Federal Court  Cour fédérale

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Citation: 2015 FC 1161

Ottawa, Ontario, October 14, 2015

PRESENT: The Honourable Mr. Justice Manson

BETWEEN:

APOTEX INC, APOTEX PHARMACHEM INDIA PVT LTD AND APOTEX RESEARCH PRIVATE LIMITED

Applicants

and

MINISTER OF HEALTH AND ATTORNEY GENERAL OF CANADA

Respondents

Table of Contents

I. Introduction 2
II. Background 3
A. Regulatory Regime 3
B. The Parties 4
C. Interlocutory Proceedings 5
III. Facts 6
A. Chronological Outline 6
B. Supporting Affidavit Evidence 13
(1) Applicants' Supporting Affidavits 13
(2) Respondents' Supporting Affidavits 15
IV. Relevant Legislation 18
V. Issues 18
VI. Decision Summary 18

VII. Standard of Review 20
A. What is the Appropriate Standard of Review of Health Canada's Decision? 20
(1) Applicants' Submissions 20
(2) Respondents' Submissions 21
VIII. Analysis 25
A. Did the Minister Afford Adequate Procedural Fairness when she Implemented the Import Ban and Amended the EL Letters? 25
(1) What Degree of Procedural Fairness is Apotex Entitled to? 25
(2) Improper Purpose and Reasonable Apprehension of Bias 28
(a) Apprehension of Bias 28
(b) Improper Purpose 31
(3) Failure to Act in Accordance with Natural Justice 35
B. Did the Minister Act Beyond or Without Legislative Authority? 39
(1) EL Action 39
(a) Legislative / Regulatory Scheme 39
(b) Analysis 40
(c) Are the Regulations Unconstitutional Under Paragraph 2(e) of the Bill of Rights? 47
(2) CBSA Action 48
C. Was the Minister's Decision Reasonable? 50
D. Can this Court Grant the Relief Sought? 50

JUDGMENT AND REASONS

I. Introduction

[1] This is an application for judicial review by Apotex Inc. [Apotex], Apotex Pharmachem India Pvt Ltd. [APIPL] and Apotex Research Private Limited [ARPL] [collectively "the Applicants"] of the decision of the Respondent Minister of Health [the Minister] to impose an Import Ban preventing the importation of drug products into Canada from two of Apotex's manufacturing facilities in India (APIPL and ARPL) on September 30, 2014, and the related issuance by the Minister, on October 2, 2014, of four "EL Letters" which purported to amend Apotex's establishment licences [ELs], prohibiting import of all products, apart from those deemed medically necessary.

[2] Apotex commenced this application for judicial review on October 29, 2014, on the basis that the Minister's decision to implement the Import Ban and amend Apotex's ELs was unreasonable and unlawful. They allege that the Minister failed to act in accordance with the principles of natural justice by acting for an improper motive, failing to provide Apotex with notice or an opportunity to be heard, and acting in such a manner so as to give rise to a reasonable apprehension of bias. The Applicants also allege that the Minister acted outside of her regulatory powers conferred under the *Food and Drugs Act*, RSC 1985, c F-27 [*FD Act* or *Act*], the *Food and Drugs Regulations*, CRC, c 870 [*FD Regulations* or *Regulations*] and/or the *Customs Act*, RSC 1985, c 1 (2nd Supp).

[3] The Applicants request that the Minister's decision to implement and her implementation of the Import Ban be deemed unlawful and should be quashed, with costs to Apotex. Among other things, they request an order quashing the four letters issued by the Minister on October 2, 2014, which amend Apotex's ELs, and an order compelling the Minister to retract her public statement and requiring her to direct Health Canada to retract their statement released on September 30, 2014.

II. Background

A. *Regulatory Regime*

[4] The *FD Act* and *Regulations* govern the manufacture, import and sale of all drug products in Canada. Various guidelines and policies of Health Canada also help to interpret the *Act* and *Regulations*.

[5] Drugs sold in Canada must have a drug identification number [DIN] pursuant to the *FD Regulations* that has not been cancelled. To sell new drugs in Canada, a manufacturer must also possess a notice of compliance [NOC] issued by the Minister when satisfied that the manufacturing process meets the required standards and that the new drug is safe, effective and adequately labelled under the *Regulations*.

[6] To fabricate, distribute or import into Canada for sale any drug, the manufacturer must also hold an establishment licence [EL], which is granted when the holder of the EL demonstrates its facilities comply with Good Manufacturing Practices [GMP] and meet the requirements of Part C, Division 2 of the *FD Regulations*.

[7] The Regions and Programs Bureau [RAPB] of Health Canada inspects domestic and foreign facilities to evaluate GMP compliance. To assess GMP compliance of foreign manufacturing sites, Health Canada may perform a "desktop" review of documentary evidence gathered by international regulatory partners, external experts or consultants, or it may conduct on-site inspections, at times with other regulatory partners. GMP observations are classified by level of risk and depending on the severity and number of observations, may result in the addition of terms and conditions to the ELs, or a non-compliant rating.

B. *The Parties*

[8] Apotex is the largest pharmaceutical manufacturer in Canada and is affiliated with the Indian companies APIPL and ARPL. Apotex purchases and imports into Canada active

pharmaceutical ingredients [APIs] produced by APIPL and finished dosage form [FDF] pharmaceutical products produced by ARPL.

[9] The Respondent Minister of Health is responsible, through her delegates at Health Canada, for administering the *FD Act* and *Regulations*.

[10] Health Canada is the federal government department that oversees the regulation of drug products in Canada. It consists of various branches, bureaus and offices, most notable to this application: the Minister and Minister's Office; the Health Products and Food Branch [HPFB], which includes the Inspectorate, the branch responsible for compliance and enforcement activities and oversight of establishment licensing for health products; and the RAPB, responsible for inspection.

C. *Interlocutory Proceedings*

[11] Both parties filed motions on September 10, 2015; the Respondents requested dismissal of the application for judicial review as moot, and the Applicants requested that material from the Respondents' record that was not served and filed properly or in a timely way be struck from the record. The motions were heard at the outset of the judicial review and orders have been issued separately.

III. Facts

A. *Chronological Outline*

[12] In late January 2014, the United States Food and Drug Administration [FDA] inspected APIPL's manufacturing facility and issued a Form 483, detailing their observations that APIPL was non-compliant with US GMP requirements due to data reliability problems. On April 2, 2014, the FDA issued an Import Alert on all products coming from APIPL, save one medically necessary product. No issues of product quality were cited, nor were any drugs originating from APIPL recalled.

[13] Health Canada's receipt of APIPL's Form 483 prompted a desktop review by the RAPB in April 2014. The FDA's observations were classified according to Canadian risk classification ratings and a non-compliant rating was recommended.

[14] On April 29, 2014, Health Canada informed Apotex of the non-compliant rating and requested that it cease sale of drugs containing API made by APIPL until new evidence demonstrating GMP compliance was provided. The following day Apotex, through counsel, responded to Health Canada's request, stating that there was no basis for ceasing sale and inviting Health Canada to inspect APIPL itself.

[15] At a meeting on June 10, 2014, Apotex provided Health Canada with their corrective action plan for addressing deficiencies outlined in APIPL's Form 483. Further discussions throughout June led to the adoption of a protocol [the Protocol], whereby Apotex would re-test

all APIs produced at APIPL in Canada for quality assurance. The Protocol was intended as an interim measure until Health Canada's on-site inspection of APIPL in August, but was later extended until October 31, 2014.

[16] On June 16, 2014, the FDA issued a "warning letter" to Apotex detailing that APIPL's corrective and preventative actions continued to be insufficient to prevent recurrence of GMP deviations. A copy was provided shortly thereafter to Health Canada.

[17] With this information, in early August of 2014, Health Canada conducted an on-site inspection of APIPL jointly with Australia's Therapeutic Goods Administration [TGA], with the purpose of verifying that APIPL was indeed implementing corrective actions spurred by the FDA Import Alert [Health Canada-TGA APIPL August Inspection]. In a teleconference with the FDA, Canadian and Australian inspectors were informed of the FDA's main concerns from FDA inspections of APIPL and ARPL, to which they specifically followed up on as part of their August inspection. An email to the HPFB summarizing the RAPB's observations indicated that "the deficiencies noted are not critical (no risk 1 observations) that will require immediate action to be taken" (Sharma First Affidavit, Exh 19; AR, Tab 8(19), p 1628).

[18] During this same period, there were other developments relating to Apotex's FDF facility, ARPL. In May of 2014, ARPL was issued GMP Certificates of Compliance from both the United Kingdom Medicines and Healthcare Products Regulatory Agency [MHRA] and Health Canada, who had conducted a joint inspection of ARPL in mid-February 2014.

[19] In the final week of June 2014, the FDA inspected ARPL, following which they issued a Form 483, finding data integrity problems and deviations from GMP. Health Canada received a copy shortly thereafter and an RAPB inspector who compared the FDA and Health Canada-MHRA inspections recommended a non-compliant rating be assigned to ARPL. This is despite the fact that the Health Canada-MHRA inspection "did not find data integrity / laboratory practices issues," and had assigned a compliant rating just over a month before. The inspector was of the opinion that the scope of the inspections differed, with that of the FDA centering on data integrity issues. He also suggested that follow-up with Apotex would be necessary to "further clarify the issues and determine what corrective actions the company is planning," as per Health Canada's usual practice (Sharma First Affidavit, Exh 22; AR, Tab 8(22), p 1660).

[20] Beginning on September 11, 2014, the Toronto Star began to publish a series of articles and editorials highly critical of Health Canada and the Minister, portraying them as inept in comparison to the FDA, particularly in their regulatory approach towards Apotex, and attacking them for failing to protect the health of Canadians against suspect drugs. The articles spurred vigorous questioning of the Minister in the House of Commons.

[21] The articles also caused an immediate reaction at Health Canada and in the Minister's Office, as evinced by internal communications between personnel at HPFB, the Inspectorate, the Minister's Office, the Prime Minister's Office and the Communications and Public Affairs Branch of Health Canada. In an email to Deputy Minister George DaPont, the Minister expressed concern that Health Canada did not "have a strong enough policy response" and wanted to revoke the license of Apotex "if these drugs that are considered harmful by the FDA are still on

the Canadian market," to which she was assured by staff that (i) the FDA had not recalled any products, (ii) program experts were confident no risky products were on the market, (iii) all products coming from Apotex were being re-tested in Canada, and that consequently it would be "hard to pull the license at this point" (Rule 318 Record, AR, Vol XVII, Tab 19(c)(27)).

[22] On September 22, 2014, the FDA issued an Import Alert for ARPL, except for products deemed medically necessary. No drug products were recalled from the shelves. The following day Health Canada requested that Apotex confirm it would voluntarily quarantine all products made at ARPL by close of business on September 24. This deadline was accelerated to 10:00 am on the 24th after a series of calls and emails between the Minister's Office and Health Canada personnel. Apotex acceded to this request, for one week, requesting that Health Canada undertake a review of the recent ARPL inspections and "provide compelling reasons, with specific factual bases for each affected product," if they wanted to continue the quarantine. Health Canada did not request an extension of the quarantine from Apotex.

[23] In an email, Ministerial staff expressed frustration that Apotex had been provided an opportunity to quarantine products voluntarily and indicated that "stronger action" was to be taken in response to ARPL than what had happened with APIPL. The record also reveals that Health Canada was prepared to move to an Import Ban had Apotex disagreed with the quarantine, such that either way, products from APIPL and ARPL would be off the market.

[24] Accordingly, up to September 29, 2014, there had been no indication from Health Canada to Apotex that any concerns about GMP compliance at either APIPL or ARPL could result in an Import Ban.

[25] In the interim during which ARPL had become the central focus, an internal working group at Health Canada had confirmed the assigned risk ratings from the Health Canada-TGA APIPL August Inspection. On September 25, 2014, Apotex was provided with a draft Inspection Exit Notice, proposing a Compliant with Terms and Conditions rating for APIPL, under which new terms and conditions would require Apotex to re-test APIPL products in Canada.

[26] Given the concerns at Health Canada surrounding the Apotex APIPL and ARPL facilities, the RAPB communicated to the Deputy Minister's Office that they would be providing a finalized Exit Notice to APIPL - not ARPL, the subject of the voluntary quarantine - to which they received express instructions to "[p]lease stand down re pressing send on inspection rating" (Rule 318 Record, AR, Vol XVIII, Tab 20(56) & (62)). No explanation was or has been given to Apotex regarding why the Exit Notice was not provided.

[27] On September 29, 2014, Health Canada and the FDA held a conference call, from which Health Canada allegedly learned "new information" they claim formed the basis for their regulatory action and resulting Import Ban of products from APIPL and ARPL.

[28] On September 30, 2014, without notice, Health Canada communicated to Apotex that the Minister had instructed the Canadian Border Services Agency [CBSA] to immediately restrict

importation of drug products from APIPL and ARPL [CBSA Action]. An email from the Minister's Office to the Prime Minister's Office conveyed that this move represented that Health Canada was both catching up with the US and going even further, and that the ban as compared to a voluntary quarantine was "largely cosmetic and very useful for pushback" (Rule 318 Record, AR, Vol XVIII, Tab 20(76)). Apotex was informed by way of a telephone call from Health Canada, press releases issued by both Health Canada and by the Minister, and a list of the banned products on Health Canada's website - all on September 30, 2014.

[29] In the September 30 phone call, Health Canada maintained it could not rely on data coming from APIPL and ARPL, and that due to the "new information" received from the FDA, it was re-reviewing the compliant status communicated to Apotex by way of the draft Inspection Exit Notice five days earlier, and terms and conditions would be applied to Apotex's ELs [EL Action]. The CBSA Action and EL Action collectively constitute what is hereinafter referred to as the Import Ban.

[30] The Minister's public statement conveyed that "Health Canada has taken decisive action today to stop the import into Canada of all drug products from [APIPL and ARPL]," but reassured that "Health Canada has received no evidence that the problems pose an immediate risk," and that like the FDA, no recall would be required. Further, the Minister stated "when trust between a regulator and a company is broken, strong actions are required" (Rule 318 Record, AR, Vol XVIII, Tab 20(90)). Health Canada's statement is to a similar effect.

[31] Despite repeated requests for disclosure, Apotex remained unaware of what "new information" prompted Health Canada to immediately impose the Import Ban until after initiation of this judicial review. Health Canada attributes this to their confidentiality agreement with the FDA, which prevented them from sharing the acquired information. The new information that is set out in Dr. Supriya Sharma's First Affidavit at paragraphs 89 to 94, includes:

a) selective reporting of positive test results;

b) the FDA's investigation was more detailed and lengthy than previously appreciated;

c) it would be an in-depth process for the company to rectify serious problems; and

d) the FDA had intercepted at the US Border API subject to the Import Alert "mistakenly" listed with incorrect information (this ended up being a misunderstanding, and was not an issue in the proceeding).

[32] During this period, there was no correspondence between Health Canada and Apotex regarding GMP compliance at APIPL or ARPL, nor regarding any clarification of information learned from the FDA.

[33] On October 2, 2014, Apotex received copies of four form letters [the EL Letters], which purported to amend Apotex's ELs by applying new terms and conditions that effectively banned import of all drug products from APIPL and ARPL, save for medically necessary products if re-tested by a third party once in Canada.

[34] Neither the TGA nor MHRA, with which Health Canada shares mutual recognition agreements, have implemented import bans for these Indian facilities, despite being aware of the FDA and Health Canada's import bans for APIPL and ARPL products. They claim to have relied

on their own inspections and detailed analysis of information to make independent risk-based decisions.

B. *Supporting Affidavit Evidence*

[35] The Affidavits filed by the parties describe in detail communications between Apotex and Health Canada leading up to and following imposition of the Import Ban and amendment of the ELs. The Minister's (and her delegates') actions prior to September 30, 2014, are most pertinent to this proceeding: evidence post-dating the regulatory action taken by Health Canada is of little relevance to the decision under review, save for some contextual significance as to what actions preceded the September 30, 2014 Import Ban.

(1) Applicants' Supporting Affidavits

[36] Affidavits were filed by Dr. Jeremy Desai, Mr. Ed Carey and Mr. Kiran Krishnan.

[37] Dr. Desai, President and Chief Executive Officer of Apotex Inc., swore two affidavits. He describes Apotex's compliance with the *FD Regulations* for obtaining DINs, NOCs and ELs and affirms that Apotex has continually held valid, unsuspended DINs, NOCs and ELs for the banned products and facilities where the banned products were made, APIPL and ARPL.

[38] Dr. Desai's description of events leading up to the Import Ban demonstrates a transparent relationship between Apotex and Health Canada, whereby FDA observations, the corresponding US Import Alert, and Apotex's corrective actions were openly communicated to Health Canada.

Dr. Desai asserts that Health Canada did not express concern regarding the safety of products coming from APIPL or ARPL, and in fact conducted their own inspections of the facilities, which resulted in GMP compliant ratings.

[39] Dr. Desai sets out the Toronto Star articles scrutinizing Health Canada. On September 30, 2014, Dr. Desai learned, without warning, that an Import Ban had been placed on drug products coming from APIPL and ARPL. Health Canada told Dr. Desai that "new information" from the FDA constituted the basis for the Ban. In his experience, this was not Health Canada's usual regulatory response, which typically involves communication and cooperation with the companies - as had been happening up until this point.

[40] Press releases by Health Canada and the Minister on September 30, 2014, also alleged that trust with Apotex had been broken. This is the only information provided to Apotex until after initiation of the judicial review.

[41] Ed Carey, Vice President of Global Quality & Compliance at Apotex Pharmachem Inc., is responsible for compliance and oversight of foreign API manufacturers and works closely with Dr. Desai. In his Affidavit, he claims that Health Canada was fully aware of concerns, claimed to be "new information" since at least January of 2014, as evinced by the following; correspondence with the FDA, Apotex's corrective action plans, investigations by Health Canada with international regulatory partners, and implementation of the Protocol for testing in Canada.

[42] The Krishnan affidavit explained a misunderstanding by Health Canada of some information provided by the FDA that has since been clarified. It is no longer relevant to the proceeding, other than to demonstrate that some information upon which Health Canada relied in forming an opinion of mistrust towards Apotex was potentially inaccurate.

(2) Respondents' Supporting Affidavits

[43] Each of the Respondents' affiants, Ms. Robin Chiponski and Dr. Supriya Sharma, provided two affidavits.

[44] Ms. Chiponski is Director General of the HPFB and is involved in oversight of Health Canada's establishment licensing. Her evidence sets out the events of September 2014, from Health Canada's perspective. It explains that Health Canada reviewed and assessed potential compliance and enforcement approaches for Apotex, including the option of restricting import.

[45] Ms. Chiponski claims that information from the FDA led her to believe that the data integrity problems at Apotex were more widespread and deeper-rooted than previously thought. She asserts that Health Canada's restriction of import and imposition of terms and conditions on APIPL and ARPL's ELs stemmed from a concern that products from APIPL and ARPL posed a potential risk to Canadians' health and safety. She does not point to evidence that the banned products constituted a risk to health and safety, apart from GMP non-compliance at the facilities.

[46] Ms. Chiponski also explains that Health Canada does not notify a regulated party of import restrictions before they take effect in order to prevent the importer from flooding the market with product prior to the ban.

[47] Dr. Sharma is the Senior Medical Advisor at HPFB and at the relevant time held the position of Acting Associate Deputy Minister and Senior Medical Advisor. Her affidavit describes the regulatory framework and outlines the guidelines and policies that set out Health Canada's interpretation of the *FD Act* and *FD Regulations*. Potential compliance and enforcement approaches used in the event of GMP non-compliance are outlined in Health Canada's Compliance and Enforcement policy (POL-0001). A brief summary of the relevant points follows:

a) Non-compliance is brought to the company's attention and the Inspectorate will clarify what is necessary to achieve compliance. Enforcement actions are undertaken when necessary, mainly when the regulated party is unable or unwilling to comply with the *Regulations*.

b) To identify the appropriate enforcement action, Health Canada will consider; the risk to health and safety, compliance history of the regulated party, whether the regulated party acted with indifference or premeditation, the degree of cooperation, whether the problem is systemic, the effectiveness of the response, and the need to maintain public confidence in the programs administered by the HPFB and the Inspectorate.

c) The Inspectorate has broad powers to enforce the *Act* and *Regulations*. If a regulated party does not respond voluntarily, the Inspectorate can consider a variety of measures, including; customs activities, public warning or advisory, seizure and detention, and refusal, suspension or amendment of establishment licences.

d) Fairness is a guiding principle of the policy, requiring that the Inspectorate follow a predictable, uniform, non-discriminatory and unbiased approach to enforcement in Canada for all regulated products.

e) The primary objective of the response strategy is to manage the risk to Canadians and use the most appropriate level of intervention to ensure that the regulated party brings the product or activity into compliance.

[48] Dr. Sharma emphasizes the importance of adhering to GMP to ensure the quality, efficacy and safety of drugs. She also highlights the policy considerations weighed by Health Canada in the implementation of regulatory measures. In this case, she claims that Health Canada's regulatory action was spurred by the lengthy history of communication and engagement between Health Canada and Apotex over the course of 2014.

[49] After the call with the FDA on September 29, 2014, Dr. Sharma doubted that Health Canada could trust Apotex due to the FDA's data integrity concerns, "all other information Health Canada had about Apotex," and Apotex's insufficient remedial actions to date.

[50] That same day, Dr. Sharma discussed the agreed-upon regulatory action, the Import Ban, with Deputy Minister DaPont and Associate Deputy Minister Glover, following which she then spoke with the Minister's office.

[51] The Respondents' affiants claim to have received no direction from the Minister or her staff about what regulatory actions to take against Apotex. The record demonstrates that both were included in much of the email correspondence between the Minister's Office and Health Canada following the Toronto Star Articles regarding what to do about Apotex.

[52] As a result of the Respondents' motion heard prior to this judicial review, in a separate order I have granted leave to file the affidavit of Laura Van Soelen containing exhibits of correspondence between Health Canada and Apotex, dated August 31, 2015, pertaining to the issuance of new ELs for both APIPL and ARPL (on September 1, 2015). It is of limited

relevance, but provides a contextual framework of the ongoing regulatory relationship between the parties up to September 30, 2014.

IV. Relevant Legislation

[53] The relevant legislation is attached in Annexes A and B.

V. Issues

[54] The issues are:

A. What is the appropriate standard of review of Health Canada's decision?

B. Did the Minister act in accordance with the duty of procedural fairness when she implemented the Import Ban and amended the EL Letters?

C. Did the Minister act beyond or not in accordance with her regulatory powers under the *FD Act*, the *FD Regulations* and/or the *Customs Act*?

   i. Are the *Regulations* unconstitutional under paragraph 2(e) of the *Canadian Bill of Rights*?

   ii. If the Minister employed the proper regulatory powers, was her decision reasonable?

D. Can this Court grant the relief sought?

VI. Decision Summary

[55] The standard of review is correctness for allegations of procedural fairness. A correctness standard should also be applied to the issue of whether the Minister employed the correct statutory mechanisms to carry out the Import Ban (EL Action and CBSA Action). The Minister's

actual decision of whether to implement the Import Ban should be reviewed on a standard of reasonableness, as this is a question of mixed fact and law.

[56] The Minister acted for an improper purpose and did not act in accordance with the duty of procedural fairness when she implemented the Import Ban and amended the EL Letters. Consequently, the Import Ban should be quashed.

[57] For the EL Action, the Minister employed the proper statutory provision to add terms and conditions to Apotex's ELs (subsection C.01A.008(4)). However, in the circumstances, that provision should encompass the procedural fairness afforded to EL holders throughout the rest of the regulatory scheme, requiring at least notice and reasons for the addition of terms and conditions.

[58] There is no need to consider the CBSA Action, as the Customs Target has expired and has not been renewed.

[59] Paragraph 2(e) of the *Canadian Bill of Rights*, SC 1960, c 44 [*Bill of Rights*] does not apply in the circumstances.

VII. Standard of Review

A. *What is the Appropriate Standard of Review of Health Canada's Decision?*

(1) Applicants' Submissions

[60] The Applicants submit that the appropriate standard of review for determining issues of procedural fairness is correctness (*Rt Hon Jean Chretien v Hon John H Gomery et al,* 2008 FC 802 at paras 65-66, aff'd 2010 FCA 283; *Mission Institution v Khela,* 2014 SCC 24 at para 79 [*Khela*]).

[61] They claim that correctness also governs the issue of whether the Minister had authority to act and, if so, pursuant to which particular legislative provision, as this is a question of jurisdiction (*New Brunswick (Board of Management) v Dunsmuir*, 2008 SCC 9 at para 59 [*Dunsmuir*]; *Burnell v Nova Scotia (Registrar of Motor Vehicles),* 2009 NSSC 341 at paras 5-10, aff'd 2010 NSCA 22).

[62] Further, recent FCA jurisprudence has determined that the EL Action is to be reviewed on a correctness standard (*Takeda Canada Inc v Minister of Health*, 2013 FCA 13 at paras 26, 111, leave to appeal denied 2013 CarswellNat 1867 (SCC) [*Takeda*]; *Canada (Minister of Health) v Celgene Inc*, 2013 FCA 43 at paras 34-35 [*Celgene*].

(2) Respondents' Submissions

[63] The Respondents submit that although the appropriate standard of review for procedural matters is generally correctness, a decision-maker's choice of procedure that involves a Ministerial decision related to public health considerations under her own statute is entitled to deference (*Forest Ethics Advocacy Assn v National Energy Board*, 2014 FCA 245 at para 70 [*Forest Ethics*]; *Maritime Broadcasting System Ltd v Canadian Media Guild*, 2014 FCA 59 at para 55 [*Maritime Broadcasting*]).

[64] The Respondents also argue that the Minister's decision to implement the Import Ban, and the mechanisms she used to carry it out, are reviewable on a reasonableness standard. The need for discretion stems from the Minister's expertise in assessing drug safety and efficacy, and the fact that she is interpreting her home statute – a circumstance for which the Supreme Court has set out a rebuttable presumption of reasonableness (*Information & Privacy Commissioner v Alberta Teachers Association*, 2011 SCC 61 at para 34 [*ATA*]; *British Columbia (Securities Commission) v McLean*, 2013 SCC 67 at para 21 [*McLean*]).

[65] Furthermore, the Respondents argue that issues of fact or mixed fact and law are subject to reasonableness review (*Tervita v Canada (Commissioner of Competition)*, 2015 SCC 3 at para 39; *Agraira v Canada (Minister of Public Safety and Emergency Preparedness)*, 2013 SCC 36 at para 50).

[66] In my opinion, the standard of review for procedural fairness in the present circumstances is correctness. The Supreme Court has determined that deference is not owed when determining whether the decision-maker's process is fair (*Khela*, above, at para 79).

[67] The recent FCA cases suggesting otherwise cited by the Respondents do not aptly apply to the present facts. *Forest Ethics* and *Maritime Broadcasting*, above, contemplate situations where tribunals were given discretion to determine their own procedures. In such a situation, the FCA has found that deference is owed to procedural rulings made by a tribunal with the authority to control its own process. In the present case, the Minister was given no such discretion to control her own process, but instead must comply with the procedures set out in the extensive regulatory regime governed by the *FD Act* and *FD Regulations*.

[68] The parties disagree as to the appropriate standard to apply with respect to the review of the Minister's decision. The Applicants argue that the issue is jurisdictional. I disagree. The Supreme Court has expressed serious reservations about the presence of jurisdictional issues: they are narrow and will be exceptional (*ATA*, above, at para 33). Further, the case law cited by the Applicants in support is not applicable on the present facts.

[69] The Respondents submit that cases involving public health and safety are reviewed on a reasonableness standard. Although prior jurisprudence has established that the appropriate standard of review of decisions on questions of fact and the exercise of discretion by Health Canada under the *FD Regulations* is reasonableness (*North American Nutriceutical Inc v Canada (Attorney General)*, 2012 FC 1044 at para 78 citing *Wellesley Therapeutics Inc v Canada*

(Minister of Health), 2010 FC 573 at para 31), the Minister's interpretation of her power under the *FD Regulations* to implement the EL Action, and under the *Customs Act* to carry out the CBSA Action, are not questions of fact or discretion.

[70] The issue is best characterized as one of statutory interpretation: the EL Action comes down to the Minister's interpretation of her powers under the *FD Regulations*, specifically whether subsection C.01A.008(4) authorizes her to add terms and conditions to Apotex's ELs; and the CBSA Action involves the Minister's interpretation of her powers under the *Act, Regulations* and the *Customs Act*. Statutory interpretation is a question of law (*Canadian National Railway v Canada (Attorney General)*, 2014 SCC 40 at para 33).

[71] Only once it is determined that Minister chose the correct statutory mechanisms would her decision to implement the Import Ban – a policy-based question involving public health considerations – be properly characterized as one of mixed fact and law, with the applicable standard of review at this stage being reasonableness.

[72] According to *Dunsmuir*, the Court must first ascertain whether judicial precedents have satisfactorily established the standard of review applicable to the Minister's interpretation of the *FD Act* and *Regulations*. Where prior jurisprudence has not indicated the proper standard, the Court must analyze the *Dunsmuir* factors.

[73] In *Takeda*, above, Justice David Stratas in dissent on a separate issue, and Justice Eleanor Dawson of the FCA, conclude that the Minister's interpretation of the data protection provisions

of the *FD Regulations* is correctness. Justice Stratas arrives at correctness by rebutting the Supreme Court's presumption of reasonableness set by *ATA*, through an analysis of the *Dunsmuir* factors. Justice Dawson found that the issue had been determined in recent prior jurisprudence.

[74] Although there is no prior jurisprudence setting out the appropriate standard of review on the specific provisions at issue, Justice Stratas' analysis of the *Dunsmuir* factors is helpful: the present facts involve the same Minister and the same regulations. He writes at paras 29 and 30:

> 29 In my view, the presumption [of reasonableness set out in *ATA*] is overcome. All of the factors relevant to determining the standard of review lean in favour of correctness review. In this case, the nature of the question is purely legal. There is no privative clause. The Minister has no expertise in legal interpretation. There is nothing in the structure of the Act, this regulatory regime or this particular legislative provision that suggests that deference should be accorded to the Minister's decision. This analysis of the factors mirrors that in *Georgia Strait Alliance v. Canada (Minister of Fisheries & Oceans)*, 2012 FCA 40 (F.C.A.) at paragraphs 101-105 (sometimes also referred to as "Georgia Strait"); *Sheldon Inwentash & Lynn Factor Charitable Foundation v. R.*, 2012 FCA 136 (F.C.A.) at paragraphs 18-23.
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> 30 I am comforted in this conclusion by the application of the correctness standard to Ministerial interpretations of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133: *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533 (S.C.C.) at paragraph 36; *Astrazeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560 (S.C.C.); *Purdue Pharma v. Canada (Attorney General)*, 2011 FCA 132 (F.C.A.) at paragraph 13. Although different regulations are involved in this case, both concern Minister-administered regimes governing the period before drugs are authorized for sale. It would be anomalous if the standards of review differed.

[75] Justice Stratas' analysis applies to the present facts: statutory interpretation is a legal question, the *FD Regulations* contain no privative clause and the Court is as well placed as the Minister to determine the proper statutory interpretation of the *Regulations*. Part C, Division 1A does not confer a large degree of deference to the Minister. Although the particular provision, subsection C.01A.008(4), which the Respondents contend provides statutory authority for the Minister's actions, does provide the Minister with some degree of deference to set out terms and conditions, the contextual and legal scheme for establishment licensing provides little deference to the Minister. Even in situations where the Minister is given some discretion, she is required to consider certain factors and follow specific procedures.

[76] While I find that the appropriate standard is correctness, given my decision below, whether one applies the standard of correctness or reasonableness on interpretation, the result would be the same.

VIII. Analysis

A. *Did the Minister Afford Adequate Procedural Fairness when she Implemented the Import Ban and Amended the EL Letters?*

(1) What Degree of Procedural Fairness is Apotex Entitled to?

[77] The Applicants submit that the Minister was under a common law duty to act fairly: her decision affected Apotex's rights and interests - mainly, Apotex's pre-existing authorization to import products from APIPL and ARPL. Consequently, it requires that they be provided the opportunity to present their case fully and fairly, and that decisions are made using a fair,

impartial and open process (*Baker v Canada (Citizenship and Immigration)*, [1999] 2 SCR 817 at paras 20, 22, 28 [*Baker*]).

[78] The Respondents argue that procedural fairness is not owed under the *Regulations* at the time terms and conditions are imposed. A party disputing the imposition may apply for an amendment under section C.01A.006, and will then be granted procedural protection pursuant to subsection C.01A.010(3) of the *FD Regulations*.

[79] The Respondents cite *Baker* as authority for the importance of context to assessing the content of procedural fairness, and analyse the *Baker* factors. They argue that if the Court finds a duty of procedural fairness is owed prior to the imposition of terms and conditions, the factors indicate the duty is low for the following reasons:

a) Ministerial decisions must ensure legislative policy is implemented (*Imperial Oil Ltd v Quebec*, 2003 SCC 58 at paras 34, 37-38).

b) In the context of public safety procedural guarantees will be adjusted "in accordance with the degree of risk and urgency" (*Miel Labonte Inc v Canada*, 2006 FC 195 at para 70).

c) The decision was a non-final regulatory decision reached by a non-adjudicative process.

d) The purpose of the *FD Act* and *Regulations* is the protection and promotion of Canadians' health and safety. The Minister is provided discretion to apply her expertise and is statutorily mandated to protect public health.

e) Apotex's interest is purely economic, which cannot outweigh the public interest of having safe products on the market (*Hilbert Honey Co v Canada (Canadian Food Inspection Agency)*, 2009 FC 818 at paras 63 and 120-122).

f) Tribunals with expertise, such as Health Canada in this context, are to be afforded deference in establishing decision-making processes (*Maritime Broadcasting*, at para 56).

[80] The Respondents claim that a finding that low procedural fairness is owed to Apotex is consistent with other case law arising under the *Regulations* (*Canadian Pharmaceutical Technologies International (CPT) Inc v Canada (Attorney General)*, 2009 FC 244 at paras 54-55; *Duchesnay Inc v Canada (Attorney General)*, 2012 FC 976 at para 64).

[81] With regard to some of the above points, on the facts before me, there is no evidence to support the contention that the Minister was concerned about immediate health risks posed by the products subject to the ban, nor that the situation was highly urgent, and that consequently, the level of procedural fairness should be less. Moreover, in terms of the statutory scheme, the Minister is not given "wide discretionary power" under the *Regulations*, in all but few provisions (such as paragraph C.01A.008(4)(b)). Further, the statutory scheme provides procedural protections (notice, reasons and/or the opportunity to be heard) for the licensees in all sections, apart from those relating to issuance. This indicates that some procedural fairness was intended for the EL scheme.

[82] The regulatory regime and the present circumstances suggest procedural fairness should have been afforded prior to implementation of the Import Ban. The Minister made an administrative decision that affected Apotex's rights, privileges and interests. Even at the mid-to-low end of the spectrum, Apotex was entitled to basic participatory rights and the required procedural fairness as set out in the *Regulations*.

[83] The Minister was procedurally unfair. She failed to provide any notice and thus denied Apotex an opportunity to be heard before unilaterally imposing the Import Ban on September 30, 2014.

(2) Improper Purpose and Reasonable Apprehension of Bias

(a) *Apprehension of Bias*

[84] Apotex submits that that the Minister and her delegates conducted themselves so as to give rise to a reasonable apprehension of bias, both for lack of impartiality and for lack of independence.

[85] The legal test for reasonable apprehension of bias is confirmed in *Baker*, above, at para 46 to be:

> What would an informed person, viewing the matter realistically and practically – and having thought the matter through – conclude. Would he think that it is more likely than not that [the decision-maker], whether consciously or unconsciously, would not decide fairly?

[86] The Applicants allege that this test is met and that a lack of impartiality arose from the Minister's improper motives and the fact that she and her delegates had made a decisive decision to take strong action against Apotex.

[87] They cite a September 16, 2014 email from the Minister to her Chief of Staff and the Deputy Minister in which the Minister expresses her concern that they didn't "have a strong enough policy response," and that she wanted to say she would "revoke the license [sic] of

[Apotex] if they do not remove these products asap" (Rule 318 Record, Tab 26, AR, Vol XVII, Tab 19(c)(26)).

[88] An email from the Minister's Director of Issues Management, Mr. Olsen, to the Prime Minister's Office on September 23, 2014, also indicates that the Minister's Office directed the department (presumably the RAPB) to take "stronger action" (Rule 318 Record, Tab 34, AR, Vol. XVII, Tab 19(C)(34)).

[89] Apotex also submits that the Minister (and delegates) lacked independence in the particular circumstances, as there was no one involved in the process of deciding whether or not to implement an import ban who could render an independent decision, free from external pressure. Apotex claims that by September 29, 2014, everyone who was involved in the issue of what to do about Apotex were tainted by the media coverage and Ministerial pressure.

[90] The obligation of impartiality on the Minister is not equivalent to the impartiality that is required of a judge or an administrative decision-maker whose primary function is adjudication. The Minister is dealing with polycentric considerations and has as her duty the protection of the Canadian public's health and safety (*Imperial Oil Ltd v Quebec*, 2003 SCC 58 at paras 31, 34).

[91] While the Minister expressed a desire to pull Apotex's ELs following intense questioning in the House of Commons on September 16, 2014, I do not think an "informed person," looking to context and with information (i) about the events between Health Canada and Apotex from April 2014 onwards, (ii) of APIPL and ARPL's GMP non-compliance, and (iii) considering the

complex regulatory interplay of the various Health Canada branches (as evinced by communication between individuals in all departments) would think it is more likely than not that the decision-maker (not solely involving the Minister) would not at least be amenable to persuasion. Legally, the threshold has not been met.

[92] With respect to the alleged lack of independence, there is evidence from the record that discussions and meetings were taking place up and down the ladder at Health Canada. However, in considering the regulatory regime and the division of powers at Health Canada, based on the facts before me, the Applicants have not met their burden of demonstrating that no one at Health Canada could render an independent decision free from external pressure.

[93] Internal emails indicate that Health Canada was indeed concerned with the Toronto Star articles and what to do about Apotex. As Ms. Chiponski stated in her First Affidavit, it is Health Canada's responsibility to be apprised of information, including from the media, falling within its mandate. The articles were highly critical of Health Canada and of the Minister and it is not unusual or in my opinion probative for demonstrating a lack of independence that Health Canada personnel were discussing same.

[94] The Applicants have not met the burden of establishing that the Minister demonstrated a reasonable apprehension of bias, either from a lack of independence or impartiality, given the high threshold for establishing that bias (*Balta v Canada (Minister of Citizenship and Immigration)*, 2011 FC 1509 at para 18; *Fletcher v Canada (Minister of Citizenship and Immigration)*, 2008 FC 909 at para 8).

(b) *Improper Purpose*

[95] The evidence does however demonstrate that the Minister acted for an improper purpose.

[96] Discretionary decisions are constrained by the confines of the enabling legislation and must be exercised in accordance with the rule of law. It is thus *ultra vires* for a Minister to make a decision for a purpose other than for which that power was granted by the legislature (*Roncarelli v Duplessis*, [1959] SCR 121 at 140, 143).

[97] The Applicants allege that the Minister's actions were not motivated by a desire to protect the health and safety of Canadians and ensure compliance with the *FD Regulations*, but were instead for the purpose of easing political pressure stemming from heavy criticism by the media and in the House of Commons.

[98] The evidence they assert supports this allegation includes:

a) An email from the Minister's staff expressing frustration with the Inspectorate's decision to offer Apotex the option of voluntary quarantine, thereby precluding any immediate "stronger measures" (Rule 318 Record, Tab 36, AR, Vol XVII, Tab 19(c)(36)).

b) Frequent requests by the Minister's staff for "stronger action," following which they were indeed taken: Health Canada accelerated Apotex's deadline for responding to their request for voluntary quarantine, and then withheld the Exit Notice for APIPL that granted a Compliant with Terms and Conditions rating.

c) When asked why Health Canada's action was more severe than that of the FDA, Health Canada personnel pointed to Toronto Star coverage, not a concern for health and safety.

d) Public assurances by the Minister, Dr. Sharma and Health Canada that there were no health and safety concerns of the banned products, and the fact that no APIPL or ARPL products were recalled.

e) Interactions between Health Canada and Apotex prior and subsequent to the Toronto Star criticism. In April 2014, the FDA Import Alert for APIPL products resulted in discussions between Health Canada and Apotex, further inspection and a jointly agreed upon testing protocol. The FDA alert regarding ARPL products in September – in the midst of media attacks – resulted in a demand for voluntary quarantine and Import Ban.

f) Finally, a FDA Import Alert in 2013 for another foreign manufacturer charged with serious data integrity issues, including fraudulent falsification, did not result in an import ban by Health Canada, but instead ended in cooperation with the company. That situation was not in the wake of highly critical media attention, as was present here.

[99] The Applicants emphasize that the motivation behind the Minister's actions was to ease political pressure – clearly unrelated to the intent and purpose of the *FD Act* and *Regulations*.

[100] The purpose of the *FD Act* and *Regulations* is the protection and promotion of Canadians' health and safety. It is not contested that Health Canada had concerns about GMP compliance at Apotex's Indian facilities. Nor is it disputed that in order to protect Canadians' health and safety, Health Canada has the option to ban products from facilities found to be non-compliant with GMP, as is set out by their Compliance and Enforcement Policy (POL-0001).

[101] However, the issue for the Court is whether, on the facts contained in the record before me, the Import Ban was implemented based on a legitimate concern for protecting Canadians' health and safety, and not to silence criticism in the media or in Parliament, or for any other improper purpose.

[102] In my opinion, a consideration of the following facts illustrates that it is more likely than not that an improper purpose was at play. In September of 2014, in the absence of media criticism on the Minister or Health Canada, evidence of the on-going regulatory relationship

between Apotex and Health Canada demonstrates that it is unlikely and against past and customary practice that Health Canada would have:

a) suddenly and without explanation withdrawn its own inspectors' Compliant with Terms and Conditions rating for APIPL, which stemmed from an inspection expressly aimed at investigating FDA concerns of the APIPL and ARPL facilities;

b) immediately and without notice ceased the usual pattern of ongoing dialogue for working with regulated parties and taking corrective actions in situations of GMP non-compliance, as outlined by their own policies;

c) banned products from both facilities targeted in the Toronto Star articles, despite the fact that APIPL had just been granted a Compliant with Terms and Conditions rating by Health Canada inspectors and only ARPL had been the subject of the most recent FDA Import Alert; and

d) implemented an Import Ban without first attempting to consult with Apotex regarding the newly learned FDA concerns, or requesting an extension of Apotex's voluntary quarantine.

[103] There is nothing in the evidence to suggest that the events of September were so different from the previous six months such that the Import Ban was needed immediately, without notice or any opportunity to be heard, and for both APIPL and ARPL – facilities expressly mentioned in the critical articles.

[104] A review of the "new information" obtained by Health Canada on September 29, 2014, also does not explain the urgency of the regulatory action taken. The evidence reveals that Health Canada: had been apprised of the FDA's Form 483s, which detailed their observations and concerns; had been informed of the FDA warning letter to APIPL in June 2014, regarding its failure to sufficiently correct problems; had come to a mutually agreed upon Protocol for re-testing products; and had conducted an inspection specifically for the purpose of reviewing APIPL's progress in light of the FDA findings. Although in September ARPL came under the

spotlight, observations from the FDA inspection outlined in ARPL's Form 483 were not so disparate or egregious to those found for APIPL that such a different course of regulatory action was justified. The way this Import Ban was carried out fell outside Health Canada's customary regulatory practice, but publicly represented that they were going further than the US FDA.

[105] Further, if the Import Ban was motivated by the purpose of protecting health and safety, it is curious that the Minister and Health Canada would publicly assure that the banned drug products' were safe and at no point issued any recall for those products available in the Canadian market. Upon cross-examination, the Respondents' affiants stated that there was no evidence that products from APIPL or ARPL produced a risk or threat to the health of consumers.

[106] While the Minister is provided some discretion under the *FD Regulations* and has been charged with protecting Canadians' health and safety through her implementation of the *FD Act* and *Regulations*, her discretionary decisions must be prescribed by law and fall within the confines of her mandate. They are also restricted by the requirements of natural justice (*Morton v Canada (Minister of Fisheries and Oceans)*, 2015 FC 575 at paras 29-31 citing *Comeau's Sea Foods Ltd v Canada (Minister of Fisheries & Oceans)*, [1997] 1 SCR 12 at para 36).

[107] The above facts suggest that the Import Ban was motivated by the Minister's desire to ease pressure triggered from the media and in the House of Commons – a purpose falling outside her delegated authority from the enabling legislation, which must be exercised in accordance with the rule of law. The Minister's actions were therefore *ultra vires* and she erred in her exercise of jurisdiction by implementing an Import Ban on September 30, 2014. The public

statements released on September 30, 2014, by the Minister and Health Canada constituted a manifestation of this improper purpose; they were a way for the Minister to publicly convey she was taking strong action and was not weaker than her US regulatory counterpart.

(3) Failure to Act in Accordance with Natural Justice

[108] The Respondents submit that Apotex cannot credibly argue it was unaware of Health Canada's concerns. Ongoing correspondence and information exchange between a regulator and regulated party can constitute notice. Thus, the Respondents argue Apotex was aware of Health Canada's concerns of data integrity since April 2014.

[109] They further maintain that the Applicants also cannot claim to have been denied an opportunity to be heard: Apotex provided information to Health Canada relating to data integrity issues and the corresponding corrective actions taken, such as re-testing of products once in Canada pursuant to the Protocol.

[110] The Respondents also claim that the statutory basis and reasons for the decision were explained in the EL Letters and Health Canada's call with Apotex on September 30, 2014. To the extent the reasons given are inadequate, the Court must look to supplement them, as suggested by Justice Abella in *Newfoundland and Labrador Nurses' Union v Newfoundland and Labrador (Treasury Board)*, 2011 SCC 62 at paras 12-16.

[111] In addition to reviewing inspection reports of APIPL and ARPL, documents from the Respondents' Rule 318 Response and sworn evidence from Ms. Chiponski and Dr. Sharma

demonstrate Health Canada's consideration of all the information provided to it. The Respondents thus claim that the history of engagement and ongoing correspondence between Apotex and Health Canada constituted adequate notice.

[112] I disagree.

[113] Participatory rights are afforded so that the interested parties have an opportunity to bring evidence and arguments relevant to the decision to be made to the attention of the decision-maker (*Baker*, above, at paras 22, 28). Although the content of procedural fairness varies with the circumstances, notice is a fundamental element. Its main purpose is to afford those affected with a reasonable opportunity to present their case and to respond to what is presented in opposition. Notice must thus be given sufficiently in advance to allow for preparation and must provide adequate information to allow meaningful participation (Brown and Evans, *Judicial Review of Administrative Action in Canada*, looseleaf (Toronto: Thomson Reuters Canada Limited, 2014) at 9:1100, 9:1200).

[114] Apotex is a large pharmaceutical manufacturer that works with various international facilities and functions within a complex regulatory and licensing scheme: they are seemingly in constant correspondence with their regulator. It is obvious they knew of Health Canada's concerns regarding data integrity issues at APIPL and ARPL – they themselves supplied Health Canada with information regarding same and of corrective actions taken in response, and in cooperation with, the FDA. This correspondence does not constitute notice or an opportunity to be heard.

[115] The last communication between Apotex and Health Canada prior to the Import Ban was the draft Inspection Exit Notice, conveying that APIPL had received a Compliant with Terms and Conditions rating from Health Canada on September 25, 2014, four days prior to imposition of the Import Ban. If anything, this correspondence conveyed to Apotex that Health Canada's data integrity concerns had lessened and were being addressed, in the ordinary course of the parties' normal, ongoing dialogue in dealing with regulatory concerns.

[116] Further, both the Respondents' affiants attest to the fact that "new information" obtained from the FDA on September 29, 2014, called into question the reliability of data coming from APIPL and ARPL and caused concerns that corrective actions to that point "might not be sufficient" (Sharma Supplementary Affidavit, para 20; AR, Tab 10, p 2466). This conversation and the "new information" do not form part of the ongoing correspondence between Apotex and Health Canada, yet it was a decisive factor in Health Canada's decision to amend Apotex's ELs and detain their products at the border.

[117] Apotex was informed of the Import Ban over the phone on September 30, 2014, and via press releases by Health Canada and the Minister that day. This cannot amount to notice, which must be prospective in order to provide a *meaningful* opportunity to be heard.

[118] The Respondents also claim that Health Canada took "escalating action" to address problems at APIPL and ARPL and warned that additional steps may be taken in the future. The evidence demonstrates that between April and September of 2014, rather than escalating, the correspondence and actions taken exemplify the cooperative approach outlined in Health

Canada's Compliance and Enforcement Policy (POL-0001) whereby non-compliance is brought to the attention of the regulated party and the Inspectorate clarifies what is necessary to achieve compliance (section 8.0, POL-0001) – this is what happened in the context of APIPL. Although non-binding, the policy provides insight into Health Canada's usual regulatory practice. It states:

> When a non-compliance issue is identified, it is brought to the attention of the company or individual involved. Initially, the Inspectorate will clarify what is necessary to achieve compliance. It is then the organization or individual's responsibility to take timely and appropriate action to comply with legislative and regulatory requirements. Enforcement actions will be undertaken by the Inspectorate when necessary, particularly when the regulated party is unable or unwilling to comply with legislative and/or regulatory requirements.

[119] Health Canada's warning that they may take "additional steps" if necessary, does not constitute adequate notice, as it did not provide sufficient information to allow Apotex to participate.

[120] Consequently, without proper notice Apotex was not provided with a meaningful opportunity to be heard. Although Health Canada had information about Apotex's corrective actions, this preceded the new information conveyed by the FDA, and did not provide an opportunity to be heard on the factors leading to the decision.

[121] The Minister did not act in accordance with natural justice and denied Apotex the basic procedural rights required in the circumstances.

B. *Did the Minister Act Beyond or Without Legislative Authority?*

(1) EL Action

(a) *Legislative / Regulatory Scheme*

[122] While I need not consider whether the Minister acted without legislative authority, given my findings of the Minister's procedural unfairness and acting for an improper purpose, it is an issue that warrants clarification by this Court. The record before me is extensive and a consideration of this issue has consequences for ascertaining future licensees' rights under the *FD Regulations*.

[123] The *FD Regulations* create a scheme whereby no person can manufacture, import or sell a drug, except in accordance with an EL. Once the requisite information is provided, section C.01A.008 regulates issuance. Subsection C.01A.008(4) authorizes the Minister to set out terms and conditions in an EL regarding required testing and "any other matters necessary to prevent injury to the health of consumers, including conditions under which drugs are fabricated, packaged/labelled or tested".

[124] The Minister is authorized to amend these terms and conditions under section C.01A.012, if necessary, to prevent injury to the health of the consumer, provided 15 days' notice and the reasons for the amendment are given in writing.

[125] The Minister may suspend ELs in respect of any matters indicated in subsection C.01A.008(2) if the Minister has reasonable grounds to believe that (a) the licensee contravened the *Act* or *Regulations*; or (b) the licensee made a false or misleading statement in the application for the EL (section C.01A.016). Under subsection C.01A.016(3), the Minister cannot suspend an EL until the licensee is provided written notice that sets out the reason for the proposed suspension and any required corrective action, and the licensee has been given an opportunity to he heard.

[126] Section C.01A.017 grants the Minister power to suspend a licence without providing an opportunity to be heard if necessary to prevent injury to the health of the consumer. Reasons for the suspension must be provided in writing and within 45 days the licensee must be provided an opportunity to be heard if requested.

(b) *Analysis*

[127] Apotex contends that under the *FD Regulations*, the Import Ban (partially carried out via the Minister's amendment of APIPL and ARPL's ELs) could only legitimately be pursued under sections C.01A.016 or C.01A.017, both of which implicate procedural rights that were not provided.

[128] On September 30, Health Canada informed Apotex that it was restricting import and would be amending Apotex's ELs. The added terms and conditions effectively prohibit import into Canada of all products from APIPL and ARPL, save those deemed medically necessary by the Minister, which are then subject to additional third-party testing.

[129] The Applicants submit that "terms and conditions" were not intended to be interpreted so as to nullify Apotex's right to carry on a designated activity. This amounts to suspension, for which the Minister's power stems from section C.01A.016, and under which she is required to provide Apotex notice, reasons and an opportunity to be heard. Under urgent circumstances, she is still required to provide an opportunity to be heard if requested (section C.01A.017). By effectively suspending Apotex's EL's without complying with the requirements, the Minister acted without legislative authority.

[130] Apotex submits that the Minister's claimed reliance on subsection C.01A.008(4) was in error for some of the following reasons:

a) all of section C.01A.008 addresses the Minister's powers in the context of a fresh application or amendment sought by the licensee – section C.01A.012 grants the Minister authority to amend terms and conditions by her own initiative;

b) the power to set terms and conditions under one subsection cannot be read to include the power to revoke primary rights granted in another.

[131] They note that the Court's interpretation of the *FD Regulations* should be reviewed in light of paragraph 2(e) of the *Bill of Rights*: all Canadian laws are to be construed so not to hinder the right to a fair hearing in accordance with the principles of fundamental justice. Alternatively, if subsection C.01A.008(4) is found to authorize the Minister's EL action, it is a decision that includes the common law right to a fair hearing before imposition of the terms and conditions. See the subsequent section for a discussion of the Applicants' argument on paragraph 2(e) of the *Bill of Rights*.

[132] The Applicants argue that the Minister also lacked factual basis to implement the Import Ban: she did not believe on reasonable grounds that the amendment was necessary to prevent injury to the health of consumers, as required by the *Regulations*.

[133] Despite the Minister's assertion that the new terms and conditions were "necessary to prevent injury to the health of consumers," cross-examinations of Ms. Chiponski and Dr. Sharma reveal that there was no evidence that products from APIPL or ARPL produced an immediate risk or threat to the health of consumers. Also, the Chiponski and Sharma Affidavits speak of a concern with a "potential risk" to the consumer, which does not meet the conditions set out in subsection C.01A.008(4).

[134] The Minister is given broad discretion under subsection C.01A.008(4), which states (for ease of reference):

> (4) The Minister may, in addition to the requirements of subsection (2), set out in an establishment licence terms and conditions respecting
>
> (a) the tests to be performed in respect of a drug, and the equipment to be used, to ensure that the drug is not unsafe for use; and
>
> (b) any other matters necessary to prevent injury to the health of consumers, including conditions under which drugs are fabricated, packaged/labelled or tested.

[135] In my opinion, subsection C.01A.008(4) does authorize the Minister to add new terms and conditions to previously issued ELs. However, procedural rights that are provided to EL holders throughout Division 1A of the *Regulations* in similar circumstances should also be afforded when terms and conditions are added to existing ELs.

[136] This is a matter of statutory interpretation, for which the approach set out in *Rizzo v Rizzo Shoes Ltd*, [1998] 1 SCR 27 at para 21 is to be followed:

> the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament.

[137] Section C.01A.008 is the only provision falling under the heading "Issuance". It initially appears odd that Ministerial authority to add new terms and conditions to existing ELs at any given time (not just upon issuance or application by the licensee for amendment) would fall within the section dealing with issuance. This is especially so considering Division 1A contains a separate part devoted to "Terms and Conditions," under which section C.01A.012 authorizes the Minister, by her own initiative, to amend (not impose) terms and conditions to an EL if she has reasonable grounds to believe it is necessary.

[138] However, Ministerial power to impose new terms and conditions to existing ELs – grammatically and on an ordinary meaning of the words – reasonably falls under the heading "Issuance," as the provision could be interpreted to apply to both issuance of a new EL, as well as issuance of new terms and conditions.

[139] The interpretation that subsection C.01A.008(4) does not provide the Minister with authority to add new terms and conditions to existing ELs leads to an absurd result, as the Minister is thus precluded from adding terms and conditions if she did not do so at the outset.

[140] Terms and conditions can in fact be added to ELs following an on-site inspection or desktop review. This is what occurred in the present case when Apotex was provided a draft Inspection Exit Notice for APIPL, setting out a Compliant with Terms and Conditions rating. Notably, the statutory basis for adding terms and conditions cited in the Exit Notice was sections C.01A.008(4) and C.01A.012. This Exit Notice was provided by a Health Canada employee, without the knowledge or authorization of the Minister. Nevertheless, the Inspection Exit Notice on which new terms and conditions were imposed pursuant to these sections provides notice and an opportunity to be heard:

> If you disagree with the content of the Inspection Exit Notice, you have ten (10) calendar days to bring your concerns to the attention of the Regional Manager… If you exercise this option, please do so in written submission outlining the basis of the dispute citing the specific sections of the Inspection Exit Notice that are contentious (Desai First Affidavit, Exh I; AR, Tab 3(I), p 242).

[141] Thus, if Health Canada is concerned with a licensee's compliance with the *FD Act* or *Regulations*, terms and conditions may be added to ELs following an inspection, and the licensee is provided an opportunity to be heard.

[142] Analysis of the suspension provisions (sections C.01A.016, C.01A.017) further supports the interpretation that subsection C.01A.008(4) was intended to provide the Minister power to add terms and conditions to existing ELs. The Applicants claim that suspension may be "in whole or in part," while the Respondents argue that the suspension applies to a category of products – hence why the Minister could not suspend Apotex's licences, as she needed to allow importation of medically necessary products.

[143] The Respondents' interpretation is more tenable on a reading of the words in their grammatical and ordinary sense: section C.01A.016 states that the Minister may suspend an EL "in respect of any or all matters indicated in subsection C.01A.008(2)…". The terms "any or all" do not provide that any or all drug products may be suspended, rather they indicate that suspension may stem from contravention of one or more matters listed under subsection C.01A.008(2). The matters listed under that subsection include authorized activities, such as importation.

[144] An interpretation that subsection C.01A.008(4) was the proper statutory basis authorizing the Minister to impose new terms and conditions to APIPL and ARPL's existing ELs is consistent with the intent of the legislative scheme, as the Minister must be able to impose terms and conditions other than at the time of issuance to protect Canadians' health and safety. However, using this provision to impose new terms and conditions on existing ELs should encompass a right to notice and reasons for the new terms and conditions.

[145] If subsection C.01A.008(4) permits adding new terms and conditions to existing ELs, but does not provide notice or reasons, a nonsensical outcome ensues. Under section C.01A.012, when the Minister changes the parameters of an EL by amending existing terms and conditions of an EL, the Minister is required to provide at least 15 days' notice in writing and reasons for the amendment, but when the Minister changes the parameters of an EL by adding new terms and conditions, no notice or reasons are required. There is no logical basis for the requirement for notice and reasons in one of these situations, but not the other.

[146] Further support that the some procedural fairness should apply to the Minister's use of subsection C.01A.008(4) to impose terms and conditions on ELs is that the regulatory scheme provides such procedural rights, even to those not holding an EL: the Minister is required to provide notice, reasons and an opportunity to be heard to applicants for which she has refused to issue an EL (subsection C.01A.010(3)). It would be procedurally unfair that at the very least notice and reasons are not provided to EL holders.

[147] Once an EL is issued, the licensee is granted procedural protection for Minister-initiated actions: upon annual licence review under section C.01A.009, if the Minister refuses to issue the EL or amend terms and conditions (as requested by the licensee under section C.01A.006) she is required to notify the licensee and provide an opportunity to be heard (subsection C.01A.010(3)); under section C.01A.012 the Minister may amend terms and conditions on an existing EL, but must provide at least 15 days' notice in writing, as well as reasons; under section C.01A.016, upon suspension the Minister must provide written notice and reasons, if corrective action is required, and provide the licensee an opportunity to be heard; and even when urgent, section C.01A.017 requires the Minister to provide an opportunity to be heard if requested.

[148] Basically, anytime the Minister purports to do anything affecting an already-issued EL, the Minister must also provide notice and/or reasons and/or an opportunity to be heard as set out in the *Regulations*. Parliament clearly intended that licensees be afforded at least these components of procedural fairness.

[149] The Applicants argue that "terms and conditions" should not be interpreted so as to nullify Apotex's right to carry on a designated activity, and that this amounts to suspension under section C.01A.016. The terms and conditions imposed on Apotex's ELs are stringent; however, if the Minister were to suspend Apotex's ELs to prevent against importation of non-compliant drugs, then she may be putting at risk the health and safety of Canadians if a shortage of essential drugs ensued as a result. The *Regulations* cannot be read so as to frustrate the purpose for which they were enacted.

[150] In my opinion, the Minister used the correct statutory mechanism to add terms and conditions to Apotex's ELs. However, in the present circumstances (when the Minister imposes terms and conditions on an existing EL under subsection C.01A.008(4)), the most basic procedural protections, like notice and reasons for imposing the new terms and conditions, should be afforded. This is consistent with the regulatory scheme and Health Canada's own policies.

(c) *Are the Regulations Unconstitutional Under Paragraph 2(e) of the Bill of Rights?*

[151] The Applicants submit that if the *Regulations* are construed to have permitted the Minister to remove Apotex's right to import without a fair hearing it is unconstitutional and thus inoperative for contravening paragraph 2(e) of the *Bill of Rights*.

[152] The Respondents counter that paragraph 2(e) of the *Bill of Rights* does not create a right to a hearing where neither the legislation nor the common law require it and since Apotex was

not owed a hearing pursuant to subsection C.01A.008(4) of the *Regulations*, the *Bill of Rights* does not apply (*Amaratunga v Northwest Atlantic Fisheries Organization*, 2013 SCC 66 at para 61 [*Amaratunga*]).

[153] The Supreme Court has made it clear that paragraph 2(e) of the *Bill of Rights* does not create a free-standing right to a hearing – it "provides for a fair hearing if and when a hearing is held" (*Amaratunga,* above, at para 61). I have determined that basic procedural fairness should have been provided when Health Canada imposed new terms and conditions on Apotex's ELs, however this is not synonymous with imposing a right to a fair hearing. As clarified by the Supreme Court, the protections afforded by paragraph 2(e) of the *Bill of Rights* are operative only in the application of law to individual rights and obligations in a proceeding before a court, tribunal or similar body (*Authorson (Litigation Guardian of) v Canada (Attorney General)*, 2003 SCC 39 at paras 59-61).

(2) CBSA Action

[154] To execute the Import Ban, the Minister stopped import into Canada of all drug products from APIPL and ARPL by way of Lookouts sent to CBSA on September 30, 2014, which cited data reliability problems at APIPL and ARPL as justification.

[155] The purported statutory basis for implementing the ban stems from contravention of sections C.02.003, C.02.003.1 and C.02.003.3 of the *FD Regulations*, together with section 101

of the *Customs Act*. Apotex submits the Minister acted without legislative authority and that reliance on these provisions is illegitimate for the following reasons:

a) There is no legitimate basis to rely on the *Customs Act* and ignore section C.01A.017, which gives the Minister power to prevent importation in urgent circumstances.

b) Section 101 states "[g]oods that have been imported or are about to be exported may be detained." This confers power to detain goods already in Canada, not to "prevent", "prohibit" or "ban" importation of anything.

c) Section 101 is an interim regulatory mechanism; it contemplates detention until the goods have been "dealt with in accordance with" the applicable legislation.

d) Sections 23 to 27 of the *FD Act*, which authorize inspectors to seize products in relation to which the *Regulations* have been contravened, requires the inspector to release the goods under section 26 once satisfied of compliance. If not satisfied, he or she must either obtain consent to their destruction or bring proceedings in a superior court – which affords procedural protections (section 27).

[156] The Respondents claim that the Customs Target is not reviewable under section 18.1 of the *Federal Courts Act* because it is not a final determination of admissibility of products under the *Customs Act* and does not affect the rights or interests of an applicant, as not one Apotex product was seized as a result of the Customs Target. To challenge a final determination of product admissibility from APIPL or ARPL, Apotex must have brought a proceeding under section 106 of the *Customs Act*, which it did not do.

[157] The Applicants have requested that the Minister's decision to implement, and her implementation of the Import Ban, be quashed, which includes the CBSA Action. The Customs Target expired on March 31, 2015, and was not renewed. The Applicants argue that the CBSA Action was a vital component of the Import Ban. While this may be true, this facet of the Import Ban does not have continuing effects or lasting repercussions on Apotex's current right to import products from APIPL or ARPL, as the EL Action may. Even should this Court decide that the

Minister's decision was without legislative authority and or unreasonable, there is no further remedy the Court may grant, since the Customs Target has expired and is not in force.

C. *Was the Minister's Decision Reasonable?*

[158] The Minister implemented an Import Ban that was motivated by an improper purpose, and without affording Apotex the procedural protections required by law. This is neither a reasonable decision nor a correct one – it is an action taken without legal authority and thus must be quashed.

D. *Can this Court Grant the Relief Sought?*

[159] Under subsection 18.1(3) of the *Federal Courts Act*, RSC 1985, c F-7 [*FCA*] the Court is provided broad powers under (a) to order a federal board, commission or other tribunal to do any act or thing it has unlawfully failed to do or under (b) to "declare invalid or unlawful, or quash, set aside or set aside and refer back for determination in accordance with such directions as it considers to be appropriate, prohibit or restrain, a decision, order, act or proceeding of a federal board, commission or other tribunal".

[160] The Respondents argue that this Court cannot grant Apotex's requested order that the Court compel the Minister to retract her statement and that she require Health Canada to retract their statement, both released on September 30, 2014. The Respondents claim that these statements are not amenable to judicial review, as they do not affect Apotex's substantive rights or carry any legal consequences (*Girouard v Canadian Judicial Council*, 2014 FC 1176

[*Girouard*]; *Toronto Coalition to Stop the War v Canada (Public Safety and Emergency Preparedness)*, 2010 FC 957 [*Toronto Coalition*]).

[161] In *Girouard*, Justice Luc Martineau found that a press release issued by the Canadian Judicial Council [CJC] announcing members of an inquiry committee was not a reviewable decision, as it had no legal effect. The sole purpose of the press releases was to inform the public of the composition of the Inquiry Committee and the name of the CJC's independent counsel.

[162] The *Toronto Coalition* case cited by the Respondents involved an informational letter sent by a CBSA employee to the Applicant regarding admissibility to Canada, who did not have statutory authority to make a final decision regarding the Applicant's admissibility. The letter constituted notice, but did not affect rights or carry legal consequences because a final decision on admissibility must be done at the border.

[163] The above cases are not applicable to the present facts. While the Minister and Health Canada's public statements do not constitute the decision in and of itself, they form part of the Minister's implementation of the decision that was procedurally unfair and motivated by an improper purpose. The facts suggest that publicly showing strong and decisive action towards Apotex in light of intense media criticism was the motivation behind the import ban – issuing two public statements would help to achieve these ends.

[164] Contrary to *Toronto Coalition*, this is not a situation where the decision-maker was not the individual authorized with making such decisions. Further, the public statements cannot be

said to embody notice to Apotex about a decision not yet made – it was made clear to Apotex on September 30 that the Import Ban was effective immediately.

[165] The Applicants argue that the Minister and Health Canada's statements of September 30, 2014, constitute an "act" under subsection 18.1(3), and request that the Court compel the Minister to retract the statements. Use of the term "matter" under subsection 18.1(1) encompasses a variety of administrative actions, including any matter in respect of which a remedy may be available under section 18 of the *FCA* (*Krause v Canada*, [1999] 2 FCR 476 (FCA) at para 21).

[166] The Applicants cite *McCabe v Canada (Attorney General)*, [2001] 3 FCR 430 [*McCabe*] to support their argument that information released to the media is judicially reviewable. In that case, Justice Danièle Tremblay-Lamer found that a recommendation by the National Parole Board was not a valid expression of their statutory power in the circumstances and that as a result, the Board acted beyond its jurisdiction in releasing its recommendation to the media. The Court granted the judicial review and ordered that the Board remove all copies of the recommendation from the Applicant's files and declared that the Board acted without jurisdiction in releasing the recommendation to the media.

[167] The present facts are analogous: the Minister acted without jurisdiction by implementing the Import Ban for an improper purpose. Thus, the statements released by the Minister and Health Canada conveying the information to the public, which also contained statements potentially harmful to Apotex, were invalid.

[168] The Minister and Health Canada acted without jurisdiction in releasing the statements to the media. Nothing in subsection 18.1(3) suggests that if a declaration of invalidity can be ordered, as in *McCabe*, that a declaration of invalidity and order for retraction of such a statement, made for an improper purpose and without procedural fairness, could not also be part of such a remedy.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The Minister's decision of September 30, 2014, made under the 2014 Terms and Conditions applied to Apotex's ELs, to issue an Import Ban on products manufactured, exported, distributed or sold from the APIPL and ARPL facilities to Apotex in Canada, is quashed;

2. The public statements issued by the Minister and her delegates at Health Canada on September 30, 2014, relating to the Import Ban on APIPL and ARPL products imported, distributed and sold by Apotex in Canada shall be retracted on terms to be agreed to by the parties. If no agreement as to form and content is reached, either of the parties may remit the matter back to me for further direction;

3. The Applicants' application is otherwise dismissed;

4. Costs to Apotex. Given the complexity of this matter, costs at the higher end of Column IV, Tariff B should be awarded.

"Michael D. Manson"

Judge

ANNEX A – EL ACTION

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

Part C, Division 1A, Establishment Licences	**Partie C, Titre 1A, Licence d'établissement**
Prohibition	*Interdiction*
C.01A.004. (1) Subject to subsection (2), no person shall, except in accordance with an establishment licence,	**C.01A.004.** (1) Sous réserve du paragraphe (2), il est interdit, sauf conformément à une licence d'établissement :
a) fabricate, package/label or import a drug;	a) de manufacturer, d'emballer-étiqueter et d'importer une drogue;
b) perform the tests, including examinations, required under Division 2;	b) d'effectuer les analyses, y compris les examens, exigées au titre 2;
c) distribute a drug as set out in section C.01A.003 that is not an active pharmaceutical ingredient; or	c) de distribuer à titre de distributeur visé à l'article C.01A.003 une drogue autre qu'un ingrédient actif pharmaceutique;
d) wholesale a drug that is not an active pharmaceutical ingredient.	d) de vendre en gros une drogue autre qu'un ingrédient actif pharmaceutique.
…	…
Application	*Demande*
C.01A.005. (1) A person who wishes to apply for an establishment licence shall submit an application to the Minister, in a form established by the Minister, that contains the following information and documents:	**C.01A.005.** Toute demande de licence d'établissement est présentée au ministre, en la forme établie par celui-ci, et contient les renseignements et documents suivants :
a) the applicant's name, address and telephone number, and their facsimile number and	a) les nom, adresse et numéro de téléphone du demandeur ainsi que, le cas échéant, son

electronic mail address, if any;

numéro de télécopieur et son adresse électronique;

b) the name and telephone number, and the facsimile number and electronic mail address, if any, of a person to contact in case of an emergency;

b) les nom et numéro de téléphone d'une personne qu'il est possible de joindre en cas d'urgence ainsi que, le cas échéant, son numéro de télécopieur et son adresse électronique;

c) each activity set out in Table I to section C.01A.008 for which the licence is requested;

c) chaque activité visée par la demande et figurant au tableau I de l'article C.01A.008;

d) each category of drugs set out in Table II to section C.01A.008 for which the licence is requested;

d) chaque catégorie de drogues visée par la demande et figurant au tableau II de l'article C.01A.008;

e) each dosage form class in respect of which the applicant proposes to carry out a licensed activity, and whether it will be in a sterile dosage form;

e) chaque classe de forme posologique à l'égard de laquelle le demandeur se propose d'exercer une activité visée par sa licence et une mention indiquant s'il s'agit d'une drogue sous forme posologique stérile;

f) whether the applicant proposes to carry out a licensed activity in respect of an active ingredient;

f) une mention indiquant si le demandeur se propose d'exercer une activité visée par sa licence à l'égard d'un ingrédient actif;

g) the address of each building in Canada in which the applicant proposes to fabricate, package/label, test as required under Division 2 or store drugs, specifying for each building the activities and the categories of drugs and, for each category, the dosage form classes, if any, and whether any drug will be in a sterile form;

g) l'adresse de chacun des bâtiments au Canada où le demandeur se propose de manufacturer, d'emballer-étiqueter, d'effectuer les analyses exigées au titre 2 ou d'entreposer des drogues, avec indication, pour chaque bâtiment, des activités et des catégories de drogues ainsi que, pour chaque catégorie de drogues, la classe de forme

	posologique, le cas échéant, et une mention indiquant s'il s'agit d'une drogue stérile;
h) the address of each building in Canada at which records will be maintained;	h) l'adresse de chacun des bâtiments au Canada où seront conservés les dossiers;
i) whether any building referred to in paragraphs (g) and (h) is a dwelling-house;	i) pour tout bâtiment visé aux alinéas g) ou h), une mention indiquant s'il s'agit d'une maison d'habitation;
j) the drug identification number, if any, or a name that clearly identifies the drug,	j) l'identification numérique, le cas échéant, ou le nom qui identifie clairement la drogue s'il s'agit :
(i) for each narcotic as defined in the Narcotic Control Regulations or each controlled drug as defined in subsection G.01.001(1) for which the licence is requested, and	(i) d'un stupéfiant au sens du Règlement sur les stupéfiants ou d'une drogue contrôlée au sens du paragraphe G.01.001(1) du présent règlement, pour lequel la licence est demandée,
(ii) for each other drug within a category of drugs for which the licence is requested, unless the licence is to perform tests required under Division 2, distribute as set out in paragraph C.01A.003(a), or wholesale;	(ii) de toute autre drogue d'une catégorie visée par la demande, à moins que la licence ne vise les analyses effectuées conformément au titre 2, la distribution à titre de distributeur visé à l'alinéa C.01A.003a) ou la vente en gros;
k) if any of the buildings referred to in paragraph (g) have been inspected under the Act or these Regulations, the date of the last inspection;	k) la date de la dernière inspection des bâtiments visés à l'alinéa g), le cas échéant, effectuée aux termes de la Loi ou du présent règlement;
l) evidence that the applicant's buildings, equipment and proposed practices and procedures meet the applicable requirements of Divisions 2 to	l) la preuve que les bâtiments, l'équipement et les méthodes et pratiques que le demandeur propose satisfont aux exigences applicables des titres

4;	2 à 4;
m) in the case of an importer of a drug that is fabricated, packaged/labelled or tested in an MRA country at a recognized building,	m) dans le cas de l'importateur d'une drogue qui, dans un pays participant, est manufacturée, emballée-étiquetée ou analysée dans un bâtiment reconnu :
(i) the name and address of each fabricator, packager/labeller and tester of the drug and the address of each building in which the drug is fabricated, packaged/labelled or tested, specifying for each building the activities and the categories of drugs and, for each category, the dosage form classes, if any, and whether any drug will be in a sterile form,	(i) les nom et adresse de chaque manufacturier, emballeur-étiqueteur et analyste ainsi que l'adresse de chaque bâtiment où la drogue est manufacturée, emballée-étiquetée ou analysée, avec indication, pour chaque bâtiment, de l'activité et de la catégorie de drogues ainsi que, pour chaque catégorie de drogues, la classe de forme posologique, le cas échéant, et une mention indiquant s'il s'agit d'une drogue stérile,
(ii) in respect of each activity done in an MRA country at a recognized building, the name of the regulatory authority that is designated under subsection C.01A.019(1) in respect of that activity for that drug and that has recognized that building as meeting its good manufacturing practices standards in respect of that activity for that drug, and	(ii) à l'égard de chaque activité qui, dans un pays participant, est effectuée dans un bâtiment reconnu, le nom de l'autorité réglementaire désignée aux termes du paragraphe C.01A.019(1) à l'égard de cette activité pour cette drogue, qui reconnaît ce bâtiment comme satisfaisant à ses normes de bonnes pratiques de fabrication qui ont trait à cette activité pour cette drogue,
(iii) in respect of any other activities,	(iii) à l'égard des autres activités, selon le cas :
A. a certificate from a Canadian inspector indicating that the fabricator's, packager/labeller's or tester's buildings, equipment, practices and procedures meet the	(A) le certificat d'un inspecteur canadien indiquant que les bâtiments, l'équipement et les méthodes et pratiques du manufacturier, de l'emballeur-étiqueteur ou de l'analyste

applicable requirements of Divisions 2 to 4, or

satisfont aux exigences applicables des titres 2 à 4,

B. other evidence establishing that the fabricator's, packager/labeller's or tester's buildings, equipment, practices and procedures meet the applicable requirements of Divisions 2 to 4;

(B) toute autre preuve établissant que les bâtiments, l'équipement et les méthodes et pratiques du manufacturier, de l'emballeur-étiqueteur ou de l'analyste satisfont aux exigences applicables des titres 2 à 4;

n) in the case of any other importer, the name and address of each fabricator, packager/labeller and tester of the drugs proposed to be imported and the address of each building in which the drugs will be fabricated, packaged/labelled and tested, specifying for each building the activities and the categories of drugs and, for each category, the dosage form classes, if any, and whether any drug will be in a sterile form; and

n) dans le cas de tout autre importateur, les nom et adresse du manufacturier, de l'emballeur-étiqueteur et de l'analyste de qui il se propose d'importer la drogue, l'adresse de chaque bâtiment où elle sera manufacturée, emballée-étiquetée et analysée, avec indication, pour chaque bâtiment, de l'activité et de la catégorie de drogues ainsi que, pour chaque catégorie de drogues, la classe de forme posologique, le cas échéant, et une mention indiquant s'il s'agit d'une drogue stérile;

o) in the case of an importer referred to in paragraph (n),

o) dans le cas de l'importateur visé à l'alinéa n), selon le cas :

(i) a certificate from a Canadian inspector indicating that the fabricator's, packager/labeller's and tester's buildings, equipment, practices and procedures meet the applicable requirements of Divisions 2 to 4, or

(i) le certificat d'un inspecteur canadien indiquant que les bâtiments, l'équipement et les méthodes et pratiques du manufacturier, de l'emballeur-étiqueteur et de l'analyste satisfont aux exigences applicables des titres 2 à 4,

(ii) other evidence establishing that the fabricator's, packager/labeller's and tester's buildings, equipment, practices and procedures meet the

(ii) une autre preuve établissant que les bâtiments, l'équipement et les méthodes et pratiques du manufacturier, de l'emballeur-étiqueteur et de

applicable requirements of Divisions 2 to 4.

l’analyste satisfont aux exigences applicables des titres 2 à 4.

C.01A.006. (1) A person who wishes to amend an establishment licence shall submit an application to the Minister, in a form established by the Minister, that contains the information and documents referred to in section C.01A.005 that relate to the amendment.

C.01A.006. (1) Toute demande de modification d’une licence d’établissement est présentée au ministre, en la forme établie par celui-ci, et contient les renseignements et documents visés à l’article C.01A.005 relativement à la modification demandée.

(2) An establishment licence must be amended where the licensee proposes

(2) Une licence d’établissement doit faire l’objet d’une modification lorsque le titulaire se propose:

a) to add an activity or category of drugs, as set out in the tables to section C.01A.008;

a) d’ajouter une ou plusieurs activités ou une catégorie de drogues visées aux tableaux de l’article C.01A.008;

b) in respect of a category of drugs and activity indicated in the licence, to authorize sterile dosage forms of the category;

b) à l’égard d’une catégorie de drogues et d’une activité visées par la licence, d’autoriser des formes posologiques stériles;

c) to add any building in Canada at which drugs are authorized to be fabricated, packaged/labelled, tested as required under Division 2 or stored, or to add, for an existing building, an authorization to fabricate, package/label, test or store a category of drugs, or sterile dosage forms of the category; and

c) d’ajouter un ou plusieurs bâtiments au Canada où il est autorisé de manufacturer, d’emballer-étiqueter, d’analyser conformément au titre 2 ou d’entreposer une drogue ou, pour un bâtiment existant, d’ajouter l’autorisation de manufacturer, d’emballer-étiqueter, d’analyser ou d’entreposer une catégorie de drogues ou des formes posologiques stériles de celle-ci;

d) in addition to the matters set out in paragraphs (a) to (c), in

d) dans le cas de tout importateur, en plus des

the case of an importer,	éléments visés aux alinéas a) à c) :
(i) to add a fabricator, packager/labeller or tester of a drug,	(i) d'ajouter le nom d'un manufacturier, emballeur-étiqueteur ou analyste,
(ii) to amend the name or address of a fabricator, packager/labeller or tester indicated in the licence, and	(ii) de modifier le nom ou l'adresse d'un manufacturier, emballeur-étiqueteur ou analyste indiqué dans la licence,
(iii) if the address of the buildings at which drugs are authorized to be fabricated, packaged/labelled or tested is indicated in the licence, to add additional buildings or, for an existing building, to add an authorization to fabricate, package/label or test a category of drugs, or sterile dosage forms of the category.	(iii) lorsque l'adresse des bâtiments où il est autorisé de manufacturer, d'emballer-étiqueter ou d'analyser une drogue est indiquée sur la licence, d'ajouter un ou plusieurs bâtiments ou, pour un bâtiment existant, d'ajouter l'autorisation de manufacturer, d'emballer-étiqueter ou d'analyser une catégorie de drogues ou des formes posologiques stériles de celle-ci.
C.01A.007. (1) The Minister may, on receipt of an application for an establishment licence, an amendment to an establishment licence or the review of an establishment licence, require the applicant to submit further details pertaining to the information contained in the application that are necessary to enable the Minister to make a decision.	**C.01A.007.** (1) Sur réception de la demande de licence d'établissement ou de modification ou d'examen d'une telle licence, le ministre peut, en vue de prendre une décision, exiger des précisions quant aux renseignements contenus dans la demande.
(2) When considering an application, the Minister may require that	(2) Au cours de l'examen d'une demande, le ministre peut exiger :
a) an inspection be made	a) qu'une inspection soit

during normal business hours of any building referred to in paragraph C.01A.005(1)(g) or (h); and

effectuée aux heures normales de bureau de tout bâtiment visé aux alinéas C.01A.005g) et h);

b) the applicant, if a fabricator, a packager/labeller, a person who performs tests required under Division 2, a distributor referred to in paragraph C.01A.003(b) or an importer, supply samples of any material to be used in the fabrication, packaging/labelling or testing of a drug.

b) que le demandeur, s'il s'agit du manufacturier, de l'emballeur-étiqueteur, de la personne qui effectue les analyses conformément au titre 2, du distributeur visé à l'alinéa C.01A.003b) ou de l'importateur, fournisse des échantillons de tout matériau servant à manufacturer, emballer-étiqueter ou analyser une drogue.

Issuance

Délivrance

C.01A.008. (1) Subject to section C.01A.010, the Minister shall, on receipt of the information and material required by sections C.01A.005 to C.01A.007, issue or amend an establishment licence.

C.01A.008. (1) Sous réserve de l'article C.01A.010, le ministre délivre ou modifie une licence d'établissement sur réception des renseignements et des matériaux visés aux articles C.01A.005 à C.01A.007.

(2) The establishment licence shall indicate

(2) La licence indique à la fois :

a) each activity that is authorized and the category of drugs for which each activity is authorized, as set out in the tables to this section, specifying for each activity and category whether sterile dosage forms are authorized;

a) chacune des activités autorisées et la catégorie de drogues pour chacune d'entre elles, selon les tableaux du présent article, en précisant pour chaque activité et catégorie de drogues, si des formes posologiques stériles sont autorisées;

b) the address of each building in Canada at which a category of drugs is authorized to be fabricated, packaged/labelled, tested as required under

b) l'adresse de chacun des bâtiments au Canada où il est autorisé de manufacturer, d'emballer-étiqueter, d'analyser conformément au

Division 2 or stored, specifying for each building which of those activities and for which category of drugs, and whether sterile dosage forms of the category are authorized; and

titre 2 et d'entreposer une catégorie de drogues en précisant, pour chacun d'eux, l'activité et la catégorie de drogues, et si des formes posologiques stériles sont autorisées;

c) in addition to the matters referred to in paragraphs (a) and (b), in the case of an importer,

c) dans le cas de tout importateur, en plus des indications visées aux alinéas a) et b) :

(i) the name and address of each fabricator, packager/labeller and tester from whom the importer is authorized to obtain the drug for import, and

(i) les nom et adresse de chaque manufacturier, emballeur-étiqueteur et analyste auprès de qui il est autorisé à obtenir la drogue pour l'importation,

(ii) the address of each building at which the drug is authorized to be fabricated, packaged/labelled or tested, specifying for each building the activities and the category of drugs that are authorized, and whether sterile dosage forms are authorized.

(ii) l'adresse de chaque bâtiment où est autorisé la manufacture, l'emballage-étiquetage ou l'analyse de la drogue avec indication, pour chacun d'eux, des activités et de la catégorie de drogues autorisées et si des formes posologiques stériles sont autorisées.

d) [Repealed, SOR/2002-368, s. 5]

d) [Abrogé, DORS/2002-368, art. 5]

(3) The Minister may indicate in an establishment licence a period for which records shall be retained under Division 2 that, based on the safety profile of the drug or materials, is sufficient to ensure the health of the consumer.

(3) Le ministre peut indiquer dans la licence d'établissement toute période pendant laquelle les dossiers doivent être conservés sous le régime du titre 2 et qui, selon le profil de sûreté de la drogue ou des matériaux, est suffisante pour assurer la protection du consommateur.

(4) The Minister may, in addition to the requirements of

(4) Le ministre peut, outre les exigences visées au paragraphe

subsection (2), set out in an establishment licence terms and conditions respecting

a) the tests to be performed in respect of a drug, and the equipment to be used, to ensure that the drug is not unsafe for use; and

b) any other matters necessary to prevent injury to the health of consumers, including conditions under which drugs are fabricated, packaged/labelled or tested.

(2), assortir la licence d'établissement de conditions portant sur :

a) les analyses à effectuer à l'égard de la drogue et l'équipement à utiliser afin que la drogue puisse être utilisée sans danger;

b) tout autre élément nécessaire pour prévenir le risque pour la santé des consommateurs, notamment la façon dont la drogue est manufacturée, emballée-étiquetée ou analysée.

TABLE I (Activities)

1. Fabricate

2. Package/label

3. Perform the tests, including any examinations, required under Division 2

4. Distribute as set out in paragraph C.01A.003(a) a drug that is not an active pharmaceutical ingredient

5. Distribute as set out in paragraph C.01A.003(b)

6. Import

7. Wholesale a drug that is not an active pharmaceutical ingredient

TABLEAU I (Activité)

1. Manufacturer

2. Emballer-étiqueter

3. Analyser, y compris examiner, conformément au titre 2

4. Distribuer à titre de distributeur visé à l'alinéa C.01A.003a) une drogue autre qu'un ingrédient actif pharmaceutique

5. Distribuer à titre de distributeur visé à l'alinéa C.01A.003b)

6. Importer

7. Vendre en gros une drogue autre qu'un ingrédient actif pharmaceutique

TABLE II (Categories of drugs)

1. Pharmaceuticals

TABLEAU II (Catégorie de drogues)

1. Produit pharmaceutique

1.1 Active ingredients	1.1 Ingrédient actif
2. Vaccines	2. Vaccin
3. [Repealed, SOR/2013-179, s. 2]	3. [Abrogé, DORS/2013-179, art. 2]
4. Drugs that are listed in Schedule D to the Act, other than vaccines	4. Drogue, autre qu'un vaccin, visée à l'annexe D de la Loi
5. Drugs listed in Schedule C to the Act	5. Drogue visée à l'annexe C de la Loi
6. Drugs that are prescription drugs, controlled drugs as defined in subsection G.01.001(1) and narcotics as defined in the Narcotic Control Regulations	6. Drogue qui est une drogue sur ordonnance, drogue contrôlée au sens du paragraphe G.01.001(1), et stupéfiant au sens du Règlement sur les stupéfiants
Annual Licence Review	*Examen annuel de la licence*
C.01A.009. (1) The holder of an establishment licence that is not suspended shall submit an application for the review of their licence to the Minister before April 1 of each year and include with it the information and documents referred to in section C.01A.005.	**C.01A.009**. (1) Le titulaire d'une licence d'établissement qui n'est pas suspendue doit, avant le 1er avril de chaque année, présenter au ministre la demande d'examen de sa licence accompagnée des renseignements et documents visés à l'article C.01A.005.
(2) The Minister shall conduct an annual review of the licence on the basis of the information and documents submitted by the holder and any other relevant information in the Minister's possession.	(2) Le ministre fait un examen annuel de la licence en se fondant sur les renseignements et documents fournis par le titulaire et sur toute autre information utile qu'il a en sa possession.
Refusal to Issue	*Refus*
C.01A.010. (1) The Minister may refuse to issue or amend an establishment licence in respect of any or all matters	**C.01A.010**. (1) Le ministre peut refuser de délivrer ou de modifier une licence d'établissement à l'égard de

indicated in subsection C.01A.008(2) if

toute indication visée au paragraphe C.01A.008(2) dans les cas suivants :

a. the applicant has made a false or misleading statement in relation to the application for the licence; or

a) le demandeur a fait une déclaration fausse ou trompeuse au sujet de sa demande de licence d'établissement;

b. the applicant has had an establishment licence suspended in respect of the matter.

b) sa licence d'établissement a été suspendue au même égard.

(2) The Minister shall refuse to issue or amend an establishment licence in respect of any or all matters indicated in subsection C.01A.008(2) if the Minister has reasonable grounds to believe that issuing or amending an establishment licence in respect of the matter would constitute a risk to the health of the consumer.

(2) Le ministre refuse de délivrer ou de modifier une licence d'établissement à l'égard de toute indication visée au paragraphe C.01A.008(2) s'il a des motifs raisonnables de croire que la délivrance ou la modification d'une telle licence constituerait un risque pour la santé des consommateurs.

(3) Where the Minister refuses to issue or amend an establishment licence, the Minister shall

(3) Lorsqu'il refuse de délivrer ou de modifier la licence d'établissement, le ministre :

a. notify the applicant in writing of the reasons for the refusal; and

a) en avise le demandeur par écrit, motifs à l'appui;

b. give the applicant an opportunity to be heard.

b) donne au demandeur la possibilité de se faire entendre.

Terms and Conditions

Conditions

C.01A.011. (1) Every person who holds an establishment licence shall comply with

C.01A.011. (1) Le titulaire d'une licence d'établissement est tenu de se conformer :

a. the requirements and the terms and conditions of the

a) aux conditions qui y sont

establishment licence; and

b. the applicable requirements of Divisions 2 to 4.

(2) [Repealed, SOR/2000-120, s. 4]

C.01A.012. (1) The Minister may amend the terms and conditions of an establishment licence if the Minister believes on reasonable grounds that an amendment is necessary to prevent injury to the health of the consumer.

(2) The Minister shall give at least 15 days notice in writing to the holder of the establishment licence of the proposed amendment, the reasons for the amendment and its effective date.

…

Suspension

C.01A.016. (1) Subject to subsection (3), the Minister may suspend an establishment licence in respect of any or all matters indicated in subsection C.01A.008(2) if the Minister has reasonable grounds to believe that

a) the licensee has contravened any provision of the Act or these Regulations; or

b) the licensee has made a false or misleading statement in the application for the

énoncées;

b) aux exigences applicables des titres 2 à 4.

(2) [Abrogé, DORS/2000-120, art. 4]

C.01A.012. (1) Le ministre peut modifier les conditions d'une licence d'établissement s'il a des motifs raisonnables de croire que la modification est nécessaire pour prévenir des risques pour la santé des consommateurs.

(2) Le ministre donne au titulaire de la licence d'établissement un préavis d'au moins 15 jours indiquant les motifs de la modification et sa date d'entrée en vigueur.

…

Suspension

C.01A.016. (1) Sous réserve du paragraphe (3), le ministre peut suspendre la licence d'établissement à l'égard de toute indication visée au paragraphe C.01A.008(2) lorsqu'il a des motifs raisonnables de croire que :

a) le titulaire de la licence d'établissement ne s'est pas conformé pas aux dispositions de la Loi ou du présent règlement;

b) il a fait une déclaration fausse ou trompeuse au sujet de sa demande de licence.

establishment licence.

(2) Before suspending an establishment licence, the Minister shall consider

(2) Avant de suspendre une licence d’établissement, le ministre prend en compte les faits suivants :

a) the licensee’s history of compliance with the Act and these Regulations; and

a) les antécédents du titulaire pour ce qui est de la conformité aux dispositions de la Loi ou du présent règlement;

b) the risk that allowing the licence to continue in force would constitute for the health of the consumer.

b) le risque que présenterait le maintien de la licence pour la santé des consommateurs.

(3) Subject to subsection C.01A.017(1), the Minister shall not suspend an establishment licence until

(3) Sous réserve du paragraphe C.01A.017(1), le ministre ne peut suspendre la licence d’établissement que si, à la fois :

a) an inspector has sent the licensee a written notice that sets out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;

a) l’inspecteur a envoyé au titulaire un avis écrit précisant les motifs de la suspension, et, le cas échéant, les mesures correctives qui s’imposent ainsi que le délai accordé pour les prendre;

b) if corrective action is required, the time set out in the notice has passed without the action having been taken; and

b) lorsque l’avis prévoit des mesures correctives, le titulaire ne les a pas prises dans le délai prévu;

c) the licensee has been given an opportunity to be heard in respect of the suspension.

c) le titulaire a eu la possibilité de se faire entendre à l’égard de la suspension.

C.01A.017. (1) The Minister may suspend an establishment licence without giving the licensee an opportunity to be heard if it is necessary to do so to prevent injury to the health of the consumer, by giving the licensee a notice in writing that

C.01A.017. (1) Le ministre peut, lorsque cela est nécessaire pour prévenir des risques pour la santé des consommateurs, suspendre la licence d’établissement sans que le titulaire ait la possibilité de se faire entendre, en lui

states the reason for the suspension.

(2) A licensee may request of the Minister, in writing, that the suspension be reconsidered.

(3) The Minister shall, within 45 days after the date of receiving the request, provide the licensee with the opportunity to be heard.

C.01A.018. The Minister may reinstate an establishment licence after it has been suspended.

Cancellation

C.01A.018.1 The Minister shall cancel an establishment licence in either of the following circumstances:

a) the licence has been suspended for a period of more than 12 months, or

b) the licence holder has failed to submit an application for the review of their licence in accordance with subsection C.01A.009(1).

faisant parvenir un avis motivé.

(2) Le titulaire d'une licence d'établissement peut demander, par écrit, au ministre que la suspension soit revisée.

(3) Le ministre doit, dans les 45 jours suivant la date de réception de la demande, donner au titulaire la possibilité de se faire

C.01A.018. Le ministre peut mettre fin à la suspension d'une licence d'établissement.

Annulation

C.01A.018.1 Le ministre annule une licence dans les circonstances suivantes :

a) la licence a été suspendue pour plus de douze mois;

b) le titulaire a omis de présenter une demande d'examen annuel de sa licence conformément au paragraphe C.01A.009(1).

ANNEX B – CBSA ACTION

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

PART A, Administration	**PARTIE A, Administration**
Importations	*Importations*
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.	**A.01.040.** Sous réserve de l'article A.01.044, il est interdit d'importer pour la vente des aliments ou des drogues dont la vente au Canada enfreindrait la Loi ou le présent règlement.
A.01.041. An inspector may examine and take samples of any food or drug sought to be imported into Canada.	**A.01.041.** L'inspecteur peut examiner et prélever des échantillons de tout aliment ou drogue destinés à être importés au Canada.
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 or drug or sample to an analyst for analysis or examination.	**A.01.042.** L'inspecteur peut référer à un analyste, pour examen, les échantillons des aliments ou drogues examinés ou prélevés en vertu de l'article A.01.041.
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.

Part C, Division 2, Good Manufacturing Practices	**Partie C, Division 2, Bonnes pratiques de fabrication**
Sale	*Vente*
C.02.003. No distributor referred to in paragraph C.01A.003(b) and no importer shall sell a drug unless it has been fabricated, packaged/labelled, tested and stored in accordance with the requirements of this Division.	**C.02.003.** Il est interdit au distributeur visé à l'alinéa C.01A.003b) et à l'importateur de vendre une drogue qui n'a pas été manufacturée, emballée-étiquetée, analysée et entreposée conformément aux exigences du présent titre.
C.02.003.1 No person shall sell a drug that they have fabricated, packaged/labelled, tested or stored unless they have fabricated, packaged/labelled, tested or stored it in accordance with the requirements of this Division.	**C.02.003.1** Il est interdit à la personne qui manufacture, emballe-étiquette, analyse ou entrepose une drogue de la vendre à moins d'avoir effectué l'activité conformément aux exigences du présent titre.
Use in Fabrication	*Utilisation pour la manufacture*
C.02.003.3 No person shall use an active ingredient in the fabrication of a drug unless it is fabricated, packaged/labelled, tested and stored in accordance with the requirements of this Division.	**C.02.003.3** Il est interdit d'utiliser dans la manufacture d'une drogue tout ingrédient actif qui n'a pas été manufacturé, emballé-étiqueté, analysé et entreposé conformément aux exigences du présent titre.

Food and Drugs Act *(RSC, 1985, c F-27)*

PART II	**PARTIE II**
ADMINISTRATION AND ENFORCEMENT	**ADMINISTRATION ET CONTRÔLE D'APPLICATION**
Inspection, Seizure and Forfeiture	**Inspection, saisie et confiscation**
Powers of inspectors	*Pouvoirs de l'inspecteur*
23. (1) Subject to subsection (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	23. (1) Sous réserve du paragraphe (1.1), l'inspecteur peut, à toute heure convenable, procéder à la visite de tout lieu où, à son avis, sont fabriqués, préparés, conservés, emballés ou emmagasinés des articles visés par la présente loi ou ses règlements. Il peut en outre :
(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) examiner ces articles et en prélever des échantillons, et examiner tout objet qui, à son avis, est utilisé — ou susceptible de l'être — pour la fabrication, la préparation, la conservation, l'emballage ou l'emmagasinage de semblables articles;
(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;	a.1) procéder à la visite de tout moyen de transport qui, à son avis, est utilisé pour le transport d'un article visé par l'article 6 ou 6.1, examiner l'article qui s'y trouve et en prélever des échantillons;
(b) open and examine any receptacle or package that the inspector believes on reasonable grounds contains any article to which this Act or	b) ouvrir tout contenant ou emballage qui, à son avis, contient un article visé par la présente loi ou ses règlements;

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	c) examiner tout livre, registre ou autre document trouvé sur les lieux qui, à son avis, contient des renseignements sur un article visé par la présente loi ou ses règlements, et en faire la reproduction totale ou partielle;
(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.	d) saisir et retenir aussi longtemps que nécessaire tout article qui, à son avis, a servi ou donné lieu à une infraction à la présente loi ou à ses règlements.
Definition of "article to which this Act or the regulations apply"	*Disposition interprétative*
(2) In subsection (1), "article to which this Act or the regulations apply" includes	(2) Pour l'application du paragraphe (1), sont compris parmi les articles visés par la présente loi ou ses règlements :
(a) any food, drug, cosmetic or device;	a) les aliments, drogues, cosmétiques ou instruments;
(b) anything used for the manufacture, preparation, preservation, packaging or storing thereof; and	b) les objets utilisés pour la fabrication, la préparation, la conservation, l'emballage ou l'emmagasinage des articles visés à l'alinéa a);
(c) any labelling or advertising material.	c) le matériel servant à l'étiquetage ou à la publicité.
Storage and removal	*Entreposage*
25. Any article seized under	25. Les articles saisis en

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.

application de la présente partie peuvent être entreposés sur les lieux par l'inspecteur; ils peuvent également, à son appréciation, être transférés dans un autre lieu.

Release of seized articles

26. 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.

Mainlevée de saisie

26. L'inspecteur, après avoir constaté que les dispositions de la présente loi et de ses règlements applicables à l'article qu'il a saisi en vertu de la présente partie ont été respectées, donne mainlevée de la saisie.

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.

Destruction sur consentement

27. (1) Le propriétaire ou le dernier possesseur de l'article saisi en application de la présente partie peut consentir à sa destruction. L'article est dès lors confisqué au profit de Sa Majesté et il peut en être disposé, notamment par destruction, conformément aux instructions du ministre ou du ministre de l'Agriculture et de l'Agroalimentaire.

Customs Act *(RSC, 1985, c 1 (2nd Supp))*

Detention of controlled goods

101. Goods that have been imported or are about to be exported may be detained by an officer until he is satisfied that the goods have been dealt with in accordance with this Act, and any other Act of

Rétention des marchandises contrôlées

101. L'agent peut retenir les marchandises importées ou en instance d'exportation jusqu'à ce qu'il constate qu'il a été procédé à leur égard conformément à la présente loi ou à toute autre loi fédérale

Parliament that prohibits, controls or regulates the importation or exportation of goods, and any regulations made thereunder.

prohibant, contrôlant ou réglementant les importations ou les exportations, ainsi qu'à leurs règlements d'application.

Limitation of action against officer or person assisting

Prescription : action contre l'agent ou la personne requise de l'assister

106. (1) No action or judicial proceeding shall be commenced against an officer for anything done in the performance of his duties under this or any other Act of Parliament or a person called on to assist an officer in the performance of such duties more than three months after the time when the cause of action or the subject-matter of the proceeding arose.

106. (1) Les actions contre l'agent, pour tout acte accompli dans l'exercice des fonctions que lui confère la présente loi ou toute autre loi fédérale, ou contre une personne requise de l'assister dans l'exercice de ces fonctions, se prescrivent par trois mois à compter du fait générateur du litige.

Limitation of action to recover goods

Prescription : action en recouvrement

(2) No action or judicial proceeding shall be commenced against the Crown, an officer or any person in possession of goods under the authority of an officer for the recovery of anything seized, detained or held in custody or safe-keeping under this Act more than three months after the later of

(2) Les actions en recouvrement de biens saisis, retenus ou placés sous garde ou en dépôt conformément à la présente loi, contre la Couronne, l'agent ou le détenteur de marchandises que l'agent lui a confiées, se prescrivent par trois mois à compter de celle des dates suivantes qui est postérieure à l'autre :

(a) the time when the cause of action or the subject-matter of the proceeding arose, and

a) la date du fait générateur du litige;

(b) the final determination of the outcome of any action or proceeding taken under this

b) la date du règlement définitif de toute instance introduite en vertu de la

Act in respect of the thing seized, detained or held in custody or safe-keeping.

présente loi au sujet des biens en cause.

Stay of action or judicial proceeding

(3) Where, in any action or judicial proceeding taken otherwise than under this Act, substantially the same facts are at issue as those that are at issue in an action or proceeding under this Act, the Minister may file a stay of proceedings with the body before whom that action or judicial proceeding is taken, and thereupon the proceedings before that body are stayed pending final determination of the outcome of the action or proceeding under this Act.

Suspension d'instance

(3) Lorsque dans deux actions distinctes, l'une intentée en vertu de la présente loi, l'autre non, des faits sensiblement identiques sont en cause, il y a suspension d'instance dans la seconde action, sur demande du ministre présentée à la juridiction saisie, jusqu'au règlement définitif de la première action.

FEDERAL COURT

SOLICITORS OF RECORD

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PLACE OF HEARING:	TORONTO, ONTARIO
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APPEARANCES:

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