Federal Court  Cour fédérale

Date: 20121211

Docket: T-410-12

Citation: 2012 FC 1465

[UNREVISED ENGLISH CERTIFIED TRANSLATION]

Ottawa, Ontario, December 11, 2012

PRESENT: The Honourable Mr. Justice Scott

BETWEEN:

ZEN CIGARETTE INC

Applicant

and

HEALTH CANADA

Respondent

REASONS FOR JUDGMENT AND JUDGMENT

I. Introduction

[1] Zen Cigarette Inc. (Zen) is seeking judicial review of the decision dated January 18, 2012, by Health Canada, prohibiting the entry of electronic cigarettes into Canada because of several violations to the *Food and Drug Regulations*, CRC, c 870 (Regulations).

[2] For the following reasons, this application for judicial review is dismissed.

II. Facts

[3] On October 26, 2011, the Border Integrity and Emergency Preparedness Unit within the Inspectorate Program of Health Canada, Quebec Region, recommended that Zen's 200 cartridges, each with 18 mg of nicotine, bearing customs identification number A1X-7897333776 be prohibited entry. The label on the cartridges subject to the prohibition indicated that they each contain 18 mg of nicotine. Nicotine is a drug identified in Schedule F of the Regulations.

[4] Vincent DeBlois was importing those electronic cigarettes on behalf of Zen, which he is the founder, President and majority shareholder of. The exporter, C&M Technology (C/O Bilstar International Limited), is a company with a business address in Hong Kong.

[5] The entry prohibition recommendation was based on subsection C.01.045(1) of the Regulations.

C.01.045. (1) Subject to subsection (2), no person other than	**C.01.045.** (1) Sous réserve du paragraphe (2), est interdite l'importation d'une drogue de l'annexe F par toute personne autre qu'un
(*a*) a practitioner,	*a*) praticien;
(*b*) a drug manufacturer,	*b*) fabricant de drogues;
(*c*) a wholesale druggist,	*c*) pharmacien en gros;
(*d*) a registered pharmacist, or	*d*) pharmacien inscrit; ou
(*e*) a resident of a foreign	*e*) résident d'un pays

country while a visitor in Canada,	étranger, durant son séjour au Canada.
shall import a Schedule F Drug.	

[6] In accordance with the terms of section A.01.043 of the Regulations, the entry prohibition recommendation was sent to the Canada Border Services Agency (CBSA) and the importer.

[7] Zen operates a business selling its electronic cigarettes in Canada through its internet site, Zencig.com.

[8] On November 3, 2011, Mr. DeBlois, Zen's President, gave an interview with the Journal de Montréal. He stated that the electronic cigarettes helped him quit smoking tobacco cigarettes but that Zen [TRANSLATION] "does not claim to help people quit smoking". He also stated that Zen does not intend to complete the registration process for the electronic cigarettes because [TRANSLATION] "what company would want to pay to open the market to other companies" (Respondent's Record, Exhibit MP-9).

[9] On November 7, 2011, François Lévesque, counsel for Zen, wrote to Health Canada. He maintained that [TRANSLATION] "nicotine and/or its derivatives are not prescription drugs, but are sold freely in Canada" (Respondent's Record, Exhibit MP-11).

[10] On November 29, 2011, Manon Parent, a supervisor with the Border Integrity and Emergency Preparedness Unit within the Inspectorate Program of the Department of Health

Canada, Quebec Region, replied to Zen. She explained the reasons for the recommendation that the Zen cartridges be prohibited entry to Canada, namely, the absence of a marketing authorization from Health Canada for the electronic cigarettes and the fact that nicotine appears in Schedule F of the Regulations.

[11] On November 30, 2011, François Levesque replied to Ms. Parent. He argued that the electronic cigarette cartridges imported by Zen deliver 4 mg or less of nicotine per dosage. Consequently, they cannot, according to him, constitute a Schedule F drug and cannot be prohibited for importation or over-the-counter sales.

[12] On January 18, 2012, Ms. Parent specified Health Canada's official position in a letter sent to Mr. Levesque. She reiterated the reasons listed in her letter dated November 29 and added that Zen must hold an establishment licence to legally import and sell electronic cigarettes in Canada.

[13] On February 23, 2012, Zen filed its application for judicial review with respect to Health Canada's official decision.

III. Legislation

[14] The applicable provisions of the *Food and Drug Regulations*, CRC, c 870, Schedule F of the said Regulations and the *Food and Drugs Act*, RSC 1985, c F-27, are reproduced in the annex to this decision.

IV. Issue and standard of review

A. Issue

- ***Is Health Canada's decision to prohibit the entry of the electronic cigarettes imported by Zen reasonable?***

B. Standard of review

[15] In *Dunsmuir v New Brunswick*, 2008 SCC 9, [2008] 1 SCR 190 at paragraph 62 (*Dunsmuir*), the Supreme Court of Canada described the two steps that need to be taken in order to determine the applicable standard of review:

> [62] In summary, the process of judicial review involves two steps. First, courts ascertain whether the jurisprudence has already determined in a satisfactory manner the degree of deference to be accorded with regard to a particular category of question. Second, where the first inquiry proves unfruitful, courts must proceed to an analysis of the factors making it possible to identify the proper standard of review.

[16] In this case, Health Canada justified its refusal to allow the entry of the electronic cigarettes imported by Zen by relying on the Regulations. Health Canada applied the definition of "drug" in the *Food and Drugs Act*, RSC 1985, c F-27 at paragraph 2(*b*) (Act) to nicotine to determine that Zen violated subsection of the Regulations. This case therefore involves the application of statutory provisions to specific facts.

[17] In *Canadian Pharmaceutical Technologies International (C.P.T.) Inc v Canada (Attorney General)*, 2006 FC 708, 295 FTR 285, at paragraph 17, Justice Kelen found that the applicable standard of review for such cases is reasonableness (see also *Hospira Healthcare Corp. v Canada (Attorney General)*, 2010 FC 213 at paragraph 33).

[18] Because the applicable standard is reasonableness, the Court must determine whether Health Canada's decision falls within a range of "possible, acceptable outcomes which are defensible in respect of the facts and law [applicable in this case]" (see *Dunsmuir*, above, at paragraph 47).

V. Position of the parties

A. Zen's position

[19] Zen contends that electronic cigarettes are not a drug under the Act and the Regulations. As a result, Health Canada cannot prohibit the entry of electronic cigarettes into Canada.

[20] Zen claims that Health Canada considers electronic cigarettes a drug because the cartridges contain nicotine. Nicotine is found in Schedule F of the Regulations. Zen also argues that they fall under the exception set out in paragraph (*d*) of Schedule F because the electronic cigarette cartridges that it imports deliver 4 mg or less of nicotine per dosage unit.

[21] Zen claims that Health Canada erred by attributing a dosage unit of 18 mg of nicotine per cartridge for several reasons. First, Zen argues that [TRANSLATION] "electronic cigarettes are not a

medicament, so there is no dosage" (Applicant's Record, page 17, paragraph 10). Second, given that one electronic cartridge is intended to replace twenty-five tobacco cigarettes and that it is used one inhalation at a time, Zen contends that the dosage unit should instead be the dosage delivered per inhalation, which does not exceed 4 mg of nicotine.

[22] According to Zen, given the low nicotine content delivered by one electronic cigarette inhalation, it should not be considered a drug under Schedule F of the Regulations or under the Act. As a result, Zen submits that Health Canada's decision is *ultra vires*.

[23] Zen is therefore asking the Court to allow its application for judicial review and declare that the electronic cigarettes that it imports are not subject to Schedule F of the Regulations.

B. Health Canada's position

[24] Health Canada argues that its decision dated January 18, 2012, recommending the refusal of the entry of the electronic cigarettes imported by Zen is justified and reasonable. The Inspectorate, through the National Border Integrity Program and in partnership with CBSA, ensures the compliance of health products with the Act and its associated Regulations as well as their administration. The January 18 decision identified several failures to comply with the provisions of the Regulations. Zen is challenging only the violation with respect to subsection C.01.045(1).

[25] Moreover, Health Canada points out that Zen violated three separate provisions of the Regulations. Some are not being challenged by Zen. The first offence concerns subsection

C.01.014(1) of the Regulations, which states that no manufacturer shall sell a drug in dosage form unless a drug identification number has been assigned. The second offence relates to the need to obtain a notice of compliance to sell a drug that meets the definition of a new drug under section C.08.001 of the Regulations. The third offence concerns subsection C.01A.004(1) of the Act, which states that no person shall, except in accordance with an establishment licence, import or sell a drug.

[26] Health Canada alleges that the electronic cigarettes imported by Zen fall under the definition of "drug" under paragraphs 2(*a*) and 2(*b*) of the Act. Because electronic cigarettes contain nicotine, which modifies organic functions, they thus meet the definition of a drug set out under paragraph 2(*b*) of the Act. Health Canada relies on Doctor Thea Christa Mueller's affidavit, which identifies several modifications to human functions caused by nicotine consumption:

> Such modifications include . . . increased heart rate and blood pressure, stimulation of the nervous system, constriction of blood vessels causing a temperature drop in the hands and feet, altered brain waves and muscles relaxation. (Respondent's Record, page 140, paragraph 11)

[27] Health Canada contends that electronic cigarettes also meet the definition of drug in paragraph 2(*a*) of the Act because Zen claims that they can be used for the treatment of the addiction to nicotine. In her affidavit, Doctor Mueller explained the following:

> When drugs containing nicotine are manufactured, sold or represented for use for the treatment of the addiction to nicotine, they also fall within paragraph a) of the definition of drug since nicotine addiction is a chronic, relapsing, disease that results from prolonged effects of nicotine on the brain (Respondent's Record, pages 140-141, paragraph 12).

[28] Health Canada relies on a passage from the Zen Web site that states that electronic cigarettes "[m]ay help you to stop smoking" in the "Top 10" reasons for using Zen E-cigarettes (Respondent's Record, page 85).

[29] Health Canada also claims that Zen violated subsection C.01A.004(1) of the Regulations because it did not obtain an establishment licence before importing its electronic cigarettes. Health Canada also points out that Zen is not challenging this claim.

[30] Under subsection C.01.014(1) of the Regulations, a drug sold in dosage form must have been assigned a drug identification number. According to Health Canada, Zen failed to comply with this requirement because its electronic cigarettes each contain 18 mg of nicotine (Health Canada's Record, Thea Christa Mueller's affidavit, at paragraphs 15 to 19).

[31] Paragraph C.08.002(1)(*b*) of the Regulations states that no person shall sell a new drug under section C.008.001 unless the Minister has issued, under section C.08.004, a notice of compliance to the manufacturer of the new drug in respect of the submission. The submission must include data and studies that convince Health Canada of the safety and effectiveness of the drug. Health Canada points out that no notice of compliance was issued for the electronic cigarettes imported by Zen (Health Canada's Record, Thea Christa Mueller's affidavit, at paragraphs 13-14). This therefore constitutes a violation of the Regulations by Zen.

[32] Health Canada also alleges that electronic cigarettes are a drug under Schedule F of the Regulations. In light of subsection C.01.045(1), Zen cannot import them if it does not comply with

the Regulations because the cigarettes deliver more than 4 mg per dosage unit and do not fall under exception (*d*) of Schedule F. Health Canada considers the dosage unit to be 18 mg, that is, the quantity of total nicotine contained in each cartridge.

[33] Health Canada compares electronic cigarettes to a Nicorette inhaler, the only nicotine inhalation system approved by the Department. Nicorette cartridges contain 10 mg of nicotine and deliver 40% of its content, that is, 4 mg. Assuming that electronic cigarette cartridges deliver the same percentage, Health Canada claims that the electronic cigarettes sold by Zen would deliver 7.2 mg per dosage unit (Respondent's Record, Thea Christa Mueller's affidavit, page 144, paragraph 21).

[34] Furthermore, Doctor Mueller found that the electronic cigarettes sold by Zen deliver a higher percentage of nicotine than Nicorette inhalers:

> The above calculation is conservative, given the two distinct modes of nicotine delivery represented by the Nicorette Inhaler on the one hand and the e-cigarette on the other. . . . The nicotine delivered by the e-cigarette is generated by devices that are activated by the inhalation of the user. In particular, e-cigarettes operate by way of an electric circuit that vapourizes nicotine. This process creates the potential for delivering much higher amounts of nicotine than what would be possible with a passive form of delivery such as a [Nicorette] inhaler. . . . This line of reasons suggests that the 18mg nicotine Zen e-cigarette cartridge delivers much more nicotine than the conservative estimate of 7.2mg. (Thea Christa Mueller's affidavit at paragraph 22).

[35] Health Canada therefore found that [TRANSLATION] "electronic cigarettes do not fall under the exception of an 'inhalation device delivering 4 mg or less of nicotine per dosage unit' set out in

paragraph (*d*) of Schedule F of the [Regulations]" and that Zen violated subsection C.01.045(1) of the Regulations by importing them.

VI. Analysis

- ***Is Health Canada's decision to prohibit the entry of the electronic cigarettes imported by Zen reasonable?***

[36] For the following reasons, the Court finds that Health Canada's decision to prohibit the entry of the electronic cigarettes imported by Zen is reasonable.

[37] First, it is necessary to determine whether electronic cigarettes are a drug under the Act. It is clear from the evidence submitted by Health Canada that electronic cigarettes are used primarily to deliver nicotine. Schedule F of the Regulations defines "nicotine and its salts" as being a drug. Section 2 of the Act specifies the following:

"drug" includes any substance or mixture of substances manufactured, sold or represented for use in	« drogue » Sont compris parmi les drogues les substances ou mélanges de substances fabriqués, vendus ou présentés comme pouvant servir :
(*a*) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,	*a*) au diagnostic, au traitement, à l'atténuation ou à la prévention d'une maladie, d'un désordre, d'un état physique anormal ou de leurs symptômes, chez l'être humain ou les animaux;

(*b*) restoring, correcting or modifying organic functions in human beings or animals, or	*b*) à la restauration, à la correction ou à la modification des fonctions organiques chez l'être humain ou les animaux;
(*c*) disinfection in premises in which food is manufactured, prepared or kept;	*c*) à la désinfection des locaux où des aliments sont gardés.

[38] Health Canada claims that electronic cigarettes are a drug under paragraph 2(*a*) of the Act because Zen promotes them for the treatment of the addition to nicotine, a disease, according to Doctor Thea Christa Mueller. Health Canada also relies on the interview of Mr. DeBlois, President of Zen, in the Journal de Montréal and on a passage from the Zen internet site. The Court, after reviewing the evidence submitted by each party, agrees that electronic cigarettes meet the definition of a drug contained in paragraph 2(*a*) of the Act because Zen promotes them for the treatment of the addition to nicotine. Electronic cigarettes can therefore be used [TRANSLATION] "to treat . . . a disease", in this case, the addition to nicotine.

[39] The Court also finds that electronic cigarettes are a drug under paragraph 2(*b*) of the Act because the evidence submitted clearly shows that nicotine modifies organic functions in human beings. In her affidavit filed into the Court Record, Doctor Mueller listed some of the physical modifications caused by nicotine. The Court agrees with Health Canada's argument that electronic cigarettes are sold to meet the physical needs of consumers who are addicted to nicotine. Consequently, electronic cigarettes also meet the definition of a drug according to paragraph 2(*b*) of the Act.

[40] In its letter dated January 18, 2012, Health Canada raised several violations of the Regulations to support the prohibition of the entry of the electronic cigarettes imported by Zen. One of the objectives of the Inspectorate (a unit of Health Canada) is to ensure, through the National Border Integrity Program:

> [TRANSLATION]
>
> the administration of the Act . . . at the Canadian borders by systematically assessing the compliance of health products that are suspected to be in violation of the Act and its associated Regulations (Respondent's Record, page 190).

[41] Where there is a violation of the Act or one of its associated Regulations, the Court recognizes that it therefore becomes reasonable to prohibit the entry of products that violate statutory provisions.

[42] Subsection C.01.045(1) of the Regulations states that no person other than a practitioner, a drug manufacturer, a wholesale druggist or a registered pharmacist shall import a Schedule F drug. Nicotine and its salts are part of Schedule F of the Regulations except when they are, in particular, "(*d*) in a form to be administered orally by means of an inhalation device delivering 4 mg or less of nicotine per dosage unit".

[43] Dr. Mueller attributed a dosage unit of 7.2 mg of nicotine to each electronic cigarette cartridge containing 18 mg. Is that reasonable? Zen also maintains that an electronic cigarette's dosage unit is only one inhalation, which would be less than 4 mg, and therefore below the threshold set out by the exception in paragraph (*d*) of Schedule F.

[44] The evidence submitted makes it possible to determine that the seized boxes indicated that one cartridge is equivalent to 25 regular cigarettes (Respondent's Record, Exhibit MP-8). Zen did not submit any evidence that made it possible to scientifically establish the quantity of nicotine delivered by inhaling its electronic cigarettes. It argues that it is less than 4 mg, but the record contains no scientific evidence establishing the truthfulness of that statement. Furthermore, by drawing a parallel with a Nicorette inhaler approved by Health Canada, Health Canada nevertheless argues that the threshold of 4 mg per inhalation was exceeded. One electronic cigarette cartridge contains the smallest dosage form analyzed by Health Canada. Even if the Court found that the appropriate threshold is one inhalation rather than the cartridge itself, in the absence of concrete evidence on the dosage unit, Health Canada's finding that the 18 mg contained in the cartridge constituted the dosage unit for the purposes of the application of the Regulations falls within the range of possible outcomes. Because Zen failed to submit scientific data or other evidence to Health Canada making it possible to find that the dosage unit fell under exception (*d*) of Schedule F of the Regulations, Health Canada's finding seems reasonable in the circumstances. It is within the range of possible outcomes in light of the facts and the applicable law.

[45] The Court dismisses Zen's argument based on the exception contained in paragraph (*d*) of Schedule F. A drug that satisfies the criteria of exception (*d*) of Schedule F would fall outside the scope of subsection C.01.045(1) of the Regulations but would not lose its drug status under the Act.

[46] The Court agrees that it was reasonable for Health Canada to find that Zen violated paragraph C.01A.004(1)(*a*) of the Regulations by importing a drug with a view to selling it without an establishment licence. Having already established that electronic cigarettes meet the definition of

a drug under the Act and its associated Regulations, it is clear from the evidence in the record that Zen imported electronic cigarettes to sell them in Canada and that it did not hold an establishment licence.

[47] Subsection C.01.014(1) of the Regulations states the following: "No manufacturer shall sell a drug in dosage form unless a drug identification number has been assigned for that drug . . ." According to subsection C.01.014.1(1), in the case of a drug imported to Canada, the importer of the drug may make an application for a drug identification number for that drug. Health Canada claims that no drug identification number was issued for Zen's electronic cigarettes, and as a result, Zen is in violation of subsection C.01.014(1) of the Regulations by selling them. However, Zen maintains that electronic cigarettes are not a medicament and are therefore not sold in dosage form.

[48] A drug under the Act is not, however, a medicament. In *Flora Manufacturing & Distributing Ltd v Canada (Deputy Minister of National Revenue – MNR)*, [2000] FCJ No 1196, 258 NR 134 at paragraph 12, the Federal Court of Appeal stated the following: "The definition of 'drug' in the *Food and Drugs Act* is considerably broader than the meaning of 'medicament'". Furthermore, the definition of "a drug in dosage form" can be found in subsection C.01.005(3) of the Regulations and reads as follows: "For the purposes of this section and section C. 01.014, 'a drug in dosage form' means a drug in a form in which it is ready for use by the consumer without requiring any further manufacturing". In light of these elements, the Court finds that it was reasonable to conclude that Zen was violating subsection C.01.014(1) of the Regulations by selling the electronic cigarettes.

[49] Paragraph C.08.002(1)(*b*) of the Regulations states that no person shall sell a new drug under section C.008.001 unless the Minister has issued a notice of compliance to the manufacturer of the new drug in respect of the submission. The purpose of that provision is to ensure the safety and effectiveness of all new drugs before they are consumed by the Canadian public. The evidence in the record does not make it possible for the Court to determine whether Zen took steps to comply with that part of the Regulations. In the absence of such evidence and given the other evidence submitted by Health Canada, the Court determines that the finding by Health Canada that Zen violated that part of the Regulations also falls within a range of possible outcomes.

[50] For these reasons, the Court finds that the determination by Health Canada that Zen violated the Act and the Regulations is reasonable.

JUDGMENT

THE COURT ORDERS AND ADJUDGES that this application for judicial review be dismissed, with costs against Zen Cigarette Inc.

"André F.J. Scott"
Judge

Certified true translation
Janine Anderson, Translator

ANNEX

***Food and Drug Regulations*, CRC, c 870**

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.01.043. L'inspecteur qui estime, après examen d'un échantillon de l'aliment ou de la drogue ou réception du rapport de l'analyste que la vente de l'aliment, de la drogue ou du cosmétique serait contraire à la Loi ou au présent règlement, doit en notifier par écrit le percepteur des douanes ainsi que l'importateur.

C.01.005

. . .

(3) For the purposes of this section and section C.01.014, *"a drug in dosage form"* means a drug in a form in which it is ready for use by the consumer without requiring any further manufacturing.

. . .

C.01.014. (1) No manufacturer shall sell a drug in dosage form unless a drug identification number has been assigned for that drug and the assignment of the number has not been cancelled pursuant to section C.01.014.6.

. . .

C.01.014.1. (1) A manufacturer of a drug, a person authorized by a manufacturer or, in the case of a drug to be imported into Canada, the importer of the drug may make an application for a drug identification number for that drug.

. . .

C.01.005

[…]

(3) Aux fins du présent article et de l'article C.01.014, une *« drogue sous sa forme posologique »* s'entend d'une drogue prête pour la consommation sans autre transformation.

[…]

C.01.014. (1) Il est interdit à un fabricant de vendre, sous forme posologique, une drogue qui n'a pas fait l'objet d'une identification numérique, ou dont l'identification a été annulée selon l'article C.01.014.6.

[…]

C.01.014.1. (1) Le fabricant d'une drogue, une personne autorisée par lui ou, dans le cas d'une drogue devant être importée au Canada, l'importateur de la drogue, peut présenter une demande d'identification numérique pour cette drogue.

[…]

C.01.045. (1) Subject to subsection (2), no person other than

(*a*) a practitioner,

(*b*) a drug manufacturer,

(*c*) a wholesale druggist,

(*d*) a registered pharmacist, or

(*e*) a resident of a foreign country while a visitor in Canada,

shall import a Schedule F Drug.

C.01.045. (1) Sous réserve du paragraphe (2), est interdite l'importation d'une drogue de l'annexe F par toute personne autre qu'un

a) praticien;

b) fabricant de drogues;

c) pharmacien en gros;

d) pharmacien inscrit; ou

e) résident d'un pays étranger, durant son séjour au Canada.

C.01A.004. (1) Subject to subsection (2), no person shall, except in accordance with an establishment licence,

(*a*) fabricate, package/label, distribute as set out in section C.01A.003, import or wholesale a drug; or

. . .

C.01A.004. (1) Sous réserve du paragraphe (2), il est interdit, sauf conformément à une licence d'établissement :

a) de manufacturer, d'emballer-étiqueter, de distribuer à titre de distributeur visé à l'article C.01A.003, d'importer et de vendre en gros une drogue;

[…]

C.08.001. For the purposes of the Act and this Division, *"new drug"* means

(a) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component, that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug;

(*b*) a drug that is a combination of two or

C.08.001. Pour l'application de la Loi et du présent titre, *« drogue nouvelle »* désigne :

a) une drogue qui est constituée d'une substance ou renferme une substance, sous forme d'ingrédient actif ou inerte, de véhicule, d'enrobage, d'excipient, de solvant ou de tout autre constituant, laquelle substance n'a pas été vendue comme drogue au Canada pendant assez longtemps et en quantité suffisante pour établir, au Canada, l'innocuité et l'efficacité de ladite substance employée comme drogue;

b) une drogue qui entre dans une

more drugs, with or without other ingredients, and that has not been sold in that combination or in the proportion in which those drugs are combined in that drug, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that combination and proportion for use as a drug; or

association de deux drogues ou plus, avec ou sans autre ingrédient, qui n'a pas été vendue dans cette association particulière, ou dans les proportions de ladite association pour ces drogues particulières, pendant assez longtemps et en quantité suffisante pour établir, au Canada, l'innocuité et l'efficacité de cette association ou de ces proportions employées comme drogue; ou

(*c*) a drug, with respect to which the manufacturer prescribes, recommends, proposes or claims a use as a drug, or a condition of use as a drug, including dosage, route of administration, or duration of action and that has not been sold for that use or condition of use in Canada, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that use or condition of use of that drug.

c) une drogue pour laquelle le fabricant prescrit, recommande, propose ou déclare un usage comme drogue ou un mode d'emploi comme drogue, y compris la posologie, la voie d'administration et la durée d'action, et qui n'a pas été vendue pour cet usage ou selon ce mode d'emploi au Canada pendant assez longtemps et en quantité suffisante pour établir, au Canada, l'innocuité et l'efficacité de cet usage ou de ce mode d'emploi pour ladite drogue.

C.08.002. (1) No person shall sell or advertise a new drug unless

C.08.002. (1) Il est interdit de vendre ou d'annoncer une drogue nouvelle, à moins que les conditions suivantes ne soient réunies :

. . .

[…]

(*b*) the Minister has issued, under section C.08.004 or C.08.004.01, a notice of compliance to the manufacturer of the new drug in respect of the submission;

b) le ministre a délivré au fabricant de la drogue nouvelle, en application des articles C.08.004 ou C.08.004.01, un avis de conformité relativement à la présentation;

. . .

[…]

C.08.004. (1) Subject to section C.08.004.1, the Minister shall, after completing an examination of a new drug submission or abbreviated new drug submission or a supplement to either submission,

C.08.004. (1) Sous réserve de l'article C.08.004.1, après avoir terminé l'examen d'une présentation de drogue nouvelle, d'une présentation abrégée de drogue nouvelle ou d'un supplément à l'une de ces présentations, le ministre :

(*a*) if that submission or supplement complies with section C.08.002,

a) si la présentation ou le supplément est conforme aux articles C.08.002,

C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance; or

(*b*) if that submission or supplement does not comply with section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, notify the manufacturer that the submission or supplement does not so comply.

C.08.002.1 ou C.08.003, selon le cas, et à l'article C.08.005.1, délivre un avis de conformité;

b) si la présentation ou le supplément n'est pas conforme aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, ou à l'article C.08.005.1, en informe le fabricant.

(2) Where a new drug submission or abbreviated new drug submission or a supplement to either submission does not comply with section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, the manufacturer who filed the submission or supplement may amend the submission or supplement by filing additional information or material.

(2) Lorsqu'une présentation de drogue nouvelle, une présentation abrégée de drogue nouvelle ou un supplément à l'une de ces présentations n'est pas conforme aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, ou à l'article C.08.005.1, le fabricant qui l'a déposé peut le modifier en déposant des renseignements ou du matériel supplémentaires.

(3) Subject to section C.08.004.1, the Minister shall, after completing an examination of any additional information or material filed in respect of a new drug submission or an abbreviated new drug submission or a supplement to either submission,

(3) Sous réserve de l'article C.08.004.1, après avoir terminé l'examen des renseignements et du matériel supplémentaires déposés relativement à une présentation de drogue nouvelle, à une présentation abrégée de drogue nouvelle ou à un supplément à l'une de ces présentations, le ministre :

(*a*) if that submission or supplement complies with section C.08.002, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance; or

a) si la présentation ou le supplément est conforme aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, et à l'article C.08.005.1, délivre un avis de conformité;

(*b*) if that submission or supplement does not comply with the requirements of section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, notify the manufacturer that the submission or supplement does not so comply.

b) si la présentation ou le supplément n'est pas conforme aux articles C.08.002, C.08.002.1 ou C.08.003, selon le cas, ou à l'article C.08.005.1, en informe le fabricant.

(4) A notice of compliance issued in respect of a new drug on the basis of information and material contained in a submission filed

(4) L'avis de conformité délivré à l'égard d'une drogue nouvelle d'après les renseignements et le matériel contenus dans

pursuant to section C.08.002.1 shall state the name of the Canadian reference product referred to in the submission and shall constitute a declaration of equivalence for that new drug.

la présentation déposée conformément à l'article C.08.002.1 indique le nom du produit de référence canadien mentionné dans la présentation et constitue la déclaration d'équivalence de cette drogue.

Schedule F of the *Food and Drug Regulations*, CRC, c 870

Nicotine and its salts, for human use, except

. . .

(*d*) in a form to be administered orally by means of an inhalation device delivering 4 mg or less of nicotine per dosage unit; or

. . .

Nicotine et ses sels, destinés à l'usage humain, sauf :

[…]

d) sous une forme destinée à être administrée par voie orale au moyen d'un inhalateur libérant 4 mg ou moins de nicotine par unité posologique;

[…]

Section 2 of the *Food and Drugs Act*, RSC 1985, c F-27

. . .

"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 or abnormal physical state, or its symptoms, in human beings or animals,

(*b*) restoring, correcting or modifying organic functions in human beings or animals, or

[…]

« drogue » Sont compris parmi les drogues les substances ou mélanges de substances fabriqués, vendus ou présentés comme pouvant servir :

a) au diagnostic, au traitement, à l'atténuation ou à la prévention d'une maladie, d'un désordre, d'un état physique anormal ou de leurs symptômes, chez l'être humain ou les animaux;

b) à la restauration, à la correction ou à la modification des fonctions organiques chez l'être humain ou les animaux;

(*c*) disinfection in premises in which food is manufactured, prepared or kept;

. . .

c) à la désinfection des locaux où des aliments sont gardés.

[…]

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-410-12
STYLE OF CAUSE:	ZEN CIGARETTE INC. v HEALTH CANADA
PLACE OF HEARING:	Québec, Quebec
DATE OF HEARING:	November 21, 2012
REASONS FOR JUDGMENT:	SCOTT J.
DATED:	December 11, 2012

APPEARANCES:

Caroline Baillargé	FOR THE APPLICANT
Sébastien Gagné	FOR THE RESPONDENT

SOLICITORS OF RECORD:

Lévesque Goulet Gaudreault Québec, Quebec	FOR THE APPLICANT
William F. Pentney Deputy Attorney General of Canada Montréal, Quebec	FOR THE RESPONDENT