

CONTENTS CHECK LIST

The following is a list of the pages to allow subscribers to check that their Departmental Consolidation of the Food and Drugs Act and of the Food and Drug Regulations is complete and up to date as per December 31, 2002.

Page	Date	Page	Date	Page	Date
(i)	December 2002	55a	December 2002	60-55	December 2002
(ii)	December 2002	56	March 1994	60-56	December 2002
(iii)	December 2002	57	December 2002	60-57	December 2002
(iv)	May 1997	57a	December 2002	60-58	December 2002
1	December 2001	57b	December 2002	60-59	December 2002
2	May 1989	58	December 2002	60-60	December 2002
3	May 1989	58a	December 2002	60-61	December 2002
4	April 1997	58b	December 2002	60-62	December 2002
5	December 1988	59	December 2002	60-63	December 2002
6	April 1997	60	December 2002	60-64	December 2002
7	March 2000	60-1	December 2002	60-65	December 2002
8	November 2002	60-2	December 2002	60-66	December 2002
9	November 2002	60-3	December 2002	60-67	December 2002
10	May 1997	60-4	December 2002	60-68	December 2002
11	October 1999	60-5	December 2002	60-69	December 2002
12	December 1997	60-6	December 2002	60-70	December 2002
13	May 1997	60-7	December 2002	60-71	December 2002
15	December 1989	60-8	December 2002	60-72	December 2002
16	August 1970	60-9	December 2002	60-73	December 2002
17	October 1973	60-10	December 2002	60-74	December 2002
18	December 1975	60-11	December 2002	60-75	December 2002
19	April 1978	60-12	December 2002	60-76	December 2002
20	December 1980	60-13	December 2002	60-77	December 2002
21	November 1984	60-14	December 2002	60-78	December 2002
22	May 1991	60-15	December 2002	60-79	December 2002
23	July 1991	60-16	December 2002	60-80	December 2002
24	December 1993	60-17	December 2002	60-81	December 2002
25	December 1995	60-18	December 2002	60-82	December 2002
26	December 1997	60-19	December 2002	60-83	December 2002
27	December 2000	60-20	December 2002	60-84	December 2002
28	December 2002	60-21	December 2002	60-85	December 2002
28a	December 2002	60-22	December 2002	60-86	December 2002
29	August 2001	60-23	December 2002	60-87	December 2002
30	May 2000	60-24	December 2002	60-88	December 2002
31	July 2000	60-25	December 2002	60-89	December 2002
32	August 2001	60-26	December 2002	60-90	December 2002
33	August 2001	60-27	December 2002	60-91	December 2002
34	August 2001	60-28	December 2002	60-92	December 2002
35	December 2002	60-29	December 2002	60-93	December 2002
36	December 2002	60-30	December 2002	60-94	December 2002
36a	December 2002	60-31	December 2002	60-95	December 2002
36b	December 2002	60-32	December 2002	60-96	December 2002
37	December 2002	60-33	December 2002	60-97	December 2002
38	December 2002	60-34	December 2002	60-98	December 2002
38a	December 2002	60-35	December 2002	60-99	December 2002
39	December 2002	60-36	December 2002	60-100	December 2002
40	December 2002	60-37	December 2002	60-101	December 2002
41	November 2000	60-38	December 2002	60-102	December 2002
42	December 1995	60-39	December 2002	60-103	December 2002
43	November 1997	60-40	December 2002	60-104	December 2002
44	September 1998	60-41	December 2002	60-105	December 2002
45	December 1993	60-42	December 2002	60-106	December 2002
46	May 2000	60-43	December 2002	60-107	December 2002
47	December 2002	60-44	December 2002	60-108	December 2002
47a	December 2002	60-45	December 2002	60-109	December 2002
48	December 2002	60-46	December 2002	60-110	December 2002
48a	December 2002	60-47	December 2002	60-111	December 2002
49	December 2002	60-48	December 2002	60-112	December 2002
50	November 1997	60-49	December 2002	60-113	December 2002
51	November 1997	60-50	December 2002	60-114	December 2002
52	December 2002	60-51	December 2002	60-115	December 2002
53	July 1997	60-52	December 2002	60-116	December 2002
54	July 1997	60-53	December 2002	60-117	December 2002
55	December 2002	60-54	December 2002	60-118	December 2002

60-119	December 2002	127	March 1996	202	January 2002
60-120	December 2002	128	March 1996	203	March 1997
60-121	December 2002	129	December 1991	204	September 1993
60-122	December 2002	130	December 1991	205	April 1997
60-123	December 2002	131	February 1991	206	April 1997
60-124	December 2002	133	December 1997	207	April 1997
60-125	December 2002	134	March 1988	208	September 1979
60-126	December 2002	135	December 1997	209	September 1993
60-127	December 2002	136	August 1995	210	March 1994
60-128	December 2002	137	March 1997	211	November 2000
60-129	December 2002	138	October 1992	212	April 2000
60-130	December 2002	139	December 1990	213	April 2000
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73	October 1992	152	December 1997	226	December 1996
75	May 1997	153	November 1998	227	May 1997
76	May 1997	154	November 1998	228	January 1994
77	May 1997	155	November 1997	229	May 1997
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79	July 1990	157	December 2002	231	May 1997
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82	June 1980	159	November 1997	233	May 1997
83	June 1984	160	March 1994	234	July 1996
84	September 1992	161	March 1997	235	November 1981
85	September 1992	162	June 1988	236	April 1978
87	November 1984	163	April 1984	237	October 1979
88	December 1983	164	August 1982	238	November 1999
89	November 1984	165	August 1982	239	November 1999
90	November 1984	166	July 1983	240	November 1999
91	December 1983	167	January 1998	241	July 1984
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93	November 1984	171	May 2002	243	July 1984
95	October 1995	172	May 2002	244	January 1990
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109	June 1991	185-1	October 2002	259	September 1998
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118	December 1983	193	November 2002	269	March 2001
119	March 2001	194	November 2002	270	March 1991
120	February 1994	195	November 2002	271	December 1990
121	February 1994	196	May 2002	272	February 1999
122	September 1998	197	October 2002	273	March 1994
123	February 1985	198	October 2002	274	May 1993
124	May 1997	199	January 2002	275	October 1988
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280	May 1993	364a	December 2002	437	October 2002
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295	May 1997	378	December 2002	452	May 2001
296	May 1997	378a	December 2002	453	December 1999
297	May 1997	379	December 1994	454	December 1996
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300	March 1979	381a	December 2002	457	August 1982
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309	March 1987	390	August 1998	465	October 1985
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518a	December 2002	587	September 2000	663	December 1997
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520	December 2002	590	December 2001	667	November 1999
520a	December 2002	591	December 2001		
521	December 2002	592	September 2000	669	November 1999
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523a	December 2002	594	December 2001		
524	December 2002	595	November 2002		
524a	December 2002	596	December 2001		
525	December 2002	597	November 2002		
526	December 2002	598	December 2001		
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532	February 1971	603	November 2002		
533	May 2001	605	May 1998		
534	May 1997	606	March 2000		
535	May 1997	607	May 2000		
536	September 1985	608	May 2000		
537	April 1984	609	December 1997		
538	April 1984	611	August 2001		
538-1	December 2002	612	August 2001		
538-2	December 2002	613	August 2001		
538-3	December 2002	614	August 2001		
538-4	December 2002	615	August 2001		
538-5	December 2002	616	October 2001		
538-6	December 2002	617	August 2001		
538-7	December 2002	618	August 2001		
538-8	December 2002	619	December 2000		
538-9	December 2002	620	December 2000		
539	May 1978	621	December 2000		
541	November 1997	622	December 2000		
542	March 1999	623	December 2000		
543	May 1997	624	December 2000		
545	December 1997	625	December 2000		
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554	May 1997	635	May 1998		
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573	September 1975	650	June 2001		
575	November 2000	651	May 1998		
576	November 2000	652	May 1998		
577	November 2002	653	May 1998		
578	November 2002	654	May 1998		
579	May 2000	655	May 1998		
580	November 2000	656	May 1998		

DEPARTMENTAL CONSOLIDATION

OF THE

FOOD AND DRUGS ACT

AND OF THE

FOOD AND DRUG

REGULATIONS

WITH AMENDMENTS TO JANUARY 1, 2003



ISSUED BY

DEPARTMENT OF HEALTH



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TABLE OF CONTENTS

	Page
FOOD AND DRUGS ACT	1
Part I — Foods, Drugs, Cosmetics and Devices	2
General	2
Food	2
Drugs	3
Cosmetics	3
Devices	4
Part II — Administration and Enforcement	4
Inspection, Seizure and Forfeiture	4
Analysis	6
Regulations	7
Offences and Punishment	8
Exports	10
Part III — Controlled Drugs	10
Part IV — Restricted Drugs	10
Schedule A	11
Schedule B	11
Schedule C	12
Schedule D	12
Schedule E	12
Schedule F	12
Schedule G	13
Schedule H	13
 FOOD AND DRUG REGULATIONS	 15
Part A — Administration	29
General	29
Interpretation	29
Analysts; Inspectors	30
Importation	31
Exports	31
Sampling	31
Tariff of fees	32
Labelling of Food and Drugs in Pressurized Containers	32
Part B — Foods	35
Division	
1. General	35
Schedule L	60-71
2. Alcoholic Beverages	61
3. Baking Powder	73
4. Cocoa and Chocolate Products	75
5. Coffee	79
6. Food Colours	81
7. Spices, Dressings and Seasonings	87
8. Dairy Products	95
9. Fats and Oils	123
10. Flavouring Preparations	129
11. Fruits, Vegetables, their Products and Substitutes	133
12. Prepackaged Water and Ice	147
13. Grain and Bakery Products	149
14. Meat, its Preparation and Products	155
15. Adulteration of Food	167
16. Food Additives	203
17. Salt	341
18. Sweetening Agents	343
19. Vinegar	347

TABLE OF CONTENTS — Continued

	Page
Part B — Foods (<i>cont'd</i>)	
20. Tea	349
21. Marine and Fresh Water Animal Products	351
22. Poultry, Poultry Meat, their Preparations and Products	355
23. Food Packaging Materials	361
24. Foods for Special Dietary Use	363
25. Infant Foods, Infant Formula	377
26. Food Irradiation	383
27. Low-Acid Foods Packaged in Hermetically Sealed Containers	385
28. Novel Foods	387
Part C — Drugs	
Division	
1. General	389
1A. Establishment Licences	427
2. Good Manufacturing Practices	435
3. Schedule C Drugs	441
4. Schedule D Drugs	449
5. Drugs for Clinical Trials Involving Human Subjects	483
6. Canadian Standard Drugs	493
7. Schedule F Drugs	499
8. New Drugs	501
9. Non-prescription Drugs	511
10. Proprietary Medicine	515
Part D — Vitamins, Minerals and Amino Acids	
Division	
1. Vitamins in Foods	518
2. Mineral Nutrients in Foods	523
3. Addition of Vitamins, Mineral Nutrients or Amino Acids to Foods	527
4. Vitamins in Drugs	531
5. Minerals in Drugs	535
6. Schedule K	537
7. Schedule M	538-1
Part E — Cyclamate and Saccharin Sweeteners	539
Part G — Controlled Drugs	
Division	
1. General	541
2. Licences and Licensed Dealers	545
3. Pharmacists	549
4. Practitioners	553
5. Hospitals	557
6. Authority and Penalty	559
7. General	561
Part J — Restricted Drugs	565
Schedule F — Part I	575
Part II	605
Cosmetics Regulations	611
Processing and Distribution of Semen for Assisted Conception Regulations	619
Medical Devices Regulations	629
INDEX (Food Additives)	657
Appendix III - Forms	667
	669

FOOD AND DRUGS ACT

Chapter F-27 of the Revised Statutes of Canada, 1985, as amended by

R.S., C.27 (1st Supplement)
R.S., C.31 (1st Supplement)
R.S., C.27 (3rd Supplement)
R.S., C.42 (4th Supplement)

Schedule A to the Act as amended

by P.C. 1988-770 of April 28, 1988,
by P.C. 1989-2100 of October 19, 1989,
by P.C. 1990-2003 of September 20, 1990,
by P.C. 1992-641 of April 2, 1992,
by P.C. 1994-545 of April 14, 1994,

Gazetted May 11, 1988
Gazetted November 8, 1989
Gazetted September 27, 1990
Gazetted April 24, 1992
Gazetted May 4, 1994

Schedule B to the Act as amended

by P.C. 1985-907 of March 21, 1985,
by P.C. 1989-1144 of June 15, 1989,
by P.C. 1990-431 of March 8, 1990,

by P.C. 1994-546 of April 14, 1994,

Gazetted April 3, 1985
Gazetted July 5, 1989

Gazetted March 28, 1990
Gazetted May 4, 1994

Schedule C to the Act as amended

Schedule D to the Act as amended

by P.C. 1985-2354 of July 24, 1985,
by P.C. 1989-477 of March 23, 1989,
by P.C. 1993-197 of February 4, 1993,

Gazetted August 7, 1985
Gazetted April 12, 1989
Gazetted February 24, 1993

Schedule E to the Act as amended

Schedule G to the Act as amended

Repealed May 14, 1997

Gazetted May 14, 1997

Schedule H to the Act as amended

Repealed May 14, 1997

Gazetted May 14, 1997

AN ACT RESPECTING FOOD, DRUGS, COSMETICS AND THERAPEUTIC DEVICES

Short Title

Short Title 1. This Act may be cited as the Food and Drugs Act.

Interpretation

Definitions 2. In this Act,

"advertisement"
«publicité»
ou «annonce» "advertisement" includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device;

"analyst"
«analyste» "analyst" means a person designated as an analyst for the purpose of the enforcement of this Act under section 28 or under section 13 of the *Canadian Food Inspection Agency Act*;

"contraceptive device"
«moyen...» "contraceptive device" means any instrument, apparatus, contrivance or substance other than a drug, that is manufactured, sold or represented for use in the prevention of conception;

"cosmetic"
«cosmétique» "cosmetic" includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and include deodorants and perfumes;

"Department"
«ministère» "Department" means the Department of Health;

"device"
«instruments» "device" means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in
(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
(b) restoring, correcting or modifying a body function or the body structure of human beings or animals,
(c) the diagnosis of pregnancy in human beings or animals, or
(d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring,
and includes a contraceptive device but does not include a drug;

"drug"
«drogue» "drug" includes any substance or mixture of substances manufactured, sold or represented for use in
(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals,
(b) restoring, correcting or modifying organic functions in human beings or animals, or
(c) disinfection in premises in which food is manufactured, prepared or kept;

"food"
«aliment» "food" includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever;

"inspector"
«inspecteur» "inspector" means any person designated as an inspector for the purpose of the enforcement of this Act under subsection 22(1) or under section 13 of the *Canadian Food Inspection Agency Act*;

"label"
«étiquette» "label" includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package;

"Minister"
«Ministre» "Minister" means the Minister of Health;

"package"
«emballage» "package" includes anything in which any food, drug, cosmetic or device is wholly or partly contained, placed or packed;

"prescribed"
«version anglaise seulement» "prescribed" means prescribed by the regulations;

"sell"
«vendre»

"sell" includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration;

"unsanitary conditions"
«conditions...»

"unsanitary conditions" means such conditions or circumstances as might contaminate with dirt or filth, or render injurious to health, a food, drug or cosmetic.

PART I

Foods, Drugs, Cosmetics and Devices

General

Prohibited advertising

3. (1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

Prohibited label or advertisement where sale made

(2) No person shall sell any food, drug, cosmetic or device

- (a) that is represented by label, or
- (b) that the person advertises to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

Unauthorized advertising of contraceptive device prohibited

(3) Except as authorized by regulation, no person shall advertise to the general public any contraceptive device or any drug manufactured, sold or represented for use in the prevention of conception.

Food

Prohibited sales of food

4. No person shall sell an article of food that

- (a) has in or on it any poisonous or harmful substance;
- (b) is unfit for human consumption;
- (c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
- (d) is adulterated; or
- (e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

Deception etc. regarding food

5. (1) No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Food labelled or packaged in contravention of regulations

(2) An article of food that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).

Importation and interprovincial movement of food

6. (1) Where a standard for a food has been prescribed, no person shall

- (a) import into Canada,
- (b) send, convey or receive for conveyance from one province to another, or
- (c) have in possession for the purpose of sending or conveying from one province to another

any article that is intended for sale and that is likely to be mistaken for that food unless the article complies with the prescribed standard.

Not applicable to carriers

(2) Paragraphs (1)(b) and (c) do not apply to an operator of a conveyance that is used to carry an article or to a carrier of an article whose sole concern, in respect of the article, is the conveyance of the article unless the operator or carrier could, with reasonable diligence, have ascertained that the conveying or receiving for conveyance of the article or the possession of the article for the purpose of conveyance would be in contravention of subsection (1).

Labelling, etc., of food that is imported or moved interprovincially

(3) Where a standard for a food has been prescribed, no person shall label, package, sell or advertise any article that

- (a) has been imported into Canada,
- (b) has been sent or conveyed from one province to another, or
- (c) is intended to be sent or conveyed from one province to another

in such a manner that it is likely to be mistaken for that food unless the article complies with the prescribed standard.

Governor in Council may identify standard or portion thereof

6.1 (1) The Governor in Council may, by regulation, identify a standard prescribed for a food or any portion of the standard, as being necessary to prevent injury to the health of the consumer or purchaser of the food.

Where standard or portion thereof is identified

(2) Where a standard or any portion of a standard prescribed for a food is identified by the Governor in Council pursuant to subsection (1), no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that food unless the article complies with the standard or portion of a standard so identified.

Unsanitary manufacture etc., of food

7. No person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions.

Drugs

Prohibited sales of drugs

8. No person shall sell any drug that
(a) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions; or
(b) is adulterated.

Deception etc., regarding drugs

9. (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Drug labelled or packaged in contravention of regulations

(2) A drug that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).

Where standard prescribed for drug

10. (1) Where a standard has been prescribed for a drug, no person shall label, package, sell or advertise any substance in such a manner that is likely to be mistaken for that drug, unless the substance complies with the prescribed standard.

Trade standards

(2) Where a standard has not been prescribed for a drug, but a standard for the drug is contained in any publication referred to in Schedule B, no person shall label, package, sell or advertise any substance in such a manner that it is likely to be mistaken for that drug, unless the substance complies with the standard.

Where no prescribed or trade standard

(3) Where a standard for a drug has not been prescribed and no standard for the or trade drug is contained in any publication referred to in Schedule B, no person shall sell the drug, unless
(a) it is in accordance with the professed standard under which it is sold, and
(b) it does not resemble, in a manner likely to deceive, any drug for which a standard has been prescribed or is contained in any publication referred in Schedule B.

Unsanitary manufacture etc., of drug

11. No person shall manufacture, prepare, preserve, package or store for sale any manufacture drug under unsanitary conditions.

Drugs not to be sold unless safe manufacture indicated

12. No person shall sell any drug described in Schedule C or D unless the Minister has, in prescribed form and manner, indicated that the premises in which the drug was manufactured and the process and conditions of manufacture therein are suitable to ensure that the drug will not be unsafe for use.

Drugs not to be sold unless safe batch indicated

13. No person shall sell any drug described in Schedule E unless the Minister has, in prescribed form and manner, indicated that the batch from which the drug was taken is not unsafe for use.

Samples

14. (1) No person shall distribute or cause to be distributed any drug as a sample.

Exception

(2) Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists.

Schedule F drugs not to be sold

15. No person shall sell any drug described in Schedule F.

Cosmetics

Prohibited sales of cosmetics

16. No person shall sell any cosmetic that
(a) has in or on it any substance that may cause injury to the health of the user when the cosmetic is used,
(i) according to the directions on the label or accompanying the cosmetic, or
(ii) for such purposes and by such methods of use as are customary or usual therefor;
(b) consists in whole or in part of any filthy or decomposed substance or of any foreign matter; or
(c) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

Where standard prescribed for cosmetic

17. Where a standard has been prescribed for a cosmetic, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that cosmetic, unless the article complies with the prescribed standard.

Unsanitary conditions

18. No person shall manufacture, prepare, preserve, package or store for sale any cosmetic under unsanitary conditions.

Devices

Prohibited sales of devices

19. No person shall sell any device that, when used according to directions or under such conditions as are customary or usual, may cause injury to the health of the purchaser or user thereof.

Deception etc., regarding devices

20. (1) No person shall label, package, treat, process, sell or advertise any device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety.

Devices labelled or packaged in contravention of regulations

(2) A device that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).

Where standard prescribed for device

21. Where a standard has been prescribed for a device, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that device, unless the article complies with the prescribed standard.

PART II

ADMINISTRATION AND ENFORCEMENT

Inspection, Seizure and Forfeiture

Inspectors

22. (1) The Minister may designate any person as an inspector for the purpose of the enforcement of this Act.

Certificate to be produced

(2) An inspector shall be given a certificate in a form established by the Minister or the President of the Canadian Food Inspection Agency attesting to the inspector's designation and, on entering any place pursuant to subsection 23(1), an inspector shall, if so required, produce the certificate to the person in charge of that place.

Powers of inspectors

23. (1) Subject to section (1.1), an inspector may at any reasonable time enter any place where the inspector believes on reasonable grounds any article to which this Act or the regulations apply is manufactured, prepared, preserved, packaged or stored, and may

- (a) examine any such article and take samples thereof, and examine anything that the inspector believes on reasonable grounds is used or capable of being used for that manufacture, preparation, preservation, packaging or storing;
- (a.1) enter any conveyance that the inspector believes on reasonable grounds is used to carry any article to which section 6 or 6.1 applies and examine any such article found therein and take samples thereof;
- (b) open and examine any receptacle or package that the inspector believes on reasonable grounds contains any article to which this Act or the regulations apply;
- (c) examine and make copies of, or extracts from, any books, documents or other records found in any place referred to in this subsection that the inspector believes on reasonable grounds contain any information relevant to the enforcement of this Act with respect to any article to which this Act or the regulations apply; and
- (d) seize and detain for such time as may be necessary any article by means of or in relation to which the inspector believes on reasonable grounds any provision of this Act or the regulations has been contravened.

**Warrant required
to enter
dwelling-house**

(1.1) Where any place mentioned in subsection (1) is a dwelling-house, an inspector may not enter that dwelling-house without the consent of the occupant except under the authority of a warrant issued under subsection (1.2).

**Authority to
issue warrant**

(1.2) Where on ex parte application a justice of the peace is satisfied by information on oath

- (a) that the conditions for entry described in paragraph (1) exist in relation to a dwelling-house,
- (b) that entry to the dwelling-house is necessary for any purpose relating to the administration or enforcement of this Act, and
- (c) that entry to the dwelling-house has been refused or that there are reasonable grounds for believing that entry thereto will be refused,

the justice of the peace may issue a warrant under his hand authorizing the inspector named therein to enter that dwelling-house subject to such conditions as may be specified in the warrant.

Use of force

(1.3) In executing a warrant issued under subsection (1.2), the inspector named therein shall not use force unless the inspector is accompanied by a peace officer and the use of force has been specifically authorized in the warrant.

**Definition of
"article to
which this Act
or the
Regulations
apply"**

(2) In subsection (1), "article to which this Act or the regulations apply" includes

- (a) any food, drug, cosmetic or device,
- (b) anything used for the manufacture, preparation, preservation, packaging or storing thereof, and
- (c) any labelling or advertising material.

Assistance and information to be given inspector

(3) The owner or person in charge of a place entered by an inspector pursuant to subsection (1) and every person found therein shall give the inspector all reasonable assistance and furnish the inspector with any information he may reasonably require.

Obstruction and false statements

24. (1) No person shall obstruct or hinder, or knowingly make any false or misleading statement either orally or in writing to, an inspector while the inspector is engaged in carrying out his duties or functions under this Act or the regulations.

Interference

(2) Except with the authority of an inspector, no person shall remove, alter or interfere in any way with anything seized under this Part.

Storage and removal

25. Any article seized under this Part may, at the option of an inspector, be kept or stored in the building or place where it was seized or, at the direction of an inspector, the article may be removed to any other proper place.

Release of seized articles

26. (1) An inspector who has seized any article under this Part shall release it when he is satisfied that all the provisions of this Act and the regulations with respect thereto have been complied with.

Destruction with consent

27. (1) Where an inspector has seized an article under this Part and its owner or the person in whose possession the article was at the time of seizure consents to its destruction, the article is thereupon forfeited to Her Majesty and may be destroyed or otherwise disposed of as the Minister or the Minister of Agriculture and Agri-Food may direct.

Forfeiture

(2) Where a person has been convicted of a contravention of this Act or the regulations, the court or judge may order that any article by means of or in relation to which the offence was committed, and any thing of a similar nature belonging to or in the possession of the person or found with the article, be forfeited. On the making of the order, the article and thing are forfeited to Her Majesty and may be disposed of as the Minister or the Minister of Agriculture and Agri-Food may direct.

Order for forfeiture on application of inspector

(3) Without prejudice to subsection (2), a judge of a superior court of the province in which any article is seized under this Part may, on the application of an inspector and on such notice to such persons as the judge directs, order that the article and any thing of a similar nature found with it be forfeited to Her Majesty, if the judge finds, after making such inquiry as the judge considers necessary, that the article is one by means of or in relation to which any of the provisions of this Act or the regulations have been contravened. On the making of the order, the article or thing may be disposed of as the Minister or the Minister of Agriculture and Agri-Food may direct.

Analysis

Analysts

28. The Minister may designate any person as an analyst for the purpose of the enforcement of this Act.

Analysis and examination

29. (1) An inspector may submit to an analyst, for analysis or examination, any article seized by the inspector, any sample therefrom or any sample taken by the inspector.

Certificate or report

(2) An analyst who has made an analysis or examination may issue a certificate or report setting out the results of the analysis or examination.

Regulations

Regulations

- 30.** (1) The Governor in Council may make regulations for carrying the purposes and provisions of this Act into effect, and, in particular, but without restricting the generality of the foregoing, may make regulations
- (a) declaring that any food or drug or class of food or drugs is adulterated if any prescribed substance or class of substances is present therein or has been added thereto or extracted or omitted therefrom;
 - (b) respecting
 - (i) the labelling and packaging and the offering, exposing and advertising for sale of food, drugs, cosmetics and devices,
 - (ii) the size, dimensions, fill and other specifications of packages of food, drugs, cosmetics and devices,
 - (iii) the sale or the conditions of sale of any food, drug, cosmetic or device, and
 - (iv) the use of any substance as an ingredient in any food, drug, cosmetic or device, to prevent the purchaser or consumer thereof from being deceived or misled in respect of the design, construction, performance, intended use, quantity, character, value, composition, merit or safety thereof, or to prevent injury to the health of the purchaser or consumer;
 - (c) prescribing standards of composition, strength, potency, purity, quality or other property of any article of food, drug, cosmetic or device;
 - (d) respecting the importation of foods, drugs, cosmetics and devices in order to ensure compliance with this Act and the regulations;
 - (e) respecting the method of manufacture, preparation, preserving, packing, storing and testing of any food, drug, cosmetic or device in the interest of, or for the prevention of injury to, the health of the purchaser or consumer;
 - (f) requiring persons who sell food, drugs, cosmetics or devices to maintain such books and records as the Governor in Council considers necessary for the proper enforcement and administration of this Act and the regulations;
 - (g) respecting the form and manner of the Minister's indication under section 12, including the fees payable therefor, and prescribing what premises or what processes or conditions of manufacture, including qualifications of technical staff, shall or shall not be deemed to be suitable for the purposes of that section;
 - (h) requiring manufacturers of any drugs described in Schedule E to submit test portions of any batch of those drugs and respecting the form and manner of the Minister's indication under section 13, including the fees payable therefor;
 - (i) respecting the powers and duties of inspectors and analysts and the taking of samples and the seizure, detention, forfeiture and disposition of articles;
 - (j) exempting any food, drug, cosmetic or device from all or any of the provisions of this Act and prescribing the conditions of the exemption;
 - (k) prescribing forms for the purposes of this Act and the regulations;
 - (l) providing for the analysis of food, drugs or cosmetics other than for the purposes of this Act and prescribing a tariff of fees to be paid for that analysis;
 - (l.1) respecting the assessment of the effect on the environment or on human life and health of the release into the environment of any food, drug, cosmetic or device, and the measures to take before importing or selling any such food, drug, cosmetic or device;
 - (m) adding anything to any of the schedules, in the interest of, or for the prevention of injury to, the health of the purchaser or consumer, or deleting anything therefrom;
 - (n) respecting the distribution or the conditions of distribution of samples of any drug;
 - (o) respecting
 - (i) the method of manufacture, preparation, preserving, packing, labelling, storing and testing of any new drug, and
 - (ii) the sale or the conditions of sale of any new drug, and defining for the purposes of this Act the expression "new drug"; and

- (p) authorizing the advertising to the general public of contraceptive devices and drugs manufactured, sold or represented for use in the prevention of conception and prescribing the circumstances and conditions under which, and the persons by whom, those devices and drugs may be so advertised.

Regulations respecting drugs manufactured outside Canada

- (2) Without limiting or restricting the authority conferred by any other provisions of this Act or any Part thereof for carrying into effect the purposes and provisions of this Act or any Part thereof, the Governor in Council may make such regulations governing, regulating or prohibiting
- (a) the importation into Canada of any drug or class of drugs manufactured outside Canada, or
- (b) the distribution or sale in Canada, or the offering, exposing or having in possession for sale in Canada, of any drug or class of drugs manufactured outside Canada,
- as the Governor in Council deems necessary for the protection of the public in relation to the safety and quality of any such drug or class of drugs.

Regulations re the North American Free Trade Agreement and WTO Agreement

- (3) Without limiting or restricting the authority conferred by any other provisions of this Act or any Part thereof for carrying into effect the purposes and provisions of this Act or any Part thereof, the Governor in Council may make such regulations as the Governor in Council deems necessary for the purpose of implementing, in relation to drugs, Article 1711 of the North American Free Trade Agreement or paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the WTO Agreement.

Definitions

- (4) In subsection (3),

**“North American Free Trade Agreement”
« Accord de libre-échange nord-américain »**

“North American Free Trade Agreement” has the meaning given to the word “Agreement” by subsection 2(1) of the *North American Free Trade Agreement Implementation Act*;

**“WTO Agreement”
« Accord sur l’OMC »**

“WTO Agreement” has the meaning given to the word “Agreement” by subsection 2(1) of the *World Trade Organization Agreement Implementation Act*.

Offences and Punishment

Contravention of Act and regulations

- 31.** Subject to section 31.1 every person who contravenes any of the provisions of this Act or of the regulations made under this Part is guilty of an offence and liable
- (a) on summary conviction for a first offence to a fine not exceeding five hundred dollars or to imprisonment for a term not exceeding three months or to both and, for a subsequent offence, to a fine not exceeding one thousand dollars or to imprisonment for a term not exceeding six months, or to both; and
- (b) on conviction on indictment to a fine not exceeding five thousand dollars or to imprisonment for a term not exceeding three years or to both.

Offences relating to food

- 31.1** Every person who contravenes any provision of this Act or the regulations, as it relates to food, is guilty of an offence and liable
- (a) on summary conviction, to a fine not exceeding \$50,000 or to imprisonment for a term not exceeding six months or to both; or
- (b) on conviction by indictment, to a fine not exceeding \$250,000 or to imprisonment for a term not exceeding three years or to both.

Limitation period

- 32.** (1) A prosecution for a summary conviction offence under this Act may be instituted at any time within two years after the time the subject-matter of the prosecution becomes known to the Minister or, in the case of a contravention of a provision of the Act that relates to food, to the Minister of Agriculture and Agri-Food.

Minister's certificate

- (2) A document purporting to have been issued by the Minister referred to in subsection (1), certifying the day on which the subject-matter of any prosecution became known to the Minister, is admissible in evidence without proof of the signature or official character of the person appearing to have signed the document and is evidence of the matters asserted in it.

Transitional

- (2) *For greater certainty, the two year limitation period provided for in subsection 32(1) of the Act, as amended by subsection (1), only applies in respect of offences committed after the coming into force of that subsection.*

Venue	33. A prosecution for a contravention of this Act or the regulations may be instituted, heard, tried or determined in the place in which the offence was committed or the subject-matter of the prosecution arose or in any place in which the accused is apprehended or happens to be.
Want of knowledge	34. (1) Subject to subsection (2), in a prosecution for the sale of any article in contravention of this Act, except Parts III and IV, or of the regulations made under this Part, if the accused proves to the satisfaction of the court or judge that <ul style="list-style-type: none"> (a) the accused purchased the article from another person in packaged form and sold it in the same package and in the same condition the article was in at the time it was so purchased, and (b) that the accused could not with reasonable diligence have ascertained that the sale of the article would be in contravention of this Act or the regulations, the accused shall be acquitted.
Notice of reliance on want of knowledge	(2) Subsection (1) does not apply in any prosecution unless the accused, at least ten days before the day fixed for the trial, has given to the prosecutor notice in writing that the accused intends to avail himself of the provisions of subsection (1) and has disclosed to the prosecutor the name and address of the person from whom the accused purchased the article and the date of purchase.
Certificate of analyst	35. (1) Subject to this section, in any prosecution for an offence under section 31, a certificate purporting to be signed by an analyst and stating that an article, sample or substance has been submitted to, and analysed or examined by, the analyst and stating the results of the analysis or examination is admissible in evidence and, in the absence of evidence to the contrary, is proof of the statements contained in the certificate without proof of the signature or official character of the person appearing to have signed it.
Requiring attendance of analyst	(2) The party against whom a certificate of an analyst is produced pursuant to subsection (1) may, with leave of the court, require the attendance of the analyst for the purposes of cross-examination.
Notice of intention to produce certificate	(3) No certificate shall be admitted in evidence pursuant to subsection (1) unless, before the trial, the party intending to produce the certificate has given reasonable notice of that intention, together with a copy of the certificate, to the party against whom it is intended to be produced.
Proof of service	(4) For the purposes of this Act, service of any certificate referred to in sub-section (1) may be proved by oral evidence given under oath by, or by the affidavit or solemn declaration of, the person claiming to have served it.
Attendance for examination	(5) Notwithstanding subsection (4), the court may require the person who appears to have signed an affidavit or solemn declaration referred to in that subsection to appear before it for examination or cross-examination in respect of the issue of proof of service.
Proof as to manufacturer or packager	36. (1) In a prosecution for a contravention of this Act or of the regulations made under this Part, proof that a package containing any article to which this Act or the regulations apply bore a name or address purporting to be the name or address of the person by whom it was manufactured or packaged is, in the absence of evidence to the contrary, proof that the article was manufactured or packaged, as the case may be, by the person whose name or address appeared on the package.
Offence by employee or agent	(2) In a prosecution for a contravention described in subsection (1), it is sufficient proof of the offence to establish that it was committed by an employee or agent of the accused whether or not the employee or agent is identified or has been prosecuted for the offence.
Certified copies and extracts	(3) In a prosecution for a contravention described in subsection (1), a copy of a record or an extract therefrom certified to be a true copy by the inspector who made it pursuant to paragraph 23(1)(c) is admissible in evidence and is, in the absence of evidence to the contrary, proof of its contents.
Where accused had adulterating substances	(4) Where a person is prosecuted under this Part for having manufactured an adulterated food or drug for sale, and it is established that the person had in his possession or on his premises any substance the addition of which to that food or drug has been declared by regulation to cause the adulteration of the food or drug, the onus of proving that the food or drug was not adulterated by the addition of that substance lies on the accused.

Exports

Conditions under which exports exempt

37. (1) This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word "Export" or "Exportation" and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner.

Definition of "drug"

(2) Repealed May 14, 1997.

PART III

Controlled Drugs

Repealed May 14, 1997.

PART IV

Restricted Drugs

Repealed May 14, 1997.

SCHEDULE A
(Sections 3 and 30)

	Alcoholism <i>Alcoolisme</i>	Hypotension <i>Hypotension</i>	
21-10-99	Alopecia (except hereditary androgenetic alopecia) <i>Alopécie (sauf l'alopecie androgénogénétique)</i>	Impetigo <i>Impétigo</i>	
	Anxiety state <i>États d'angoisse</i>	Influenza } deleted from schedule A <i>Influenza</i> by P.C. 1990-2003 of 20-9-90	
	Appendicitis <i>Appendicite</i>	Kidney disease <i>Reins (maladies)</i>	
	Arteriosclerosis <i>Artériosclérose</i>	Leukemia <i>Leucémie</i>	
	Arthritis <i>Arthrite</i>	Liver disease (except hepatitis) } 21-10-99 <i>Foie (maladies sauf l'hépatite)</i>	
19-10-89	Asthma <i>Asthme</i>		
	Bladder disease <i>Vessie (maladies)</i>	Nausea and vomiting of pregnancy <i>Nausées et vomissements de la grossesse</i>	
	Cancer <i>Cancer</i>	Obesity <i>Obésité</i>	
	Convulsions <i>Convulsions</i>	Pleurisy <i>Pleurésie</i>	
	Depression <i>Dépression</i>	Pneumonia } deleted from schedule A <i>Pneumonie</i> by P.C. 1992-641 of 02-4-92	
	Diabetes <i>Diabète</i>	Poliomyelitis } deleted from schedule A <i>Poliomyélite</i> by P.C. 1992-641 of 02-4-92	
	Disease of the prostate <i>Prostate (maladies)</i>	Rheumatic fever <i>Rhumatisme articulaire aigu</i>	
	Disorder of menstrual flow <i>Troubles du flot menstruel</i>	Scabies } deleted from schedule A <i>Gale</i> by P.C. 1988-770 of 28-4-88	
	Dysentery <i>Dysenterie</i>	Septicemia <i>Septicémie</i>	
	Edematous state <i>Oedème</i>	Sexual impotence <i>Impuissance sexuelle</i>	
	Epilepsy <i>Épilepsie</i>	Tetanus } deleted from schedule A <i>Tétanos</i> by P.C. 1992-641 of 02-4-92	
	Gall Bladder disease <i>Vésicule biliaire (maladies)</i>	Thrombotic and Embolic disorders <i>Maladies thrombotiques et embolies</i>	
	Gangrene <i>Gangrène</i>	Thyroid disease <i>Glande thyroïdienne (affections)</i>	
	Glaucoma <i>Glaucome</i>	Tuberculosis } deleted from schedule A <i>Tuberculose</i> by P.C. 1992-641 of 02-4-92	
	Gout <i>Goutte</i>	Tumor <i>Tumeurs</i>	
	Heart disease <i>Coeur (maladies)</i>	Ulcer of the gastro-intestinal tract <i>Ulcères des voies gastro-intestinales</i>	
	Hernia <i>Hernie</i>	Vaginitis } deleted from schedule A <i>Vaginite</i> by P.C. 1994-545 of 14-4-94	
	Hypertension <i>Hypertension</i>	Venereal disease <i>Maladies vénériennes</i>	

SCHEDULE B
(Sections 10 and 30)

The most recent editions, including all errata, supplements, revisions and addenda, of the following standards:

23-1-96

<i>Item</i>	<i>Column I Name</i>	<i>Column II Abbreviation</i>
1.	European Pharmacopoeia	(Ph.Eur.)
2.	Pharmacopée française	(Ph.F.)
3.	Pharmacopoeia Internationalis	(Ph.I.)
4.	The British Pharmacopoeia	(B.P.)
5.	The Canadian Formulary	(C.F.)
6.	The National Formulary	(N.F.)
7.	The Pharmaceutical Codex: Principles and Practices of Pharmaceuticals	
8.	The United States Pharmacopoeia	(U.S.P.)

SCHEDULE C
(Sections 12 and 30)

Drugs, other than radionuclides, sold or represented for use in the preparation of radiopharmaceuticals

Drogues, autres que les radionucléides, vendues pour être employées dans la préparation de produits pharmaceutiques radioactifs ou présentées comme pouvant servir à cette fin

Radiopharmaceuticals

Produits pharmaceutiques radioactifs

SCHEDULE D
(Sections 12 and 30)

Allergenic substances used for the treatment or diagnosis of allergic or immunological diseases

Substances allergènes utilisées pour le traitement ou le diagnostic d'affections allergiques ou immunitaires

Anterior pituitary extracts

Extraits hypophysaires (lobe antérieur)

Aprotinin

Aprotinine

23-3-89

Blood and blood derivatives

Sang et dérivés du sang

Cholecystokinin

Cholécystokinine

Drugs obtained by recombinant DNA procedures

Drogues obtenues par des procédures de recombinaison de l'ADN

Drugs, other than antibiotics, prepared from micro-organisms

Drogues, sauf les antibiotiques, préparées à partir de micro-organismes

Glucagon

Glucagon

Gonadotrophins

Gonadotrophines

Human plasma collected by plasmapheresis

Plasma humain prélevé par plasmaphérèse

Immunizing agents

Agents immunisants

Insulin

Insuline

24-7-85

Interferon

9-12-97

Monoclonal antibodies, their conjugates and derivatives

Anticorps monoclonaux et leurs dérivés et conjugués

Secretin

Sécrétine

9-12-97

Sensitivity Discs and Sensitivity Tablets

Disques et comprimés de sensibilité

Repealed from schedule D
by P.C. 1997-1824 of 9-12-97

Abroger de l'annexe D par la C.P. 1997-1824 du 9 décembre 1997

Snake Venom

Venin de serpent

Urokinase

Urokinase

SCHEDULE E
(Sections 13 and 30)

SCHEDULE F
(Sections 15 and 30)

SCHEDULE G

Repealed May 14, 1997.

SCHEDULE H

Repealed May 14, 1997

FOOD AND DRUG REGULATIONS

Made by Order in Council

by P.C. 1954-1915 of 8th December, 1954,

Gazetted December 22, 1954.

as amended

by P.C. 1955-328 of 8th March, 1955,
by P.C. 1955-1093 of 21st July, 1955,
by P.C. 1956-567 of 12th April, 1956,
by P.C. 1956-871 of 7th June, 1956,
by P.C. 1956-1054 of 12th July, 1956,
by P.C. 1956-1148 of 26th July, 1956,
by P.C. 1956-1347 of 6th September, 1956,
by P.C. 1956-1423 of 20th September, 1956,
by P.C. 1956-1921 of 28th December, 1956,
by P.C. 1957-242 of 21st February, 1957,
by P.C. 1957-423 of 28th March, 1957,
by P.C. 1957-860 of 20th June, 1957,
by P.C. 1957-1294 of 25th September, 1957,
by P.C. 1958-11 of 2nd January, 1958,
by P.C. 1958-657 of 9th May, 1958,
by P.C. 1958-1299 of 18th September, 1958,
by P.C. 1959-226 of 26th February, 1959,
by P.C. 1959-912 of 16th July, 1959,
by P.C. 1959-1450 of 12th November, 1959,
by P.C. 1959-1594 of 18th December, 1959,
by P.C. 1960-607 of 5th May, 1960,
by P.C. 1960-1141 of 17th August, 1960,
by P.C. 1960-1334 of 29th September, 1960,
by P.C. 1960-1674 of 8th December, 1960,
by P.C. 1960-1769 of 29th December, 1960,
by P.C. 1961-345 of 9th March, 1961,
by P.C. 1961-1061 of 24th July, 1961,
by P.C. 1961-1097 of 31st July, 1961,
by P.C. 1961-1132 of 9th August, 1961,
by P.C. 1961-1441 of 5th October, 1961,
by P.C. 1961-1832 of 21st December, 1961,
by P.C. 1962-687 of 12th May, 1962,
by P.C. 1962-1832 of 21st December, 1962,
by P.C. 1963-365 of 4th March, 1963,
by P.C. 1963-449 of 18th March, 1963,
by P.C. 1963-687 of 2nd May, 1963,
by P.C. 1963-1051 of 11th July, 1963,
by P.C. 1963-1119 of 25th July, 1963,
by P.C. 1963-1493 of 10th October, 1963,
by P.C. 1963-1642 of 7th November, 1963,
by P.C. 1964-319 of 28th February, 1964,
by P.C. 1964-887 of 18th June, 1964,
by P.C. 1964-1309 of 25th August, 1964,
by P.C. 1964-1355 of 3rd September, 1964,
by P.C. 1964-1856 of 4th December, 1964,
by P.C. 1965-550 of 25th March, 1965,
by P.C. 1965-783 of 29th April, 1965,
by P.C. 1965-887 of 13th May, 1965,
by P.C. 1965-1165 of 23rd June, 1965,
by P.C. 1965-1791 of 4th October, 1965,
by P.C. 1965-1892 of 25th October, 1965,
by P.C. 1965-2193 of 8th December, 1965,
by P.C. 1966-165 of 31st January, 1966,
by P.C. 1966-166 of 31st January, 1966,
by P.C. 1966-310 of 18th February, 1966,
by P.C. 1966-429 of 10th March, 1966,
by P.C. 1966-594 of 31st March, 1966,
by P.C. 1966-864 of 13th May, 1966,
by P.C. 1966-865 of 13th May, 1966,
by P.C. 1966-1008 of 2nd June, 1966,
by P.C. 1966-1316 of 14th July, 1966,

Gazetted March 23, 1955.
Gazetted August 10, 1955.
Gazetted April 25, 1956.
Gazetted June 27, 1956.
Gazetted July 25, 1956.
Gazetted August 8, 1956.
Gazetted September 26, 1956.
Gazetted October 10, 1956.
Gazetted January 9, 1957.
Gazetted March 13, 1957.
Gazetted April 10, 1957.
Gazetted July 10, 1957.
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Gazetted October 8, 1958.
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Gazetted January 13, 1960.
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Gazetted September 14, 1960.
Gazetted October 12, 1960.
Gazetted December 28, 1960.
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Gazetted March 22, 1961.
Gazetted August 9, 1961.
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Gazetted March 9, 1966.
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Gazetted April 13, 1966.
Gazetted May 25, 1966.
Gazetted May 25, 1966.
Gazetted June 22, 1966.
Gazetted July 27, 1966.

FOOD AND DRUG REGULATIONS (cont'd)

as amended

by P.C. 1966-1716 of 8th September, 1966,
by P.C. 1966-2118 of 10th November, 1966,
by P.C. 1966-2452 of 29th December, 1966,
by P.C. 1967-285 of 16th February, 1967,
by P.C. 1967-504 of 16th March, 1967,
by P.C. 1967-993 of 18th May, 1967,
by P.C. 1967-1209 of 15th June, 1967,
by P.C. 1967-1369 of 12th July, 1967,
by P.C. 1967-1561 of 9th August, 1967,
by P.C. 1967-1597 of 16th August, 1967,
by P.C. 1967-1635 of 23rd August, 1967,
by P.C. 1967-1857 of 28th September, 1967,
by P.C. 1967-2040 of 26th October, 1967,
by P.C. 1967-2191 of 23rd November, 1967,
by P.C. 1968-392 of 28th February, 1968,
by P.C. 1968-856 of 2nd May, 1968,
by P.C. 1968-902 of 8th May, 1968,
by P.C. 1968-943 of 15th May, 1968,
by P.C. 1968-1045 of 29th May, 1968,
by P.C. 1968-1245 of 28th June, 1968,
by P.C. 1968-1397 of 17th July, 1968,
by P.C. 1968-1736 of 5th September, 1968,
by P.C. 1968-1872 of 1st October, 1968,
by P.C. 1968-2022 of 29th October, 1968,
by P.C. 1968-2134 of 19th November, 1968,
by P.C. 1969-73 of 14th January, 1969,
by P.C. 1969-74 of 14th January, 1969,
by P.C. 1969-276 of 11th February, 1969,
by P.C. 1969-384 of 25th February, 1969,
by P.C. 1969-479 of 11th March, 1969,
by P.C. 1969-480 of 11th March, 1969,
by P.C. 1969-735 of 15th April, 1969,
by P.C. 1969-854 of 29th April, 1969,
by P.C. 1969-981 of 13th May, 1969,
by P.C. 1969-982 of 13th May, 1969,
by P.C. 1969-1613 of 13th August, 1969,
by P.C. 1969-1614 of 13th August, 1969,
by P.C. 1969-1683 of 27th August, 1969,
by P.C. 1969-1943 of 8th October, 1969,
by P.C. 1969-2020 of 21st October, 1969,
by P.C. 1969-2143 of 5th November, 1969,
by P.C. 1969-2212 of 19th November, 1969,
by P.C. 1969-2247 of 26th November, 1969,
by P.C. 1969-2248 of 26th November, 1969,
by P.C. 1969-2357 of 12th December, 1969,
by P.C. 1969-2378 of 17th December, 1969,
by P.C. 1970-14 of 14th January, 1970,
by P.C. 1970-36 of 14th January, 1970,
by P.C. 1970-37 of 14th January, 1970,
by P.C. 1970-170 of 27th January, 1970,
by P.C. 1970-272 of 10th February, 1970,
by P.C. 1970-435 of 10th March, 1970,
by P.C. 1970-645 of 14th April, 1970,
by P.C. 1970-804 of 5th May, 1970,
by P.C. 1970-865 of 12th May, 1970,
by P.C. 1970-880 of 19th May, 1970,
by P.C. 1970-1070 of 16th June, 1970,
by P.C. 1970-1314 of 22nd July, 1970,
by P.C. 1970-1455 of 19th August, 1970,
Gazetted September 28, 1966.
Gazetted November 23, 1966.
Gazetted January 11, 1967.
Gazetted March 8, 1967.
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Gazetted June 10, 1970.
Gazetted June 24, 1970.
Gazetted August 12, 1970.
Gazetted September 9, 1970.

FOOD AND DRUG REGULATIONS (cont'd)

as amended

by P.C. 1973-3326 of 23rd October, 1973,
by P.C. 1973-3587 of 13th November, 1973,
by P.C. 1973-3678 of 27th November, 1973,
by P.C. 1973-3679 of 27th November, 1973,
by P.C. 1973-3823 of 11th December, 1973,
by P.C. 1973-3824 of 11th December, 1973,
by P.C. 1974-33 of 8th January, 1974,
by P.C. 1974-168 of 23rd January, 1974,
by P.C. 1974-403 of 26th February, 1974,
by P.C. 1974-561 of 12th March, 1974,
by P.C. 1974-588 of 12th March, 1974,
by P.C. 1974-694 of 26th March, 1974,
by P.C. 1974-979 of 30th April, 1974,
by P.C. 1974-1233 of 30th May, 1974,
by P.C. 1974-1299 of 6th June, 1974,
by P.C. 1974-1378 of 13th June, 1974,
by P.C. 1974-1379 of 13th June, 1974,
by P.C. 1974-1571 of 16th July, 1974,
by P.C. 1974-1572 of 16th July, 1974,
by P.C. 1974-1933 of 28th August, 1974,
by P.C. 1974-1953 of 3rd September, 1974,
by P.C. 1974-2113 of 24th September, 1974,
by P.C. 1974-2255 of 8th October, 1974,
by P.C. 1974-2256 of 8th October, 1974,
by P.C. 1974-2296 of 22nd October, 1974,
by P.C. 1974-2385 of 29th October, 1974,
by P.C. 1974-2386 of 29th October, 1974,
by P.C. 1974-2430 of 5th November, 1974,
by P.C. 1974-2497 of 12th November, 1974,
by P.C. 1974-2728 of 10th December, 1974,
by P.C. 1974-2762 of 13th December, 1974,
by P.C. 1974-2826 of 17th December, 1974,
by P.C. 1975-7 of 16th January, 1975,
by P.C. 1975-8 of 16th January, 1975,
by P.C. 1975-135 of 23rd January, 1975,
by P.C. 1975-191 of 28th January, 1975,
by P.C. 1975-223 of 31st January, 1975,
by P.C. 1975-418 of 25th February, 1975,
by P.C. 1975-504 of 4th March, 1975,
by P.C. 1975-609 of 18th March, 1975,
by P.C. 1975-774 of 8th April 1975,
by P.C. 1975-775 of 8th April 1975,
by P.C. 1975-918 of 24th April 1975,
by P.C. 1975-919 of 24th April, 1975,
by P.C. 1975-1026 of 6th May, 1975,
by P.C. 1975-1087 of 13th May, 1975,
by P.C. 1975-1088 of 13th May, 1975,
by P.C. 1975-1449 of 24th June, 1975,
by P.C. 1975-1656 of 17th July, 1975,
by P.C. 1975-1657 of 17th July, 1975,
by P.C. 1975-1712 of 22nd July, 1975,
by P.C. 1975-1713 of 22nd July, 1975,
by P.C. 1975-1714 of 22nd July, 1975,
by P.C. 1975-1902 of 6th August, 1975,
by P.C. 1975-2101 of 11th September, 1975,
by P.C. 1975-2175 of 18th September, 1975,
by P.C. 1975-2272 of 25th September, 1975,
by P.C. 1975-2483 of 21st October, 1975,
by P.C. 1975-2596 of 7th November, 1975,
by P.C. 1975-2665 of 7th November, 1975,
by P.C. 1975-2755 of 25th November, 1975,
by P.C. 1975-2756 of 25th November, 1975,
by P.C. 1975-2872 of 11th December, 1975,
by P.C. 1975-2952 of 18th December, 1975,
by P.C. 1975-2953 of 18th December, 1975,
by P.C. 1976-1439 of 11th June, 1976,
Gazetted November 14, 1973.
Gazetted November 28, 1973.
Gazetted December 12, 1973.
Gazetted December 12, 1973.
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Gazetted December 24, 1975.
Gazetted January 14, 1976.
Gazetted January 14, 1976.
Gazetted June 23, 1976.

FOOD AND DRUG REGULATIONS (cont'd)

as amended

by P.C. 1975-2756 of November 25, 1975,
by P.C. 1975-2872 of December 11, 1975,
by P.C. 1975-2952 of December 18, 1975,
by P.C. 1975-2953 of December 18, 1975,
by P.C. 1976-1439 of June 11, 1976,
by P.C. 1976-1645 of June 29, 1976,
by P.C. 1976-2089 of August 25, 1976,
by P.C. 1976-2090 of August 25, 1976,
by P.C. 1976-2091 of August 25, 1976,
by P.C. 1976-2092 of August 25, 1976,
by P.C. 1976-2093 of August 25, 1976,
by P.C. 1976-2781 of November 10, 1976,
by P.C. 1976-2782 of November 10, 1976,
by P.C. 1976-2783 of November 10, 1976,
by P.C. 1976-2784 of November 10, 1976,
by P.C. 1976-2942 of November 25, 1976,
by P.C. 1977-68 of January 20, 1977,
by P.C. 1977-69 of January 20, 1977,
by P.C. 1977-201 of February 3, 1977,
by P.C. 1977-202 of February 3, 1977,
by P.C. 1977-203 of February 3, 1977,
by P.C. 1977-204 of February 3, 1977,
by P.C. 1977-205 of February 3, 1977,
by P.C. 1977-368 of February 24, 1977,
by P.C. 1977-789 of March 24, 1977,
by P.C. 1977-1017 of April 5, 1977,
by P.C. 1977-1159 of April 28, 1977,
by P.C. 1977-1160 of April 28, 1977,
by P.C. 1977-1161 of April 28, 1977,
by P.C. 1977-1162 of April 28, 1977,
by P.C. 1977-1163 of April 28, 1977,
by P.C. 1977-1164 of April 28, 1977,
by P.C. 1977-1165 of April 28, 1977,
by P.C. 1977-1214 of May 5, 1977,
by P.C. 1977-1470 of May 26, 1977,
by P.C. 1977-1471 of May 26, 1977,
by P.C. 1977-2011 of July 14, 1977,
by P.C. 1977-2321 of August 10, 1977,
by P.C. 1977-2322 of August 10, 1977,
by P.C. 1977-2549 of September 15, 1977,
by P.C. 1977-2550 of September 15, 1977,
by P.C. 1977-2431 of August 31, 1977,
by P.C. 1977-2551 of September 15, 1977,
by P.C. 1977-2872 of October 7, 1977,
by P.C. 1977-3054 of October 27, 1977,
by P.C. 1977-3249 of November 17, 1977,
by P.C. 1977-3250 of November 17, 1977,
by P.C. 1977-3251 of November 17, 1977,
by P.C. 1977-3252 of November 17, 1977,
by P.C. 1977-3253 of November 17, 1977,
by P.C. 1977-3254 of November 17, 1977,
by P.C. 1977-3279 of November 17, 1977,
by P.C. 1977-3383 of December 1, 1977,
by P.C. 1977-3384 of December 1, 1977,
by P.C. 1977-3519 of December 15, 1977,
by P.C. 1978-73 of January 12, 1978,
by P.C. 1978-74 of January 12, 1978,
by P.C. 1978-207 of January 26, 1978,
by P.C. 1978-635 of March 2, 1978,
by P.C. 1978-1404 of April 27, 1978,
by P.C. 1978-1405 of April 27, 1978,
by P.C. 1978-1406 of April 27, 1978,
by P.C. 1978-1407 of April 27, 1978,
by P.C. 1978-1408 of April 27, 1978,
Gazetted December 10, 1975.
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Gazetted May 10, 1978.
Gazetted May 10, 1978.

FOOD AND DRUG REGULATIONS (cont'd)

as amended

by P.C. 1980-3503 of December 18, 1980,
by P.C. 1981-43 of January 8, 1981,
by P.C. 1981-149 of January 22, 1981,
by P.C. 1981-150 of January 22, 1981,
by P.C. 1981-347 of February 13, 1981,
by P.C. 1981-503 of February 26, 1981,
by P.C. 1981-657 of March 12, 1981,
by P.C. 1981-741 of March 19, 1981,
by P.C. 1981-1123 of April 23, 1981,
by P.C. 1981-1124 of April 23, 1981,
by P.C. 1981-1125 of April 23, 1981,
by P.C. 1981-1189 of May 7, 1981,
by P.C. 1981-1190 of May 7, 1981,
by P.C. 1981-1650 of June 8, 1981,
by P.C. 1981-1879 of July 9, 1981,
by P.C. 1981-1880 of July 9, 1981,
by P.C. 1981-1922 of July 16, 1981,
by P.C. 1981-2049 of July 23, 1981,
by P.C. 1981-2050 of July 23, 1981,
by P.C. 1981-2094 of July 29, 1981,
by P.C. 1981-2647 of September 24, 1981,
by P.C. 1981-3207 of November 12, 1981,
by P.C. 1981-3208 of November 12, 1981,
by P.C. 1982-118 of January 14, 1982,
by P.C. 1982-120 of January 14, 1982,
by P.C. 1982-383 of April 1, 1982,
by P.C. 1982-406 of April 13, 1982,
by P.C. 1982-429 of April 23, 1982,
by P.C. 1982-524 of May 21, 1982,
by P.C. 1982-541 of May 28, 1982,
by P.C. 1982-566 of June 3, 1982,
by P.C. 1982-596 of June 10, 1982,
by P.C. 1982-2304 of July 29, 1982,
by P.C. 1982-2305 of July 29, 1982,
by P.C. 1982-2378 of August 5, 1982,
by P.C. 1982-2379 of August 5, 1982,
by P.C. 1982-3104 of October 7, 1982,
by P.C. 1982-3695 of December 2, 1982,
by P.C. 1982-3717 of December 2, 1982,
by P.C. 1983-863 of March 24, 1983,
by P.C. 1983-864 of March 24, 1983,
by P.C. 1983-1105 of April 14, 1983,
by P.C. 1983-1339 of May 5, 1983,
by P.C. 1983-2085 of July 7, 1983,
by P.C. 1983-2373 of July 27, 1983,
by P.C. 1983-3440 of November 3, 1983,
by P.C. 1983-3441 of November 3, 1983,
by P.C. 1983-3875 of December 8, 1983,
by P.C. 1983-3876 of December 8, 1983,
by P.C. 1983-4019 of December 15, 1983,
by P.C. 1984-337 of February 2, 1984,
by P.C. 1984-1069 of March 29, 1984,
by P.C. 1984-1236 of April 12, 1984,
by P.C. 1984-1237 of April 12, 1984,
by P.C. 1984-1238 of April 12, 1984,
by P.C. 1984-1239 of April 12, 1984,
by P.C. 1984-1379 of April 18, 1984,
by P.C. 1984-1977 of June 7, 1984,
by P.C. 1984-1978 of June 7, 1984,
by P.C. 1984-2153 of June 21, 1984,
by P.C. 1984-2505 of July 12, 1984,
by P.C. 1984-2591 of July 18, 1984,
by P.C. 1984-2654 of July 25, 1984,
by P.C. 1984-2790 of August 8, 1984,
by P.C. 1984-3152 of September 12, 1984,
by P.C. 1984-3326 of October 11, 1984,
by P.C. 1984-3682 of November 15, 1984,
Gazetted January 14, 1981.
Gazetted January 28, 1981.
Gazetted February 11, 1981.
Gazetted February 11, 1981.
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Gazetted July 11, 1984.
Gazetted July 25, 1984.
Gazetted August 8, 1984.
Gazetted August 8, 1984.
Gazetted August 22, 1984.
Gazetted October 3, 1984.
Gazetted October 31, 1984.
Gazetted November 28, 1984.

FOOD AND DRUG REGULATIONS (cont'd)

as amended

by P.C. 1984-3797 of November 29, 1984,
by P.C. 1985-289 of January 31, 1985,
by P.C. 1985-290 of January 31, 1985,
by P.C. 1985-292 of January 31, 1985,
by P.C. 1985-478 of February 14, 1985,
by P.C. 1985-906 of March 21, 1985,
by P.C. 1985-1879 of June 12, 1985,
by P.C. 1985-1939 of June 13, 1985,
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FOOD AND DRUG REGULATIONS (cont'd)

as amended

by P.C. 1988-1457 of July 21, 1988,
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by P.C. 1988-1609 of August 11, 1988,
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by P.C. 1989-782 of May 4, 1989,
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FOOD AND DRUG REGULATIONS (cont'd)

as amended

by P.C. 1991-1434 of August 13, 1991,
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FOOD AND DRUG REGULATIONS (cont'd)

as amended

by P.C. 1995-1526 of September 13, 1995,
by P.C. 1995-1676 of October 3, 1995,
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by P.C. 1995-1724 of October 17, 1995,
by P.C. 1995-1865 of November 7, 1995,
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by P.C. 1997-845 of June 27, 1997,
by P.C. 1997-927 of July 03, 1997,
by P.C. 1997-1022 of July 25, 1997,
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by P.C. 1997-1144 of August 28, 1997,
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FOOD AND DRUG REGULATIONS (end)

as amended

by P.C. 2002-86 of January 31, 2002,	Gazetted February 13, 2002.
by P.C. 2002-87 of January 31, 2002,	Gazetted February 13, 2002.
by P.C. 2002-91 of January 31, 2002,	Gazetted February 13, 2002.
by P.C. 2002-92 of January 31, 2002,	Gazetted February 13, 2002.
by P.C. 2002-93 of January 31, 2002,	Gazetted February 13, 2002.
by P.C. 2002-94 of January 31, 2002,	Gazetted February 13, 2002.
by P.C. 2002-792 of May 9, 2002,	Gazetted May 22, 2002.
by P.C. 2002-834 of May 23, 2002,	Gazetted June 5, 2002.
by P.C. 2002-896 of May 30, 2002,	Gazetted June 19, 2002.
by P.C. 2002-1581 of September 24, 2002,	Gazetted October 9, 2002.
by P.C. 2002-1710 of October 3, 2002,	Gazetted October 23, 2002.
by P.C. 2002-1711 of October 3, 2002,	Gazetted October 23, 2002.
by P.C. 2002-1794 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1795 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1796 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1797 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1798 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1799 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1800 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1801 of October 24, 2002,	Gazetted November 6, 2002.
by P.C. 2002-1802 of October 24, 2002,	Gazetted November 6, 2002.
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by P.C. 2002-1898 of November 7, 2002,	Gazetted November 20, 2002.
by P.C. 2002-1899 of November 7, 2002,	Gazetted November 20, 2002.
by P.C. 2002-1900 of November 7, 2002,	Gazetted November 20, 2002.
by P.C. 2002-1901 of November 7, 2002,	Gazetted November 20, 2002.
by P.C. 2002-1954 of November 21, 2002,	Gazetted December 4, 2002.
by P.C. 2002-2200 of December 12, 2002,	Gazetted January 1, 2003.

PART A

ADMINISTRATION

General

A.01.001. These regulations may be cited as the Food and Drug Regulations.

11-9-75 | **A.01.002.** These regulations, where applicable, prescribe the standards of composition, strength, potency, purity, quality or other property of the article of food or drug to which they refer.

14-4-94 | **A.01.003.** Revoked by P.C. 1994-547 of April 14, 1994.

Interpretation

A.01.010. In these regulations

- 21-9-89 "acceptable method" means a method of analysis or examination designated by the Director as acceptable for use in the administration of the Act and these Regulations; (*méthode acceptable*)
"Act" means the Food and Drugs Act,
"cubic centimetre" and its abbreviation "cc." shall be deemed to be interchangeable with the term "millilitre" and its abbreviation "ml.",
- 1-8-01 * "Director" means the Assistant Deputy Minister, Health Products and Food Branch, of the Department of Health; (*Directeur*)
- 11-9-75 "inner label" means the label on or affixed to an immediate container of a food or drug,
15-9-77 "Lot number" means any combination of letters, figures, or both, by which any food or drug can be traced in manufacture and identified in distribution,
19-12-96 "manufacturer" or "distributor" means a person, including an association or partnership, who under their own name, or under a trade-, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug; (*fabricant or distributeur*)
"official method" means a method of analysis or examination designated as such by the Director for use in the administration of the Act and these Regulations, and
15-9-77 "outer label" means the label on or affixed to the outside of a package of a food or drug,
13-9-00 "principal display panel" has the same meaning as in the *Consumer Packaging and Labelling Regulations*; (*espace principal*)
31-1-85 "security package" means a package having a security feature that provides reasonable assurance to consumers that the package has not been opened prior to purchase. (*emballage de securite*).

A.01.011. The Director shall, upon request, furnish copies of official methods.

A.01.012. The Director shall, upon request, indicate that a method is acceptable or otherwise upon its submission to him for a ruling.

11-9-75 **A.01.013.** Where a food, drug or vitamin has more than one name, whether proper or common, a reference in these Regulations to the food, drug or vitamin by any of its names is deemed to be a reference to the food, drug or vitamin by all of its names.

15-9-77

A.01.014. When a lot number is required by these Regulations to appear on any article, container, package or label it shall be preceded by one of the following designations:

- (a) "Lot number";
- (b) "Lot No.";
- (c) "Lot"; or
- (d) "(L)".

* *Effective October 1, 2001.*

	A.01.015.	(1) Subject to subsection (2), any statement, information or declaration that is required by these Regulations to appear on the label of any drug shall be in either the French or the English language in addition to any other language.
31-1-85		(2) The adequate directions for use required to be shown on the inner and outer labels of a drug pursuant to subparagraph C.01.004(1)(c)(iii) shall be in both the French and English languages if the drug is available for sale without prescription in an open self-selection area.
15-9-77 11-9-75	A.01.016.	All information required by these Regulations to appear on a label of a food or drug shall be
23-6-71		(a) clearly and prominently displayed on the label, and (b) readily discernible to the purchaser or consumer under the customary conditions of purchase and use.
 Analysts; Inspectors		
	A.01.020.	Revoked by P.C. 1981-3208 of November 12, 1981.
	A.01.021.	Revoked by P.C. 1981-3208 of November 12, 1981.
11-9-75 15-9-77	A.01.022.	An inspector shall perform the functions and duties and carry out the responsibilities in respect of foods and drugs prescribed by the Act and these Regulations.
	A.01.023.	The authority of an inspector extends to and includes the whole of Canada.
29-10-92	A.01.024.	The certificate of designation required pursuant to subsection 22(2) of the Act shall
		(a) certify that the person named therein is an inspector for the purpose of the Act; and
9-3-76		(b) be signed by
		(i) the Director and the person named in the certificate, in the case of an inspector on the staff of the Department, or
4-5-00		(ii) Repealed by P.C. 2000-184 of May 4, 2000.

1-10-68 | **A.01.025.** Where authorized by a regulation made pursuant to the *Broadcasting Act*, inspectors shall act as representatives of the Canadian Radio-Television Commission for the purpose of enforcing the provisions of regulations made by the Canadian Radio-Television Commission concerning the advertising of any article to which the *Proprietary or Patent Medicine Act* or the *Food and Drugs Act* applies, or concerning recommendations for the prevention, treatment or cure of a disease or ailment.

22-11-90 | **A.01.026.** An inspector may, for the proper administration of the Act or these Regulations, take photographs of

(a) any article that is referred to in subsection 23(2) of the Act;

(b) any place where, on reasonable grounds, he believes any article referred to in paragraph (a) is manufactured, prepared, preserved, packaged or stored; and

23-1-75 | (c) anything that, on reasonable grounds, he believes is used or capable of being used for the manufacture, preparation, preservation, packaging or storing of any article referred to in paragraph (a).

Importations

15-9-77 | **A.01.040.** Subject to section A.01.044, no person shall import into Canada for sale a food or drug the sale of which in Canada would constitute a violation of the Act or these Regulations.

15-9-77 | **A.01.041.** An inspector may examine and take samples of any food or drug sought to be imported into Canada.

15-9-77 | **A.01.042.** Where an inspector examines or takes a sample of a food or drug pursuant to section A.01.041, he may submit the food, drug or sample to an analyst for analysis or examination.

12-4-84 | **A.01.043.** Where an inspector, upon examination of a food or drug or sample thereof or on receipt of a report of an analyst of the result of an analysis or examination of the food or drug or sample, is of the opinion that the sale of the food or drug in Canada would constitute a violation of the Act or these Regulations, the inspector shall so notify in writing the collector of customs concerned and the importer.

A.01.044. (1) Where a person seeks to import a food or drug into Canada for sale and the sale would constitute a violation of the Act or these Regulations, that person may, if the sale of the food or drug would be in conformity with the Act and these Regulations after its relabelling or modification, import it into Canada on condition that

(a) the person gives to an inspector notice of the proposed importation; and

27-7-00 | (b) the food or drug will be relabelled or modified as may be necessary to enable its sale to be lawful in Canada.

27-7-00 | (2) No person shall sell a food or drug that has been imported into Canada under subsection (1) unless the food or drug has been relabelled or modified within three months after the importation or within any longer period that may be specified by

(a) in the case of a drug, the Director; or

4-5-00 | (b) in the case of food, the Director or the President of the Canadian Food Inspection Agency.

Exports

22-11-90 | **A.01.045.** A certificate referred to in section 37 of the Act shall be signed and issued by the exporter in the form set out in Appendix III.

Sampling

22-11-90 | **A.01.050.** When taking a sample of an article pursuant to paragraph 23(1)(a) of the Act, an inspector shall inform the owner thereof or the person from whom the sample is being obtained of the inspector's intention to submit the sample or a part thereof to an analyst for analysis or examination, and

(a) where, in the opinion of the inspector, division of the procured quantity would not interfere with analysis or examination

(i) divide the quantity into three parts,

- 23-1-75
- (ii) identify the three parts as the owner's portion, the sample, and the duplicate sample and where only one part bears the label, that part shall be identified as the sample,
 - (iii) seal each part in such a manner that it cannot be opened without breaking the seal and
 - (iv) deliver the part identified as the owner's portion to the owner or the person from whom the sample was obtained and forward the sample and the duplicate sample to an analyst for analysis or examination, or
- (b) where, in the opinion of the inspector, division of the procured quantity would interfere with analysis or examination
- (i) identify the entire quantity as the sample,
 - (ii) seal the sample in such a manner that it cannot be opened without breaking the seal, and
 - (iii) forward the sample to an analyst for analysis or examination.

A.01.051. Where the owner or the person from whom the sample was obtained objects to the procedure followed by an inspector under A.01.050 at the time the sample was obtained, the inspector shall follow both procedures set out in that section if the owner or the person from whom the sample was obtained supplies him with a sufficient quantity of the article.

Tariff of Fees

A.01.060. The cost of analysing a sample other than for the purpose of the Act, for a department of the Government of Canada for the purpose of legal action is fifteen dollars.

15-9-77 **Labelling of Food and Drugs in pressurized containers**





A.01.060.1. In sections A.01.061 and A.01.062,

- 1-8-01 * "flame projection" means the ability of the pressurized contents of an aerosol container to ignite and the length of that ignition, when tested in accordance with official method DO-30, Determination of Flame Projection, dated October 15, 1981; (*projection de flamme*)
- 1-8-01 * "flashback" means that part of the flame projection that extends from its point of ignition back to the aerosol container when tested in accordance with official method DO-30, *Determination of Flame Projection*, dated October 15, 1981; (*retour de flamme*)
- 13-9-00 Repealed by P.C. 2000-1431 of September 13, 2000.
- 1-8-01 * **A.01.061.** (1) Subject to section A.01.063, in the case of a food or a drug packaged in a disposable metal container designed to release pressurized contents by use of a manually operated valve that forms an integral part of the container, the principal display panel of the inner and outer labels of the food or drug shall display, in accordance with sections 15 to 18 of the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, the following information:
- 12-12-91 (a) the hazard symbol set out in column II of item 10 of Schedule II to those Regulations, accompanied by the signal word "CAUTION / ATTENTION"; and
- (b) the primary hazard statement "CONTAINER MAY EXPLODE IF HEATED. / CE CONTENANT PEUT EXPLOSER S'IL EST CHAUFFÉ."
- 1-8-01 * (2) Subject to section A.01.063, one panel of the inner and outer labels of a food or drug referred to in subsection (1) shall display, in the size required by paragraph 19(1)(b) of *the Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, the following additional hazard statement:
- 12-12-91 "Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat. Do not puncture or incinerate container or store at temperatures over 50°C.
Contenu sous pression. Ne pas mettre dans l'eau chaude ni près des radiateurs, poêles ou autres sources de chaleur. Ne pas percer le contenant, ni le jeter au feu, ni le conserver à des températures dépassant 50°C."
- 15-9-77 (3) The requirements of subsections (1) and (2) do not apply where
- (a) in relation to a drug, in the opinion of the Director, or
 - (b) in relation to a food, in the opinion of the Minister of Consumer and Corporate Affairs, the design of the container, the materials used in its construction or the incorporation of a safety device eliminate the potential hazard therein.

* Effective October 1, 2001

- 1-8-01 | ***A.01.062.** (1) Subject to section A.01.063, if a food or drug is packaged in a container described in subsection A.01.061(1) and has a flame projection of a length set out in column I of any of items 1 to 3 of the table to this subsection or a flashback as set out in column I of item 4 of that table, as determined by official method DO-30, *Determination of Flame Projection*, dated October 15, 1981, the principal display panel of the inner and outer labels of the food or drug shall display, in accordance with sections 15 to 18 of *the Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, the following information:
- 12-12-91 | (a) the hazard symbol set out in column II of the same item;
 (b) in both official languages, the signal word set out in column III of the same item; and
 (c) in both official languages, the primary hazard statement set out in column IV of the same item.

TABLE

	Column I Flame Projection Length --- Flashback	Column II Hazard Symbol	Column III Signal Word	Column IV Primary Hazard Statement
12-12-91	1. Less than 15 cm		Caution	Flammable
23-7-81	2. 15 cm or more but less than 45 cm		Warning	Flammable
	3. 45 cm or more		Danger	Extremely Flammable
12-12-91	4. Flashback		Danger	Extremely Flammable

- 1-8-01 | * (2) In addition to the requirements of subsection (1), one panel of the inner label and outer labels of a food or drug referred to in that subsection shall display, in the size required by paragraph 19(1)(b) of the *Consumer Chemicals and Containers Regulations*, as they read on September 30, 2001, the following additional hazard statement:
- 12-12-91 | "Do not use in presence of open flame or spark.
 Ne pas utiliser en présence d'une flamme nue ou d'étincelles."
- 23-7-81 | **A.01.063.** (1) Where the labelled net contents of a container of a food or drug described in subsection A.01.061(1) or A.01.062(1) does not exceed 60 millilitres or 60 grams, the inner label may show only the information described in paragraph A.01.061(1)(a) or paragraphs A.01.062(1)(a) and (b), as the case may be.
 (2) Where the labelled net contents of a container of a food or drug described in subsection A.01.061(1) or A.01.062(1) exceeds 60 millilitres or 60 grams but does not exceed 120 millilitres or 120 grams, the inner label may show only the information described in subsection A.01.061(1) or subsection A.01.062(1), as the case may be.

* Effective October 1, 2001

12-12-91 (3) Where the labelled net quantity, in a container, of a food or drug referred to in subsection A.01.061(1) or A.01.062(1) is less than 30 mL or 30 g, the hazard symbol shall be of such size as to be capable of being circumscribed by a circle with a diameter of at least 6 mm.

23-7-81 (4) Where a container of a food or drug, described in subsection (1) or (2) is sold in a package, the outer label may show only the information described in subsection A.01.061(2) and, where applicable, subsection A.01.062(2).

11-5-93 **A.01.064.** Revoked by P.C. 1993-940 of May 11, 1993.

Security Packaging

A.01.065. (1) In this section, "drug for human use" means a drug that is intended for human use, whether the drug is

- (a) a mouthwash;
- (b) to be inhaled, ingested or inserted into the body; or
- (c) for ophthalmic use.

19-11-92 (2) Subject to subsection (3), no person shall sell or import a drug for human use that is packaged and available to the general public in a self-service display, unless the drug is contained in a security package.

31-1-85 (3) Subsection (2) does not apply to lozenges.

(4) Subject to subsection (5), a statement or illustration that draws attention to the security feature of the security package referred to in subsection (2) shall be carried

- (a) on the inner label of the package; and
- (b) if the security feature is a part of the outer package, on the outer label.

19-11-92 (5) Subsection (4) does not apply if the security feature of a security package is self-evident and is an integral part of the immediate product container.