing the application of the proposed measures to cigars and other specialty tobacco products. Submissions were received from the cigar manufacturers, retailers and the general public, including over 3 000 submissions as part of a tobacco industry campaign. The vast majority of these submissions expressed general support for the intent of the proposed Regulations while opposing their application to cigars specifically. They stated that there will be no public health benefit to extending PSA measures to cigars, but that small businesses will be negatively affected. They also claimed that cigars are less harmful than cigarettes, are not being used by youth, and are not appealing to youth and thus should be treated differently. Some cigar manufacturers (importers and distributors) also pointed to provincial and international precedents of accommodations for ci such as exemptions from retail display bans in Canada and from plain packaging in the United Kingdom.

Health Canada also received comments from manufacturers of other tobacco products (i.e. pipe tobacco, heated tobacco products and cigarette paper), recommending an exemption from the Regulations based on similar reasons, including the claim that some tobacco products are less harmful than cigaret not appealing to youth or have been excluded by other countries.

International counterparts, NGOs and public health organizations strongly supported the Regulations applying to all tobacco products based on lessons learned and international best practices.

Department of Health response: The harmful effects of tobacco products are indisputable. Tobacco use is the leading preventable cause of premature dea and disease in Canada. All tobacco products contain highly addictive nicotine, and exposure to tobacco increases a person's risk of developing cancer o other life-threatening diseases.

Applying PSA measures to all tobacco products is consistent with the Article 11 guideline of the WHO FCTC, which states that member Parties should adc and implement effective labelling and packaging measures for all tobacco products and that "there should be no exemptions for small-volume companies brands or for different types of tobacco products." Other countries, such as Australia, New Zealand and Ireland, have also implemented plain packaging f tobacco products. France did not apply plain packaging measures to all products and has seen greater promotion of products that were exempt, including shisha and cigarillos. For example, well-known cigarette brand names, such as Marlboro and Lucky Strike, are now being used to market cigarillos.

Health Canada's data shows that youth are also using tobacco products other than cigarettes. For example, with respect to cigars, the 2016–2017 Canadia Student Tobacco, Alcohol and Drugs Survey (CTADS) indicates that 2.5% of students in grades 7 to 12 had used a cigar in the past 30 days. The highest r of use was among males in grades 10 to 12, where 6.7% had used a cigar in the past 30 days. [119] Any form of tobacco use among youth remains a public health concern.

The information submitted during the consultation was carefully considered by Health Canada and did not change the outcome of the Department's assessment to extend PSA measures to all tobacco packages and products. Health Canada has not amended the Regulations to exclude certain tobacco products, as it would be contrary to the objectives of the Regulations. The Department will continue efforts to protect the health of Canadians in light of conclusive evidence implicating tobacco use in the incidence of numerous debilitating and fatal diseases.

Tobacco product packaging

Physical Design Features of Tobacco Packaging

Tobacco manufacturers recommended fewer restrictions on packaging. They requested permitting additional colours on the interiors of packages. They al recommended permitting irregularities on packages such as cut-out windows, fillers, stickers, tabs, perforations and creasing lines, stating that such featu have functional purposes or help to communicate information to consumers. Tobacco manufacturers requested clarification around calibration marks and an inconsistency with provincial tear tape requirements. Finally, certain tobacco industry segments (e.g. cigar) requested more flexibility in certain areas th could present difficulties for implementation and place a greater burden on their industry segment (e.g. the requirement for lining to be standardized to wh currently used for cigarette packaging).

Tobacco manufacturers also requested that additional information be permitted on packages, such as the manufacturer's website and phone number, trac codes, and unique identifiers required by international governments as part of the Protocol to Eliminate Illicit Trade in Tobacco Products.

NGOs were supportive of the measures proposed but recommended additional restrictions on the appearance of leaflets, lining, overwrap, colour of packa interiors and colour requirements (i.e. print quality specifications) to ensure consistency among all packages. They also recommended that the information permitted on packages (e.g. brand names and manufacturer's information) be further restricted to prevent manufacturers from displaying names that coulc misleading or promotional.

Department of Health response: Health Canada has carefully considered all comments from stakeholders and has amended the Regulations to outline ger and specific lining requirements, specify requirements for stickers and tabs, amend the tear tape requirement to take a specific provincial requirement into account, permit an additional exception for the colour of interiors for certain package types, and permit the display of a standardized alphanumeric code a standardized anti-counterfeiting feature that is required on packages under an enactment of a foreign government. Health Canada has also amended the Regulations to further clarify the requirements on brand names that may be displayed on packages (i.e. they cannot evoke a characteristic of a filter), calibration marks, and the prohibition on scents on packages.

Health Canada has not amended the Regulations to permit the use of additional features that could serve to make packages distinctive, as this would be contrary to the objectives of the Regulations. Health Canada has sought, in general, to align with plain packaging requirements in Australia. However, the Regulations have not been further restricted in areas that have not been exploited post-implementation in Australia.

Cigarette packaging

Cigarette manufacturers requested that flip-top packages remain authorized (in addition to slide and shell packages) as they are the most prevalent packa format in Canada and would permit them to comply with the requirements more quickly. They also requested changes to the slide and shell package requirements to prevent brand names from overlapping with other information displayed on the package surface and to take into account foreseeable deviations in package dimensions stemming from the manufacturing process.

NGOs and public health organizations were especially supportive of the requirement for cigarette packages to be limited to the slide and shell format. The believe that slide and shell packages, due to their larger size, are less appealing to youth, and that the greater surface area available for HWs on slide and shell packages will make the warnings more noticeable. One NGO noted that additional time may be required to comply with the slide and shell requireme NGOs also recommended extending a restriction on the number of cigarettes permitted in packages.

Department of Health response: Health Canada has not amended the Regulations to authorize additional cigarette package types. Consistent with plain packaging objectives, cigarette packages will be standardized to one package type (slide and shell). However, the coming into force period for this requirement has been amended to permit manufacturers additional time to acquire, install, test and calibrate slide and shell manufacturing equipment to comply with the requirements.

Health Canada has also amended the Regulations to address technical issues raised (i.e. minor adjustments to package dimensions and placement requirements for brand names).

Health Canada has carefully considered comments from NGOs but has not amended the Regulations to specify the number of cigarettes permitted in packages as the Act already specifies a minimum number of cigarettes per package (20) and the *Excise Act, 2001* imposes tax based on lots of five. As a result, cigarette packages in Canada come almost exclusively in packages of 20 or 25.

Cigar packaging

Cigar manufacturers requested more flexibility with respect to their packaging such as permitting all shapes for cigar packaging. Cigar manufacturers stat that the proposed requirements go beyond those in effect in Australia and need to account for the fact that cigars are mostly imported, come in a variety o shapes, and are often sold unpackaged. They also indicated that the material requirements were unclear.

Department of Health response: Health Canada has amended the Regulations to clarify material requirements and to remove restrictions on the shape of primary cigar packages.

Device packaging

Device manufacturers requested that labelling information related to the safe and responsible handling be permitted on device packages. They also recommended permitting irregularities in lining to keep products in place within packages and requested authorization to use to cover devices and their p for safety purposes.

Department of Health response: Health Canada has amended the Regulations to authorize, under certain conditions, labelling on packages related to pro safety, and certain irregularities in product lining in packages and overwrap on products.

Tobacco product appearance

General physical design features of tobacco products

NGOs and a member of the general public suggested additional restrictions on the appearance of tobacco products. For example, they proposed additio restrictions on alphanumeric codes to ensure that they could not be misleading or promotional.

Department of Health response: Health Canada has carefully considered the comments but has not amended the Regulations to further restrict areas that not exploited post-implementation in Australia. Amendments to the Regulations could be explored in the future should certain authorized features, such as alphanumeric code, become exploited for promotional purposes.

Cigarettes and tobacco products intended for use with a device (rolled in paper)

Some tobacco manufacturers sought clarity on whether ventilation holes on cigarettes and products intended for use with a device, and certain filter characteristics (e.g. raised features, recesses) would be permitted, stating that they are necessary to control product emissions.

Cigarette manufacturers also requested minor adjustments to the size of cigarettes to account for measurement errors during the manufacturing process a prevent unfairly targeting certain industry segments.

An NGO and a member of the general public recommended that cigarettes and tobacco products intended for use with a device (rolled in paper) be an unattractive colour other than white.

Department of Health response: Health Canada has amended the Regulations to clarify requirements around ventilation holes and to address technical iss raised by manufacturers (i.e. minor adjustments to cigarette dimensions).

Health Canada did not amend the Regulations to permit filter characteristics (e.g. filters with recesses) based on post-implementation lessons learned in Australia, where certain tobacco companies have used filters to make their products distinctive. Health Canada considered the comment on cigarette colo but did not amend the Regulations since this requirement is consistent with requirements in Australia, the United Kingdom and all other jurisdictions that ha implemented plain packaging. Furthermore, public opinion research commissioned by Health Canada found that all coloured cigarettes (i.e. other than wh tested invited curiosity.

Little cigars

Some manufacturers requested that certain features that denote brand characteristics such as non-standard tipping paper be permitted and others reque that a smaller diameter be permitted (6.5 mm rather than 7.0 mm) to ensure that certain products remain on the market and that brand characteristics for premium products are not lost.

Department of Health response: Health Canada carefully considered the comments and did not amend the Regulations, as these suggestions are contrary the objectives of the Regulations.

Cigars

Cigar manufacturers and retailers requested clarification on requirements for mouthpieces and tips for cigars. They also recommended that barcodes be permitted on cigar bands since they are often sold unpackaged and that the measures regarding bands better align with requirements in Australia.

Department of Health response: Health Canada has amended the Regulations to permit a standardized barcode on cigar bands. Health Canada has also clarified the provisions related to non-compliant bands. The Regulations and Order amending Schedule 1 to the Act were also amended to clarify the requirements for mouthpieces and tips for cigars.

Devices

NGOs recommended further restrictions on the appearance of devices such as a requirement for devices to be Pantone 448C or the natural colour of the material.

Department of Health response: Health Canada did not amend the Regulations to specify colour requirements for devices. The Act prohibits the promotion sale of a device that is a tobacco product or a part that may be used with such a device if the device or part has an appearance, shape or other sensory attribute or a function for which there are reasonable grounds that it could make the device or part appealing to young persons. The Regulations may be amended in the future to specify the colour of devices, if necessary.

Implementation

A number of tobacco manufacturers, their equipment suppliers and tobacco retailers commented that an implementation period of six months is too short that more time would be required to fully comply with all requirements. They also requested clarification of the transition period for wholesalers and retailers

Cigarette manufacturers and equipment suppliers indicated that it would take 24 months to fully comply with the requirements for slide and shell packages for straight/rigid package edges.

Cigar manufacturers indicated that they would require 15 months to comply, given their need to establish repackaging facilities and processes. Retailers recommended a period of 12–18 months beyond manufacturers to sell through non-compliant inventory given the slow turnover of cigars.

Manufacturers of devices and tobacco products intended for use with a device note that certain features that would be prohibited are necessary for the function of the product, presenting a compliance challenge.

Retailers proposed that implementation requirements apply to imports rather than sales (i.e. any new imported products must comply with the Regulations They indicated that this would allow for immediate compliance whereas checking every cigar store for compliance is not cost effective.

NGOs, public health stakeholders, academics and international counterparts recommended implementing as quickly as possible to prevent potential indu exploitation based on post-implementation research on the experience in other jurisdictions.

Department of Health response: Health Canada has amended the Regulations to provide a phased implementation. The majority of the Regulations will be implemented as quickly as possible to maximize the public health benefits, while accounting for specific compliance challenges faced by some industry segments.

Order Amending Schedule 1 to the Tobacco and Vaping Products Act (Colouring Agents)

Tobacco manufacturers requested that all items in the Schedule permit an exception for products that are manufactured or sold for export.

Department of Health response: Health Canada has amended Schedule 1 to the Act to provide an exception for products that are manufactured or sold fo export.

Other comments

Illicit tobacco

Tobacco manufacturers, their equipment suppliers, businesses and retail associations expressed concern that the Regulations will result in an increase in tobacco. They indicated that the measures would serve to provide a competitive advantage to illegal operators since plain and standardized packages (including slide and shell cigarette packages) require lower manufacturing specifications. They argued that distinctive packaging features (logos, beveled edges, decorative features, etc.) are a useful measure to prevent illicit tobacco. Further, there was concern that consumers and law enforcement officers w have difficulty identifying illicit tobacco products.

Department of Health response: The illicit trade of tobacco products is an important issue in Canada. The Government of Canada recognizes that illicit tob products undermine efforts to reduce tobacco use. Through Budget 2018 investment in CTS, the Government of Canada is committing $17.3 million in increased funding to help address the illicit trade of tobacco products.

While the Government of Canada takes the issue of illicit tobacco seriously, it should be noted that there is no credible evidence that demonstrates that illic tobacco will increase in Canada as a result of the Regulations.

Several mechanisms are already in place to help address the illicit tobacco issue. Cigarette packages sold in Canada will continue to be required to carry pictorial health warnings, and to display a tax stamp comprising both overt and covert security features. The Regulations have been amended to permit th display of several non-promotional features, codes and the use of a means of electronic communication for the purposes of tracking and tracing products preventing counterfeiting.

In Australia, where plain packaging has been in place since 2012, a cross-national survey found no evidence of increased contraband cigarettes, no incre in purchase from informal sellers, and no increased use of unbranded tobacco 15 months after plain packaging was implemented. [120] Further, The Austra Department of Immigration and Border Protection has stated that there is no evidence to suggest that tobacco plain packaging has impacted the illicit tob market since its introduction.

The Government of Canada will continue to work through the Royal Canadian Mounted Police, Canada Border Services Agency, Canada Revenue Agency Public Safety Canada to tackle the issue of illicit tobacco products and will continue to monitor the situation internationally.

Small business impact

A number of tobacco manufacturers and retailers indicated that the impact of the Regulations on small businesses is underestimated. They note that the le flexible option was not inclusive of tobacconists/specialty store retailers who will be impacted by the Regulations.

Department of Health response: The flexible option presented in the small business lens is reflective of tobacco manufacturers as most of the costs associ with the Regulations are incurred by this industry segment. Health Canada acknowledges that the Regulations will have an impact on tobacconists (retaile The amended implementation time for standardizing the appearance of cigars and packages that contain cigars will permit small businesses a longer peri sell through existing products and absorb other related costs.

Out of scope

Some submissions provided recommendations for tobacco control initiatives to support the CTS and other submissions provided recommendations relatin federal excise taxes.

Department of Health response: These recommendations fall outside the scope of the Regulations. Health Canada has noted all comments related to the C and informed the Canada Revenue Agency and the Department of Finance Canada of comments relating to federal excise taxes.

Regulatory cooperation

The Regulations are important to continue Canada's tobacco control efforts. Plain packaging is supported by the World Health Organization Framework Convention on Tobacco Control, to which Canada is a party. Country-specific plain packaging action is starting to emerge around the globe, with regulatio implemented in Australia (2012), the United Kingdom (2017), France (2017), Ireland (2018), Norway (2018), and New Zealand (2018). Hungary, Slovenia a Uruguay have announced implementation dates by 2020. At least 18 other countries have announced their intention to introduce plain packaging measure

PSA measures in the Regulations are consistent with the comprehensive measures implemented in Australia. In order to achieve additional benefits, the Regulations also include adaptations to account for lessons learned from Australia's experience, the findings of more recent studies, including Canadian studies, as well as feedback from the Canadian public consultations. The Regulations go beyond the Australian measures in that the plain appearance of tobacco product packages will apply to devices that are tobacco products and their parts; cigarette cases and bags furnished by a tobacco manufacture interior surfaces of tobacco packages will be drab brown; no variant names or contact information will be permitted on packaging; tabs are restricted to pouches and soft packages; alphanumeric codes are standardized; no colour or filter characteristics will be permitted in brand names; and the shape of secondary packages will be prescribed. Further, the Regulations will prohibit recessed filters, specify cigarette length and diameter as well as little cigar diameter.

Provincial and territorial authorities responsible for tobacco control have indicated that they strongly support the objectives of the Regulations and the measures set out in the Regulations. The Regulations complement existing provincial and territorial tobacco control measures, including Quebec's requirements for HWs on cigarette packages to have a minimum surface area.

Given that the PSA measures will only apply to tobacco products for retail sale within Canada, it will not have implications on the export of tobacco produc

Rationale

Canada has already implemented most of the internationally recognized practices in tobacco control, [121] and few other countries have been as successfu Canada in lowering smoking rates and shifting public attitudes about tobacco. However, despite such efforts to reduce tobacco use, there are still 5.3 milli tobacco users in Canada. Most tobacco use begins during adolescence. Young persons are particularly sensitive to the dependence-causing effects of nicotine in tobacco [122] and they also are more at risk of taking up tobacco products and developing long-term dependence on them. Despite the most re decline in overall tobacco use, rates for youth and young adults remain unacceptably high, suggesting more needs to be done with respect to tobacco co measures aimed at youth and young adults. Given the strength of nicotine addiction and the severe health consequences that result from tobacco use, it is imperative that tobacco control efforts seek to prevent tobacco initiation and the tobacco use that can result, particularly among young persons. Existing interventions need to be ongoing, renewed and enhanced by bold new measures.

Tobacco companies have conducted considerable market research on all aspects of packaging (e.g. colour, size, shape and opening) to make it appeal t various target groups, such as women, youth and young adults. Research has found that tobacco companies continue to use specific branding elements, colour, typography and packaging format to promote product characteristics in a manner that makes them more appealing to youth. [123], [124], [125], [126] Sinc 1997, tobacco product promotion has been prohibited in Canada, with limited exceptions. However, tobacco promotion by means of the packaging is sub to only certain restrictions (e.g. no false and misleading promotion, promotion of prohibited additives by means of packaging). Therefore, packaging is one the few remaining channels available for the promotion of tobacco products in Canada to youth and others.

The promotion of tobacco through its packages and products can be particularly effective among youth and young adults, as they are considered to be particularly impressionable and more vulnerable to inducements to use tobacco products, such as advertising. [127] Documents from the tobacco industry s that tobacco package designs have been modified to increase their appeal to adolescents and young adults. There is a need for additional tobacco contr measures to adapt in order to protect youth from commercial practices that make tobacco products more appealing and can induce tobacco use.

Independent research across several countries has consistently shown that plain packaging measures reduce the appeal of tobacco products. There is a substantial body of literature on the effect that tobacco product packaging has on the appeal of tobacco products, on consumer perceptions of the health of tobacco use and consumers' attitudes toward tobacco use. A review of this literature indicates that plain packaging can reduce the appeal of tobacco packages, products and brands; increase the salience of HWs on tobacco product packages; reduce misconceptions about the product health risks, whic can result from the appearance of the packages and products (e.g. size, colour); and help to change attitudes and beliefs toward tobacco use that foster changes in behaviour, both by discouraging people from becoming tobacco users and by encouraging current users to quit. [128]

Evidence from Australia, which implemented plain packaging in 2012, suggests that plain packaging does have an impact on the prevalence of tobacco u and the associated public health burden. It is estimated that the Australian plain packaging measures, which included the introduction of both plain packa and larger graphic warning labels, accounted for a 0.55 percentage point reduction in smoking prevalence between December 2012 and September 201

There is currently concerted momentum and important international effort to address the global tobacco epidemic. At least 9 countries have already adopt plain packaging measures and at least 18 other countries are involved in developing such measures. The adoption of plain and standardized packaging a product measures as part of CTS is in line with the international context. This should contribute to maintaining the gains made and reducing inducements t tobacco use, particularly among youth. This is an opportunity for Canada to have a positive impact, not only nationally, but also internationally, by aligning efforts to those of other countries and adopting the most comprehensive measures on plain packaging to date.

The Regulations will standardize the appearance of tobacco products and tobacco product packaging for retail sale in Canada. They will strengthen the Government's efforts to protect the health of Canadians from the health hazards of using tobacco products. The Regulations, as part of CTS, will contribute the reduction of the health, economic, social and public health costs that are associated with tobacco use.

The regulatory option chosen is considered to be the most comprehensive to date. It integrates the Australian plain packaging measures and includes additional measures that are based on findings from recent studies, including Canadian studies, as well as feedback from Canadian public consultations a from international experience with plain packaging.

The cost impacts of the Regulations have been estimated to range from $138.4 million to $195.9 million (present value) and relate to direct compliance cos potential economic impacts and government administrative costs. The benefits associated with the Regulations will support CTS and, as a result, reduce morbidity and mortality related to tobacco use. This reduction in morbidity and mortality is expected to be translated into significant savings to governmen terms of health care costs to address tobacco-related health consequences.

Given the challenges with isolating the benefit associated with PSA measures alone, due to the number and variety of tobacco control measures working i tandem, the benefits of CTS as a whole were considered. This is a more relevant measure of the benefit associated with tobacco control measures, includi the Regulations. A break-even analysis was conducted in order to estimate the effect new measures would need to have on initiation and cessation rates i order for them to provide public health benefits that equal or exceed the estimate of the costs associated with PSA measures.

The break-even analysis suggests that the break-even points for costs and benefits would be achieved if the Regulations proved to have even a minor effe cigarette initiation and cessation (over the next 30 years, a 0.03% reduction in the annual rate of smoking initiation and a 0.03% increase in the annual rate smoking cessation).

Implementation, enforcement and service standards

Coming into force

Certain provisions of the Act, referred to in subsection 11(2) of *An Act to amend the Tobacco Act and the Non-smokers Health Act and to make consequer amendments to other Acts* (An Act to amend the Tobacco Act), and relating to promotion by means of the packaging and the markings on the tobacco products, will come into force on a date to be fixed by order in council, which will be 200 days after the day the Order in Council is made. The coming into of the Regulations will be coordinated with that day.

The majority of the Regulations will come into force on the day on which subsection 11(2) of An Act to amend the Tobacco Act comes into force, which will 200 days after the day that the Regulations are made. However, specific provisions will have a phased implementation timeline to support compliance:

(1) Requirements for cigars and packages that contain cigars will come into force one year after the day on which subsection 11(2) of An Act to amen Tobacco Act comes into force, that is, one year after the day on which the majority of the provisions of the Regulations come into force.

(2) Certain appearance requirements for tobacco products intended for use with a device will come into force two years after the day on which subsection 11(2) of An Act to amend the Tobacco Act comes into force, that is, two years after the day on which the majority of the provisions of the Regulations come into force.

(3) Certain requirements for cigarette packaging (e.g. slide and shell, package dimensions) will come into force two years after the day on which subsection 11(2) of An Act to amend the Tobacco Act comes into force, that is, two years after the day on which the majority of the provisions of the Regulations come into force.

Retailers of tobacco products will have an additional 90 days after the day on which subsection 11(2) of An Act to amend the Tobacco Act comes into forc sell through products and inventory and to comply with the Regulations. However, retailers will have an extra 180 days after the day on which the relevant provisions of the Regulations come into force to comply with requirements for cigars and their packages.

The *Order Amending Schedule 1 to the Tobacco and Vaping Products Act (Colouring Agents)* and the consequential amendments to the TPIR and to the T will come into force 180 days after the day on which subsection 11(2) of An Act to amend the Tobacco Act comes into force. Certain amendments to Schedule 1 applicable to colouring agents used in cigars will come into force one year after the day on which subsection 11(2) of An Act to amend the Tob Act comes into force.

Communication and outreach activities

Communication activities will be undertaken to make stakeholders aware of the Regulations. Stakeholders will be notified through publication in the *Canad Gazette*, Part II. International stakeholders will be notified through the WTO notification process.

Enforcement of the Regulations

The compliance and enforcement approach for the Regulations includes conducting compliance monitoring and enforcement activities by Health Canada Part VI of the Act sets out a number of offences and punishments for non-compliance with the Act. Training on PSA measures will be provided to federal inspectors currently designated to enforce the Act. These inspectors will be responsible for monitoring compliance with the PSA measures, along with othe

requirements.

The Government of Canada will actively monitor compliance throughout the supply chain, including manufacturers, importers, distributors and retailers. If federal inspectors have reasonable grounds to believe that the Regulations have been contravened, appropriate measures will be taken, which could ranç from warnings, compliance plans, penalties and seizures.

Performance measurement and evaluation

Given the variety and number of tobacco control interventions working in tandem under CTS, it becomes challenging to evaluate the performance of an individual tobacco control measure. The performance measures and evaluation for PSA measures will be achieved by an overall evaluation of the strategy

CTS will be evaluated in fulfillment of the *Financial Administration Act* and the Treasury Board of Canada Secretariat's *Policy on Results* (2016) in order to assess the relevance and performance of the strategy. The horizontal evaluation will be conducted by the Health Canada and the Public Health Agency of Canada Office of Audit and Evaluation in accordance with the Five-Year Evaluation Plan and is scheduled for completion in 2022–2023. The evaluation will comprehensive and will include an analysis of all CTS-funded activities delivered by Health Canada and partner departments. An evaluation framework wi developed by the Office of Audit and Evaluation, in coordination with the Tobacco Control Directorate, as the office of primary interest. The evaluation will examine relevance (continued need and alignment with Government priorities), results (achievement of expected outcomes), and cost effectiveness (demonstration of efficiency and economy).

Contact

Saira David
Labelling and Plain Packaging Office
Tobacco Products Regulatory Office
Tobacco Control Directorate
Healthy Environments and Consumer Safety Branch
Health Canada
Address Locator: 0301A
150 Tunney's Pasture Driveway
Ottawa, Ontario
K1A 0K9
Fax: 613-948-8495
Email: hc.pregs.sc@canada.ca (mailto:hc.pregs.sc@canada.ca)

Small Business Lens Checklist

1. Name of the sponsoring regulatory organization:

Health Canada

2. Title of the regulatory proposal:

Tobacco Products Regulations (Plain and Standardized Appearance)

3. Is the checklist submitted with a RIAS for the *Canada Gazette*, Part I or Part II?

☐ *Canada Gazette*, Part I
☑ *Canada Gazette*, Part II

A. Small business regulatory design

I	Communication and transparency	Yes	No
1.	Are the proposed Regulations or requirements easily understandable in everyday language?	☑	☐
2.	Is there a clear connection between the requirements and the purpose (or intent) of the proposed Regulations?	☑	☐
3.	Will there be an implementation plan that includes communications and compliance promotion activities, that informs small business of a regulatory change and guides them on how to comply with it (e.g. information sessions, sample assessments, toolkits, websites)?	☑	☐
4.	If new forms, reports or processes are introduced, are they consistent in appearance and format with other relevant government forms, reports or processes?	☐	☐

	There are no new forms, reports or processes introduced in this regulatory proposal.		
II	**Simplification and streamlining**	**Yes**	**No**
1.	Will streamlined processes be put in place (e.g. through BizPaL, Canada Border Services Agency single window) to collect information from small businesses where possible?	☐	☐
	This proposal does not aim at collecting information from small businesses. All businesses, including small businesses are already required to provide information on their company, their products and some of their activities under the *Tobacco Reporting Regulations*. The Department relies on information that is already submitted as per the requirements of the *Tobacco Reporting Regulations* to conduct its activities.		
2.	Have opportunities to align with other obligations imposed on business by federal, provincial, municipal or international or multinational regulatory bodies been assessed?	☐	☐
3.	Has the impact of the proposed Regulations on international or interprovincial trade been assessed?	☑	☐
4.	If the data or information, other than personal information, required to comply with the proposed Regulations is already collected by another department or jurisdiction, will this information be obtained from that department or jurisdiction instead of requesting the same information from small businesses or other stakeholders? (The collection, retention, use, disclosure and disposal of personal information are all subject to the requirements of the *Privacy Act*. Any questions with respect to compliance with the *Privacy Act* should be referred to the department's or agency's ATIP office or legal services unit.)	☐	☐
	There are no new requirements for submitting data or information to comply with the proposed Regulations. As stated in subsection II(1), the Department already has access information on tobacco products, manufacturers and importers in Canada.		
5.	Will forms be pre-populated with information or data already available to the department to reduce the time and cost necessary to complete them? (Example: When a business completes an online application for a licence, upon entering an identifier or a name, the system pre-populates the application with the applicant's personal particulars such as contact information, date, etc. when that information is already available to the department.)	☐	☐
	There are no forms that businesses would be required to submit to the Department as a result of this proposal.		
6.	Will electronic reporting and data collection be used, including electronic validation and confirmation of receipt of reports where appropriate?	☐	☐
	This proposal does not entail any reporting of information to the Department. The Department already has access to information on tobacco products, manufacturers and impo and their activities under the *Tobacco Reporting Regulations*.		
7.	Will reporting, if required by the proposed Regulations, be aligned with generally used business processes or international standards if possible?	☐	☐
	No reporting will be required under this proposal.		
8.	If additional forms are required, can they be streamlined with existing forms that must be completed for other government information requirements?	☐	☐
	No forms will be required under this proposal.		
III	**Implementation, compliance and service standards**	**Yes**	**No**
1.	Has consideration been given to small businesses in remote areas, with special consideration to those that do not have access to high-speed (broadband) Internet?	☐	☑
	No small businesses that would be affected by this proposal are located in a remote area. All businesses that would be affected already submit information required under t *Tobacco Reporting Regulations* electronically via email to Health Canada.		
2.	If regulatory authorizations (e.g. licences, permits or certifications) are introduced, will service standards addressing timeliness of decision making be developed that are inclusive of complaints about poor service?	☐	☐
	No regulatory authorizations will be introduced in this proposal.		
3.	Is there a clearly identified contact point or help desk for small businesses and other stakeholders?	☑	☐

B. Regulatory flexibility analysis and reverse onus

IV	**Regulatory flexibility analysis**	**Yes**	**No**

1.	Does the RIAS identify at least one flexible option that has lower compliance or administrative costs for small businesses in the small business lens section? Examples of flexible options to minimize costs are as follows: • Longer time periods to comply with the requirements, longer transition periods or temporary exemptions; • Performance-based standards; • Partial or complete exemptions from compliance, especially for firms that have good track records (legal advice should be sought when considering such an option); • Reduced compliance costs; • Reduced fees or other charges or penalties; • Use of market incentives; • A range of options to comply with requirements, including lower-cost options; • Simplified and less frequent reporting obligations and inspections; and • Licences granted on a permanent basis or renewed less frequently.	☑	☐
2.	Does the RIAS include, as part of the Regulatory Flexibility Analysis Statement, quantified and monetized compliance and administrative costs for small businesses associated with the initial option assessed, as well as the flexible, lower-cost option?	☐	☑
	The RIAS includes quantified and monetized compliance and administrative costs for small businesses associated with the initial option assessed, as well as the flexible, low cost option, but did not use the Regulatory Cost Calculator. A detailed Excel spreadsheet was provided.		
3.	Does the RIAS include, as part of the Regulatory Flexibility Analysis Statement, a consideration of the risks associated with the flexible option? (Minimizing administrative or compliance costs for small business cannot be at the expense of greater health, security or safety or create environmental risks for Canadians.)	☑	☐
4.	Does the RIAS include a summary of feedback provided by small business during consultations?	☑	☐
V	**Reverse onus**	**Yes**	**No**
1.	If the recommended option is not the lower-cost option for small business in terms of administrative or compliance costs, is a reasonable justification provided in the RIAS?	☑	☐

Footnotes

a S.C. 2018, c. 9, s. 11

b S.C. 2018, c. 9, s. 44

c S.C. 1997, c. 13; S.C. 2018, c. 9, s. 2

1 SOR/2000-272

2 SOR/2011-177

3 Dobrescu, A., Bhandari, A., Sutherland, G., & Dinh, T. (2017). The costs of tobacco use in Canada, 2012. *The Conference Board of Canada*. Retrieved from https://www.canada.ca/en/health-canada/services/publications/healthy-living/costs-tobacco-use-canada-2012.html (https://www.canada.ca/en/health-canada/services/publications/healthy-living/costs-tobacco-use-canada-2012.html).

4 U.S. Department of Health and Human Services (2014). 50 years of progress: a report of the Surgeon General. *U.S. Department of Health and Human Services*. Retrieved from http://www.surgeongeneral.gov/library/reports/50-years-of-progress/ (http://www.surgeongeneral.gov/library/reports/50-years-of-progress/).

5 Dobrescu, A., Bhandari, A., Sutherland, G., & Dinh, T. (2017). The costs of tobacco use in Canada, 2012. *The Conference Board of Canada*. Retrieved from https://www.canada.ca/en/health-canada/services/publications/healthy-living/costs-tobacco-use-canada-2012.html (https://www.canada.ca/en/health-canada/services/publications/healthy-living/costs-tobacco-use-canada-2012.html).

* The $330 billion is the total benefits, not a net benefit estimate, since the costs associated with FTCS were not included in the analysis.

6 IEc. (2017). Economic evaluation of Health Canada's proposal to require plain and standardized packaging for tobacco products. *Prepared for Health Canada*.

7 World Health Organization (2017). WHO report on the global tobacco epidemic, 2017, country profile, Canada. Retrieved from the World Health Organization website: http://www.who.int/tobacco/surveillance/policy/country_profile/can.pdf (http://www.who.int/tobacco/surveillance/policy/country_profile/can.pdf).

8 Health Canada (2018). Canadian Tobacco, Alcohol and Drugs Survey. https://www.canada.ca/en/health-canada/services/canadian- tobacco-alc drugs-survey/2017-summary.html (https://www.canada.ca/en/health-canada/services/canadian-tobacco-alcohol-drugs-survey/2017-summary.htr

9 Health Canada (2018). Canadian Tobacco, Alcohol and Drugs Survey. https://www.canada.ca/en/health-canada/services/canadian-tobacco-alcc drugs-survey/2017-summary.html (https://www.canada.ca/en/health-canada/services/canadian-tobacco-alcohol-drugs-survey/2017-summary.htr

10 Health Canada (2018). Canadian Student Tobacco, Alcohol and Drugs Survey 2016-17. https://www.canada.ca/en/health-canada/services/canac student-tobacco-alcohol-drugs-survey/2016-2017-summary.html (https://www.canada.ca/en/health-canada/services/canadian-student-tobacco-alcohol-drugs-survey/2016-2017-summary.html).

11 U.S. Department of Health and Human Services (2010). How tobacco smoke causes disease: a report of the Surgeon General. *U.S. Department Health and Human Services*. Atlanta GA.

12 U.S. Department of Health and Human Services. (2012). The tobacco industry's influences on the use of tobacco among youth. In: preventing tobacco use among youth and young adults. A report of the Surgeon General. *U.S. Department of Health and Human Services*. Retrieved from http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/ (http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/).

13 DiFranza, J. R., Eddy, J. J., Brown, L. F., Ryan, J. L., & Bogojavlensky, A. (1994). Tobacco acquisition and cigarette brand selection among youth *Tobacco Control*, 3(4), 334-338. doi:10.1136/tc.3.4.334.

14 Moodie, C., Stead, M., Bauld, L., McNeill, A., Angusa, K., Hinds, K., et al. (2012). Plain Tobacco Packaging: A Systematic Review. *Public Health Research Consortium*. Retrieved from http://phrc.lshtm.ac.uk/project_2011-2016_006.html (http://phrc.lshtm.ac.uk/project_2011-2016_006.html).

15 Greenland, S. J. (2013). Cigarette brand variant portfolio strategy and the use of colour in a darkening market. *Tobacco Control*, 24, e1-e2. doi: 10.1136/tobaccocontrol-2014-051884.

16 Pollay, R. W. (2000). How cigarette advertising works: rich imagery and poor information. *Imperial Tobacco Ltd, Rothman, Benson & Hedges Inc RJR MacDonald Inc. vs. Attorney General of Canada*.

17 Marlboro Brand Review (1992). *Marlboro Brand Group*. Bates: 2501081089.

18 Kwechansky Marketing Research Inc. (1982). Project Plus/Minus. *Report for: Imperial Tobacco Limited*. Bates: 566627751.

19 Qualitative Science Inc. (1995). Marketing research debrief - evaluation of the opportunity for American brands in Canada. *Prepared for RJR Macdonald*, 8708-8710. bates: TA22918-TA22933.

20 Pollay, R. W. (2000). How cigarette advertising works: rich imagery and poor information. *Imperial Tobacco Ltd, Rothman, Benson & Hedges Inc RJR MacDonald Inc. vs. Attorney General of Canada*.

21 Cummings, K. M., Morley, C., Horan, J., Steger, C., & Leavell, N.-R. (2002). Marketing to America's youth: evidence from corporate documents. *Tobacco Control*, 11(suppl 1), i5–i17.

22 Hammond, D., Doxey, J., Daniel, S., & Bansal-Travers, M. (2011). Impact of female-oriented cigarette packaging in the United States. *Nicotine & Tobacco Research*, 13(7), 579–588. doi: 10.1093/ntr/ntr045.

23 White, C. M., Hammond, D., Thrasher, J. F., & Fong, G. T. (2012). The potential impact of plain packaging of cigarette products among Brazilian young women: an experimental study. *BMC Public Health*, 12(1), 737. doi: 10.1186/1471-2458-12-737.

24 Ford, A., MacKintosh, A. M., Moodie, C., Richardson, S., & Hastings, G. (2013). Cigarette pack design and adolescent smoking susceptibility: a cross-sectional survey. *BMJ Open*, 3(9), e003282. doi: 10.1136/bmjopen-2013-003282.

25 Hammond, D., White, C., Anderson, W., Arnott, D., & Dockrell, M. (2014). The perceptions of UK youth of branded and standardized, "plain" ciga packaging. *European Journal of Public Health*, 24(4), 537–543. doi: 10.1093/eurpub/ckt142.

26 Scheffels, J. (2008). A difference that makes a difference: young adult smokers' accounts of cigarette brands and package design. *Tobacco con* 17(2), 118-122. doi:10.1136/tc.2007.021592.

27 Wakefield, M., Morley, C., Horan, J. K., & Cummings, K. M. (2002). The cigarette pack as image: new evidence from tobacco industry documents *Tobacco Control*, 11(Suppl 1), I73-80. doi:10.1136/tc.11.suppl_1.i73.

28 Moodie, C., Stead, M., Bauld, L., McNeill, A., Angus, K., Hinds, K., et al. (2012). Plain tobacco packaging: A systematic review. Public health research consortium. Retrieved from http://phrc.lshtm.ac.uk/project_2011-2016_006.html (http://phrc.lshtm.ac.uk/project_2011-2016_006.html).

29 Borland, R., Savvas, S., Sharkie, F., & Moore, K. (2011). The impact of structural packaging design on young adult smokers' perceptions of tobac products. *Tobacco Control*, 22(2), 97-102. doi: 10.1136/tobaccocontrol-2011-050078.

30 Kotnowski, K., Fong, G. T., Gallopel-Morvan, K., Islam, T., & Hammond, D. (2016). The Impact of Cigarette Packaging Design Among Young Fem in Canada: Findings From a Discrete Choice Experiment. *Nicotine & Tobacco Research*, 18(5), 1348-1356. doi: 10.1093/ntr/ntv114.

31 Kotnowski, K., & Hammond, D. (2013). The impact of cigarette pack shape, size and opening: evidence from tobacco company documents. *Addiction*, 108(9), 1658-1668. doi: 10.1111/add.12183.

32 Moodie, C., Ford, A., Mackintosh, A. M., & Hastings, G. (2012). Young peoples' perceptions of cigarette packaging and plain packaging: an onlir survey. *Nicotine & Tobacco Research*, 14(1), 98-105. doi: 10.1093/ntr/ntr136.

33 Wakefield, M., Morley, C., Horan, J. K., & Cummings, K. M. (2002). The cigarette pack as image: new evidence from tobacco industry documents *Tobacco Control*, 11 (Suppl 1), I73-80. doi:10.1136/tc.11.suppl_1.i73.

34 Kotnowski, K., & Hammond, D. (2013). The impact of cigarette pack shape, size and opening: evidence from tobacco company documents. *Addiction*, 108(9), 1658–1668. doi: 10.1111/add.12183.

35 Borland, R., Savvas, S., Sharkie, F., & Moore, K. (2011). The impact of structural packaging design on young adult smokers' perceptions of tobac products. *Tobacco Contro*l, *22*(2), 97-102. doi: 10.1136/tobaccocontrol-2011-050078.

36 Doxey, J., & Hammond, D. (2011). Deadly in pink: the impact of cigarette packaging among young women. *Tobacco Control*, 20(5), 353-60. doi: 10.1136/tc.2010.038315.

37 Hammond, D., Doxey, J., Daniel, S., & Bansal-Travers, M. (2011). Impact of female-oriented cigarette packaging in the United States. *Nicotine & Tobacco Research*, 13(7), 579–588. doi: 10.1093/ntr/ntr045.

38 Kotnowski, K., & Hammond, D. (2013). The impact of cigarette pack shape, size and opening: evidence from tobacco company documents. Addiction, 108(9), 1658–1668. doi: 10.1111/add.12183.

39 Kotnowski, K., & Hammond, D. (2013). The impact of cigarette pack shape, size and opening: evidence from tobacco company documents. *Addiction*, 108(9), 1658–1668. doi: 10.1111/add.12183.

40 Hammond, D. (2009). Tobacco labelling and packaging toolkit: A guide to FCTC article 11. Retrieved from http://www.tobaccolabels.ca/wp/wp-content/uploads/2013/12/IUATLD-Tookit-Complete-Mar-3-2009.pdf (http://www.tobaccolabels.ca/wp/wp-content/uploads/2013/12/IUATLD-Tookit-Complete-Mar-3-2009.pdf).

41 Borland, R., Savvas, S., Sharkie, F., & Moore, K. (2011). The impact of structural packaging design on young adult smokers' perceptions of tobac products. *Tobacco Control*, 22(2), 97-102. doi: 10.1136/tobaccocontrol-2011-050078.

42 Kotnowski, K., Fong, G. T., Gallopel-Morvan, K., Islam, T., & Hammond, D. (2016). The Impact of Cigarette Packaging Design Among Young Fem in Canada: Findings From a Discrete Choice Experiment. *Nicotine & Tobacco Research*, 18(5), 1348-1356. doi: 10.1093/ntr/ntv114.

43 Qualitative Science (1991). Research Report – Exploration of various design parameters re: export a pack re-design. *Prepared for RJR Macdona* bates: TA23163-TA23240.

44 Hammond, D., Parkinson, C. (2009). The impact of cigarette package design on perceptions of risk. *J Public Health*, 31(3), 345-353. doi: 10.1093/pubmed/fdp066.

45 Borland, R., Savvas, S., Sharkie, F., & Moore, K. (2011). The impact of structural packaging design on young adult smokers' perceptions of tobac products. *Tobacco Contro*l, *22*(2), 97-102. doi: 10.1136/tobaccocontrol-2011-050078.

46 Kotnowski, K., & Hammond, D. (2013). The impact of cigarette pack shape, size and opening: evidence from tobacco company documents. *Addiction*, 108(9), 1658-1668. doi: 10.1111/add.12183.

47 Borland, R., Savvas, S., Sharkie, F., & Moore, K. (2011). The impact of structural packaging design on young adult smokers' perceptions of tobac products. *Tobacco Control*, 22(2), 97-102. doi:10.1136/tobaccocontrol-2011-050078.

48 Kotnowski, K., & Hammond, D. (2013). The impact of cigarette pack shape, size and opening: evidence from tobacco company documents. *Addiction*, 108(9), 1658-1668. doi: 10.1111/add.12183.

49 Goldberg, M. E., Liefeld, J., Madill, J., & Vredenburg, H. (1999). The effect of plain packaging on response to health warnings. *American Journal Public Health*, 89(9), 1434–1435. doi: 10.1136/bmjopen-2014-005836.

50 McCool, J., Webb, L., Cameron, L. D., & Hoek, J. (2012). Graphic warning labels on plain cigarette packs: will they make a difference to adolescents? *Social Science & Medicine*, 74(8), 1269–1273. doi: 10.1016/j.socscimed.2011.

51 Stead, M., Moodie, C., Angus, K., Bauld, L., McNeill, A., Thomas, J., et. al. (2013). Is consumer response to plain/standardised tobacco packagir consistent with framework convention on tobacco control guidelines? A systematic review of quantitative studies. *PloS One*, 8(10), e75919. doi: 10.1371/journal.pone.0075919.

52 Environics. (2017). Qualitative and Quantitative Research on Standardized Cigarette Design Elements and Cigarette Packages. *Prepared for Hea Canada*. Retrieved from http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2017/041-16-e/report.pdf (http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2017/041-16-e/report.pdf).

53 Wakefield, M., Coomber, K., Zacher, M., Durkin, S., Brennan, E., & Scollo, M. (2015). Australian adult smokers' responses to plain packaging with larger graphic health warnings 1 year after implementation: results from a national cross-sectional tracking survey. *Tobacco Control*, 24(Suppl 2), ii17–ii25. doi: 10.1136/tobaccocontrol-2014-052050.

54 Hammond D. (2006). Canada: A new angle on packs. *Tobacco Control*, 15(3), 146-150.

55 Borland, R., Savvas, S., Sharkie, F., & Moore, K. (2011). The impact of structural packaging design on young adult smokers' perceptions of tobac products. *Tobacco Control*, 22(2), 97-102. doi: 10.1136/tobaccocontrol-2011-050078.

56 Wakefield, M. A., Germain, D., & Durkin, S. J. (2008). How does increasingly plainer cigarette packaging influence adult smokers' perceptions ab brand image? An experimental study. *Tobacco Control*, 17(6), 416–421. doi: 10.1136/tc.2008.026732.

57 Borland R., Savvas, S., Sharkie, F., & Moore, K. (2011). The impact of structural packaging design on young adult smokers' perceptions of tobac products. *Tobacco Control*, 22(2), 97–102. doi: 10.1136/tobaccocontrol-2011-050078.

58 U.S. Department of Health and Human Services (2012). The tobacco industry's influences on the use of tobacco among youth. In: preventing tobacco use among youth and young adults. A report of the Surgeon General. U.S. *Department of Health and Human Services*. Retrieved from http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/ (http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/).

59 Hammond, D., Dockrell, M., Arnott, D., Lee, A., & McNeill, A. (2009). Cigarette pack design and perceptions of risk among UK adults and youth. *European journal of public health*, 19(6), 631-637. doi:10.1093/eurpub/ckp122.

60 Hammond, D., Doxey, J., Daniel, S., & Bansal-Travers, M. (2011). Impact of female-oriented cigarette packaging in the United States. *Nicotine & Tobacco Research*, 13(7), 579-588. doi:10.1093/ntr/ntr045.

61 Stead, M., Moodie, C., Angus, K., Bauld, L., McNeill, A., Thomas, J., et al. (2013). Is consumer response to plain/standardised tobacco packagin consistent with framework convention on tobacco control guidelines? A systematic review of quantitative studies. *PloS One*, 8(10), e75919. doi: 10.1371/journal.pone.0075919.

62 Hammond, D., Dockrell, M., Arnott, D., Lee, A., & McNeill, A. (2009). Cigarette pack design and perceptions of risk among UK adults and youth. *European Journal of Public Health*, 19(6), 631–637. doi: 10.1093/eurpub/ckp122.

63 Hammond, D., White, C., Anderson, W., Arnott, D., & Dockrell, M. (2013). The perceptions of UK youth of branded and standardized, "plain" ciga packaging. *The European Journal of Public Health*, 24(4):537-43. doi: 10.1093/eurpub/ckt142.

64 Wakefield, M., Coomber, K., Zacher, M., Durkin, S., Brennan, E., & Scollo, M. (2015). Australian adult smokers' responses to plain packaging with larger graphic health warnings 1 year after implementation: Results from a national cross-sectional tracking survey. *Tobacco Control*, 24:ii75-ii25. 10.1136/tobaccocontrol-2014-052050.

65 Greenland, S. (2016). The Australian experience following plain packaging: the impact on tobacco branding. Addiction, 111, 2248-2258. doi: 10.1111/add.13536.

66 Hammond, D., Doxey, J., Daniel, S., & Bansal-Travers, M. (2011). Impact of female-oriented cigarette packaging in the United States. Nicotine & Tobacco Research, 13(7), 579–588. doi: 10.1093/ntr/ntr045.

67 Hammond, D. (2014). Standardized packaging of tobacco products: evidence review. *Prepared on Behalf of the Irish Department of Health*. Retrieved from http://www.drugsandalcohol.ie/22106/1/Standardized-Packaging-of-Tobacco-Products-Evidence-Review.pdf (http://www.drugsandalcohol.ie/22106/1/Standardized-Packaging-of-Tobacco-Products-Evidence-Review.pdf).

68 Qualitative Science Incorperated (1995). Marketing research debrief - evaluation of the opportunity for American brands in Canada. *Prepared for RJR Macdonald*. 8708-8710. bates: TA22918-TA22933.

69 Freeman, B., Chapman, S., & Rimmer, M. (2008). The case for the plain packaging of tobacco products. *Addiction*, 103(4), 580–590. doi: 10.1111/j.1360-0443.2008.02145.x.

70 Qualitative Science (1991). Research Report – Exploration of various design parameters re: export a pack re-design. *Prepared for RJR Macdona* bates: TA23163-TA23240.

71 Cook, B. L., Wayne, G. F., Keithly, L., & Connolly, G. (2003). One size does not fit all: how the tobacco industry has altered cigarette design to targ consumer groups with specific psychological and psychosocial needs. *Addiction*, 98(11), 1547–1561. pmid: 14616181.

72 Carpenter, C. M., Wayne, G. F., Pauly, J. L., Koh, H. K., & Connolly, G. N. (2005). New cigarette brands with flavors that appeal to youth: tobacco marketing strategies. *Health Affairs*, 24(6), 1601–1610. doi: 10.1377/hlthaff.24.6.1601.

73 Ford, A., MacKintosh, A. M., Moodie, C., Richardson, S., & Hastings, G. (2013). Cigarette pack design and adolescent smoking susceptibility: a cross-sectional survey. *BMJ Open*, 3(9), e003282. doi: 10.1136/bmjopen-2013-003282.

74 Borland, R., Savvas, S. (2012). Effects of stick design features on perceptions of characteristics of cigarettes. *Tobacco Control*. doi:10.1136/tobaccocontrol-2011-050199.

75 Wakefield, M., Morley, C., Horan, J. K., & Cummings, K. M. (2002). The cigarette pack as image: new evidence from tobacco industry documents *Tobacco Control*, 11(Suppl 1), I73-80. doi:10.1136/tc.11.suppl_1.i73.

76 Burrows. D. (1984). Younger adult smoker: strategies and opportunities. *Prepared for R. J. Reynolds*. bates: 501928462-501929550.

77 Environics. (2017). Qualitative and quantitative research on standardized cigarette design elements and cigarette packages. *Prepared for Health Canada*.

78 Moodie, C., A. M. MacKintosh, K. Gallopel-Morvan, G. Hastings, A. Ford. (2016). Adolescents' perceptions of an oncigarette health warning. *Nico and Tobacco Research*. 1-6. doi:10.1093/ntr/ntw165.

79 Analytic Insight Inc. (1986). Capri: the consumer acclimation process and reactions to proposed packaging. *Prepared for Brown & Williamson*. b 465902929-465902991.

80 Carpenter C., Wayne G. & Connolly G. (2005). Designing cigarettes for women: new findings from the tobacco industry documents. *Addiction*. 100(6), 837–851. doi:10.1111/j.1360-0443.2005.01072.x.

81 RJR (1988). Review of female targeted brands. *RJ Reynolds*. bates: 507124752-4797.

82 RJR (1988). Review of female targeted brands. *RJ Reynolds*. bates: 507124752-4797.

83 Ford, A., Moodie, C., MacKintosh, A. M., & Hastings, G. (2014). Adolescent perceptions of cigarette appearance. *European Journal of Public Hea* 24(3):464-8. doi: 10.1093/eurpub/ckt161.

84 Hammond, D. (2014). Standardized packaging of tobacco products: evidence review. *Prepared on Behalf of the Irish Department of Health*. Retrieved from http://www.drugsandalcohol.ie/22106/1/Standardized-Packaging-of-Tobacco-Products-Evidence-Review.pdf (http://www.drugsandalcohol.ie/22106/1/Standardized-Packaging-of-Tobacco-Products-Evidence-Review.pdf).

85 Moodie, C., Stead, M., Bauld, L., McNeill, A., Angusa, K., Hinds, K., et al. (2012). Plain Tobacco Packaging: A Systematic Review. *Public Health Research Consortium*. Retrieved from http://phrc.lshtm.ac.uk/project_2011-2016_006.html (http://phrc.lshtm.ac.uk/project_2011-2016_006.html).

86 Wakefield, M. A., Germain, D., & Durkin, S. J. (2008). How does increasingly plainer cigarette packaging influence adult smokers' perceptions ab brand image? An experimental study. *Tobacco Control*, 17(6), 416–421. doi: 10.1136/tc.2008.026732.

87 Stead, M., Moodie, C., Angus, K., Bauld, L., McNeill, A., Thomas, J., et. al. (2013). Is consumer response to plain/ standardised tobacco packagi consistent with framework convention on tobacco control guidelines? A systematic review of quantitative studies. *PloS One*, 8(10), e75919. doi: 10.1371/journal.pone.0075919.

88 GfK (2011). Market research to determine effective plain packaging of tobacco products. *Prepared for the Department of Health and Ageing, Sin Cotterell, Drug Strategy Branch*. Retrieved from http://www.health.gov.au/internet/publications/publishing.nsf/Content/mr-plainpack-mr-tob-produc (http://www.health.gov.au/internet/publications/publishing.nsf/Content/mr-plainpack-mr-tob-products).

89 Environics (2017). Qualitative and quantitative research on standardized cigarette design elements and cigarette packages. *Prepared for Health Canada*. Retrieved from http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2017/041-16-e/report.pdf (http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2017/041-16-e/report.pdf).

90 McCool, J., Webb, L., Cameron, L. D., & Hoek, J. (2012). Graphic warning labels on plain cigarette packs: will they make a difference to adolescents? *Social Science & Medicine*, 74(8), 1269–1273. doi: 10.1016/j.socscimed.2011.12.043.

91 Stead, M., Moodie, C., Angus, K., Bauld, L., McNeill, A., Thomas, J., et. al. (2013). Is consumer response to plain/ standardised tobacco packagi consistent with framework convention on tobacco control guidelines? A systematic review of quantitative studies. *PloS One*, 8(10), e75919. doi: 10.1371/journal.pone.0075919.

92 Goldberg, M. E., Liefeld, J., Madill, J., & Vredenburg, H. (1999). The effect of plain packaging on response to health warnings. *American Journal Public Health*, 89(9), 1434–1435.

93 Environics (2017). Qualitative and quantitative research on standardized cigarette design elements and cigarette packages. *Prepared for Health Canada*. Retrieved from http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2017/041-16-e/report.pdf (http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2017/041-16-e/report.pdf).

94 GfK (2011). Market research to determine effective plain packaging of tobacco products. *Prepared for the Department of Health and Ageing, Sin Cotterell, Drug Strategy Branch*. Retrieved from http://www.health.gov.au/internet/publications/publishing.nsf/Content/mr-plainpack-mr-tob-produc (http://www.health.gov.au/internet/publications/publishing.nsf/Content/mr-plainpack-mr-tob-products).

95 Hammond, D., Dockrell, M., Arnott, D., Lee, A., & McNeill, A. (2009). Cigarette pack design and perceptions of risk among UK adults and youth. *European Journal of Public Health*, 19(6), 631–637. doi: 10.1093/eurpub/ckp122.

96 Environics. (2017). Qualitative and quantitative research on standardized cigarette design elements and cigarette packages. *Prepared for Health Canada*. Retrieved from http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2017/041-16-e/report.pdf (http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2017/041-16-e/report.pdf).

97 Environics. (2017). Qualitative and quantitative research on standardized cigarette design elements and cigarette packages. *Prepared for Health Canada*. Retrieved from http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2017/041-16-e/report.pdf (http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2017/041-16-e/report.pdf).

‡ For further detail, refer to the "Public opinion research" section.

98 Hammond, D. (2014). Standardized Packaging of Tobacco Products Evidence Review. *Prepared on Behalf of the Irish Department of Health*.

99 Borland, R., Savvas, S., Sharkie, F., & Moore, K. (2011). The impact of structural packaging design on young adult smokers' perceptions of tobac products. *Tobacco Control*, 22(2), 97-102. doi: 10.1136/tobaccocontrol-2011-050078.

100 Moodie, C., Ford, A., Mackintosh, A. M., & Hastings, G. (2012). Young peoples' perceptions of cigarette packaging and plain packaging: an onlir survey. *Nicotine & Tobacco Research*, 14(1), 98-105. doi: 10.1093/ntr/ntr136.

101 Kotnowski, K., Fong, G. T., Gallopel-Morvan, K., Islam, T., & Hammond, D. (2016). The Impact of Cigarette Packaging Design Among Young Fem in Canada: Findings From a Discrete Choice Experiment. *Nicotine & Tobacco Research*, 18(5), 1348-1356. doi: 10.1093/ntr/ntv114.

102 Kotnowski, K., & Hammond, D. (2013). The impact of cigarette pack shape, size and opening: evidence from tobacco company documents. *Addiction*, 108(9), 1658-1668. doi:10.1111/add.12183.

103 Institute for Global Tobacco Control. (2013). State of Evidence Review: Health Warning Labels on Tobacco Products. Retrieved from https://globaltobaccocontrol.org/sites/default/files/HealthWarnings_state_of_evidence_final_11_18_2013_web_0.pdf (https://globaltobaccocontrol.org/sites/default/files/HealthWarnings_state_of_evidence_final_11_18_2013_web_0.pdf).

104 World Health Organization. (2013). Guidelines for implementation: Article 5.3; Article 8; Articles 9 and 10; Article 11; Article 12; Article 13; Article 2013 edition. Retrieved from http://apps.who.int/iris/bitstream/handle/10665/80510/9789241505185_eng.pdf;jsessionid=693895BFF0686859E855BFFDDF69C362?sequence= (http://apps.who.int/iris/bitstream/handle/10665/80510/9789241505185_eng.pdf;jsessionid=693895BFF0686859E855BFFDDF69C362?sequence

105 Thrasher, J. F., Swayampakala, K., Cummings, K. M., Hammond, D., Anshari, D., Krugman, D. M., & Hardin, J. W. (2016). Cigarette package inse can promote efficacy beliefs and sustained smoking cessation attempts: A longitudinal assessment of an innovative policy in Canada. Preventive Medicine, 88(1), 59-65. doi: 10.1016/j.ypmed.2016.03.006.

106 Treasury Board of Canada Secretariat. (2007) Canadian Cost-Benefit Analysis Guide: Regulatory Proposals. Retrieved from https://www.tbs-sct.gc.ca/rtrap-parfa/analys/analys-eng.pdf (https://www.tbs-sct.gc.ca/rtrap-parfa/analys/analys-eng.pdf).

107 Guindon, G. E., Burkhalter, R., & Brown, K. S. (2016). Levels and trends in cigarette contraband in Canada. *Tobacco Control*, 26(5):518-52. doi: 10.1136/tobaccocontrol-2016-052962.

108 Scollo, M., Zacher, M., Coomber, K., & Wakefield, M. (2015). Use of illicit tobacco following introduction of standardised packaging of tobacco products in Australia: results from a national cross-sectional survey. *Tobacco Control*, 24(Suppl 2), ii76–ii81. doi: 10.1136/tobaccocontrol-2014-052072.

109 Gilmore, A. B., Tavakoly, B., Taylor, G., & Reed, H. (2013). Understanding tobacco industry pricing strategy and whether it undermines tobacco ta policy: the example of the UK cigarette market. *Addiction*, 108(7), 1317–1326. doi: 10.1111/add.12159.

110 Etter, J. F. (2012). Financial incentives for smoking cessation in low-income smokers: study protocol for a randomized controlled trial. *Trials*, 13(1) doi: 10.1186/1745-6215-13-88.

111 Scollo, M., Bayly, M., & Wakefield, M. (2015). Did the recommended retail price of tobacco products fall in Australia following the implementation plain packaging? *Tobacco Control*, 24(Suppl 2), ii90–ii93. doi: 10.1136/tobaccocontrol-2014-051948.

112 Health Canada (2018). Canadian Tobacco, Alcohol and Drugs Survey 2017. https://www.canada.ca/en/health-canada/services/canadian-tobacc alcohol-drugs-survey/2017-summary.html (https://www.canada.ca/en/health-canada/services/canadian-tobacco-alcohol-drugs-survey/2017-summary.html).

113 Australian Institute of Health and Welfare (2017). National Drug Strategy Household Survey. *Australian Government*. Retrieved from https://www.aihw.gov.au/reports/illicit-use-of-drugs/ndshs-2016-key-findings/contents/highlights-from- the-2016-survey (https://www.aihw.gov.au/reports/illicit-use-of-drugs/ndshs-2016-key-findings/contents/highlights-from-the-2016-survey).

114 Taylor, D., Hasselblad, V., Henley, S., Thun, M., & Sloan, F. (2002). Benefits of Smoking Cessation for Longevity. *American Journal of Public Healt* 92, 990–996. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447499/ (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447499/).

115 Health Canada (2013). Canadian Tobacco, Alcohol and Drugs Survey 2013. https://www.canada.ca/en/health-canada/services/canadian-tobacc alcohol-drugs-survey/2013-summary.html (https://www.canada.ca/en/health-canada/services/canadian-tobacco-alcohol-drugs-survey/2013-summary.html).

116 Chestnut, L. G., & DeCivita P. (2008). Economic valuation of mortality risk reduction: review and recommendations for policy analysis. *Governme Canada policy research initiative working paper, 037*.

117 Rehm, J., Baliunass, D., Brochu, S., Fischer, B., Gnam, W., Patra, J., et al. (2006). The Cost of Substance abuse in Canada 2002. *Canadian Cent on Substance Abuse*. Retrieved from http://www.ccsa.ca/Resource%20Library/ccsa-011332-2006.pdf (http://www.ccsa.ca/Resource%20Library/ccsa-011332-2006.pdf).

118 Max, W., Sung, H.-Y., & Shi, Y. (2009). Who Is Exposed to Secondhand Smoke? Self-Reported and Serum Cotinine Measured Exposure in the U.S 1999-2006. *International Journal of Environmental Research and Public Health*, 6(5), 1633-48. doi: 10.3390/ijerph6051633.

119 Health Canada (2018). Canadian Tobacco, Alcohol and Drugs Survey 2017. https://www.canada.ca/en/health-canada/services/canadian-tobacc alcohol-drugs-survey/2017-summary.html (https://www.canada.ca/en/health-canada/services/canadian-tobacco-alcohol-drugs-survey/2017-summary.html).

120 Wakefield M., Coomber, K. Zacher, M. Durkin S., Brennan E., Scollo M. (2015). Australian adult smokers' responses to plain packaging with large graphic health warning 1 year after implementation: results from a national cross-sectional tracking survey. *Tobacco Control*. 24. Ii17-ii25. doi: 10.1136/tobaccocontrol-2014-052050.

121 World Health Organization. (2015). WHO report on the global tobacco epidemic, 2015, country profile, Canada. Retrieved from: http://www.who.int/tobacco/surveillance/policy/country_profile/can.pdf (http://www.who.int/tobacco/surveillance/policy/country_profile/can.pdf).

122 U.S. Department of Health and Human Services. (2010). How tobacco smoke causes disease. *A report of the Surgeon General*.

123 Hammond, D., Doxey, J., Daniel, S., & Bansal-Travers, M. (2011). Impact of female-oriented cigarette packaging in the United States. *Nicotine & Tobacco Research*, 13(7), 579–588. doi: 10.1093/ntr/ntr045.

124 White, C. M., Hammond, D., Thrasher, J. F., & Fong, G. T. (2012). The potential impact of plain packaging of cigarette products among Brazilian young women: an experimental study. *BMC Public Health*, 12(1), 737. doi: 10.1186/1471-2458-12-737.

125 Ford, A., MacKintosh, A. M., Moodie, C., Richardson, S., & Hastings, G. (2013). Cigarette pack design and adolescent smoking susceptibility: a cross-sectional survey. *BMJ Open*, 3(9), e003282. doi: 10.1136/bmjopen-2013-003282.

126 Hammond, D., White, C., Anderson, W., Arnott, D., & Dockrell, M. (2014). The perceptions of UK youth of branded and standardized, "plain" ciga packaging. *European Journal of Public Health*, 24(4), 537–543. doi: 10.1093/eurpub/ckt142.

127 DiFranza, J. R., Eddy, J. J., Brown, L. F., Ryan, J. L., & Bogojavlensky, A. (1994). Tobacco acquisition and cigarette brand selection among youth *Tobacco Control*, 3(4), 334.

128 Moodie C., Stead M., Bauld L., McNeill A., Angus K., Hinds K., Kwan I., Thomas J., Hastings G. & O'Mara-Eves A. (2012). Plain tobacco packagi a systematic review. *London: University of London, Institute of Education, Social Science Research Unit, EPPI-Centre.* Retrieved from: http://phrc.lshtm.ac.uk/papers/PHRC_006_Final_Report.pdf (http://phrc.lshtm.ac.uk/papers/PHRC_006_Final_Report.pdf).

Government of Canada activities and initiatives

#YourBudget2018 – Advancement

(https://www.budget.gc.ca/2018/docs/themes/advancement-en.html?utm_source=CanCa&utm_medium=Activities_e&utm_content=AdvancingCanada&utm_campaign=YourBudget18)

Advancing our shared values

#YourBudget2018 – Reconciliation

(https://www.budget.gc.ca/2018/docs/themes/reconciliation-en.html?utm_source=CanCa&utm_medium=Activities_e&utm_content=AdvancingCanada&utm_campaign=YourBudget18)

Advancing reconciliation with Indigenous Peoples

#YourBudget2018 – Progress

(https://www.budget.gc.ca/2018/docs/themes/progres-en.html?utm_source=CanCa&utm_medium=Activities_e&utm_content=AdvancingCanada&utm_campaign=YourBudget18)

Supporting Canada's researchers to build a r innovative economy