Monday, October 25
11:00am-12:30pm

202 - Battening Down before the Storm Hits: Recall and Other Crisis Management

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Session 202

Faculty Biographies

Christine Carron

Christine Carron is a senior partner at Ogilvy Renault in Quebec and practices primarily in corporate and commercial litigation and in the areas of banking, privacy, product liability, consumer protection and e-commerce. She is chair of Ogilvy Renault's Privacy and Access to Information Team. She has been involved in a wide range of commercial litigation, including the defense of class actions in the financial services, retail and tobacco industries, and represents corporate clients in disputes involving damages for breach of commercial contracts or for latent defects and in shareholder disputes.

Ms. Carron also acts as defense counsel in major class actions. She has represented clients in parliamentary commissions on the adoption and amendment of Quebec's privacy legislation for the private sector and participated in the consultation process for Quebec's legislation on new technologies.

Chris Gidez

Chris Gidez is a senior vice president in Hill & Knowlton's Corporate Practice, and is U.S. Director of the firm's Risk Management and Crisis Communication Specialty Group. In addition, Mr. Gidez has considerable experience in litigation communications, media relations, international, energy and environmental issues and controversial political issues. Much of his time is spent working alongside political and legal counsel to assist clients in navigating complex and politically-sensitive situations. Mr. Gidez counsels a wide range of Fortune 500 companies, and has been involved in some of the most high-profile corporate crisis situations in recent years.

Mr. Gidez joined Hill & Knowlton after working with Texaco and, following its merger with Chevron, with one of the largest energy companies in the world, most recently as head of the company's corporate public relations department. During his tenure there he managed communications strategy during Texaco's merger with Chevron, and in the subsequent integration period. While at Texaco (and subsequently Chevron) Mr. Gidez managed the company's external, executive and internal communications functions, and served as the company's chief spokesperson. Previously, Mr. Gidez worked in Washington D.C., where he was an executive at Edelman
and Manning, Selvage & Lee, two communications consulting firms. Mr. Gidez began his career working as a press secretary for a member Congress.

Mr. Gidez has managed communications support for various types of litigation - including financial, employment, environmental and international. He has counseled senior executives on communications issues related to state and federal investigations, and class action lawsuits. He is a frequent speaker at conferences, and has been interviewed by Tier-1 media including CBS, CNN, BBC, PBS, CNBC, NPR and national newspapers and business publications.

Martha Healey

Martha Healey is a partner in the litigation group of Ogilvy Renault in Ottawa. She has expertise in federal and provincial regulatory matters, specifically in federally regulated matters including competition, health, agricultural and consumer products regulation, food, drug, cosmetic and consumer product recalls, transportation, privacy, records management and access to information. Ms. Healey advises clients regularly in the food, drug (human and veterinarian), medical device, natural health product, pesticide, animal feed, communications and other commercial sectors. Her practice includes telecommunications, transportation, life sciences and competition law (including mergers, marketing practices and advertising), as well as information and e-commerce regulation, and conflict of interest investigation.

Ms. Healey has appeared before the Federal Court, the Federal Court of Appeal, Ontario Superior Court of Justice, and the Ontario Court of Appeal. She has also appeared before and/or been involved in proceedings before federal and provincial tribunals, regulatory authorities and commissions including the Privacy Commissioner of Canada, the Information and Privacy Commissioners of Ontario and British Columbia, the Competition Tribunal, the Canadian Radio-television and Telecommunications Commission, the Canadian Transportation Agency, the Public Service Commission, and the Commission of Inquiry on the Blood System in Canada. Ms. Healey is also chair of Ogilvy Renault's Administrative Law and Judicial Review team.

Lynda Kuhn

Lynda Kuhn is senior vice-president, Communications for Maple Leaf Foods Inc. In this capacity, she has executive responsibility for the company's corporate communications, public relations, and investor relations activities. She joined the company as vice-president of Investor and Public Relations.

Prior to joining Maple Leaf, Ms. Kuhn managed a consulting practice specializing in crisis communications, branding, and change management. Prior to that, she was senior vice-president, Public Affairs at Philips Services Corporation, where she was employed for ten years. In this position, Ms. Kuhn was responsible for all aspects of corporate and employee communications, investor relations, marketing communications, change management, and crisis communications. She also previously worked as executive director of the Richmond County Industrial Commission in Nova Scotia for five years, and seven years working in native community development on a Miq'Maq reserve in Cape Breton, Nova Scotia. In these roles, Ms. Kuhn was extensively involved in community-based economic development, industrial promotion, government relations, and developing and implementing social and academic development programs.

She has traveled and volunteered in Kenya for many years, and recently founded a home in western Kenya that cares for children ages 3 to 17, whose families have been devastated by disease.

Teri Monti

Teri Monti is the director of employee relations at RBC Financial Group in Toronto, and is responsible for developing solutions to workplace issues and ensuring compliance with regulatory standards affecting RBC's workplaces globally. Specifically, Ms. Monti and her team develop and maintain RBC's workplace policies, including its employee code of conduct, advise RBC's managers in dealing with workplace issues and support RBC's businesses to meet regulatory requirements affecting their workplaces.

Before moving to employee relations, Ms. Monti was assistant general counsel in RBC's law group, responsible for litigation management.

She received a BA from Concordia University and is a graduate of Osgoode Hall Law School.

BATTENING DOWN BEFORE THE STORM HITS: RECALL AND OTHER CRISIS MANAGEMENT

Martha A. Healey
Ogilvy Renault LLP
Ottawa, Ontario, Canada
October 25, 2010

Even tigers sometimes take naps.

Chinese Proverb

WHAT LAW APPLIES IN CANADA?

Nature of Issue?	Applicable Law
Product hazard or technical breach or non-compliance (foods, drugs, cosmetics and other consumer products) **NOTE: Pending legislation: *Canada Consumer Product Safety Act***	*Food and Drugs Act* *Canadian Food Inspection Agency Act* *Canadian Environmental Protection Act, 1999* *Motor Vehicle Safety Act* *Food and Drug Regulations* *Cosmetic Regulations* *Natural Health Products Regulations* *Medical Devices Regulations* *Also other sector specific legislation
Theft or loss of personal information, security system breach	*Personal Information Protection and Electronic Documents Act* *Personal Information Protection Act* (British Columbia and Alberta) *Personal Information in the Privacy Sector* (Quebec) *Personal Health Information Protection Act* (Ontario) *Privacy Act* (Saskatchewan) *Also provincial personal health privacy legislation

RECALL / BREACH RESPONSE GUIDELINES

- Breach response plans now more critical than ever – for both privacy breaches and product safety/compliance issues.
- "Major event" plans are likely not sufficient.
- HR may need its own breach plan. HR issues must not get in the way of proper breach response protocol.
- Breach response plans must, at a minimum:
  - Identify trigger events, reporting protocol and communication strategy
  - Provide for escalation measures
  - Ability to protect against breach or respond substantively to a breach must be canvassed in advance – immediate, medium range and long-term "fixes" and containment measures should be identified in advance to the extent possible
  - Have senior management buy-in

Best Practices in Safeguarding Information in Outsourcing Relationships

- Written outsourcing agreement
- Outsourcing arrangements factored into organizational policies and procedures
- Oversight of any subcontracting ability and pre-approval of subcontractors
- Outsourcing agreement and execution of outsourced activities subject to oversight, monitoring, regular review, audit and revision if necessary
- Must identify protocol and procedures in the case of a crisis, recall or breach
- Training (internal and external)
- Notification process in the event of governmental investigation
- Continuous oversight by contracting party
- Disclosure of outsourcing arrangements in privacy policies/procedures

Developing a Corporate and Communications Response Plan

Identity theft has been called the crime of the 21st century, favored, according to law enforcement, for its low risks and high rewards. Not only do identity theft victims have to spend money out of pocket to clear up their records, but they also must devote their time - up to hundreds of hours in some cases – to doing so. In the meantime, victims may be unjustly harassed by debt collectors, denied credit or employment opportunities; they may lose their cars or their homes, or be repeatedly arrested for crimes they did not commit.

California Department of Consumer Affairs, Office of Privacy Protection, ***Recommended Practices on Notice of Security Breach Involving Personal Information****, February 2007*

Developing a Corporate and Communications Response Plan: The Obligation to Safeguard Information in Canada

Obligation under Canada's *Personal Information Protection and Electronic Documents Act*: Schedule 4.7 - Principle 7 – Safeguards

Personal information shall be protected by security safeguards appropriate to the sensitivity of the information.

4.7.1 – The security safeguards shall protect personal information against loss or theft, as well as unauthorized access, disclosure, copying, use, or modification. Organizations shall protect personal information regardless of the format in which it is held.

4.7.2 – The nature of the safeguards will vary depending on the sensitivity of the information that has been collected, the amount, distribution, and format of the information, and the method of storage. More sensitive information should be safeguarded by a higher level of protection.

Developing a Corporate and Communications Response Plan: The Obligation to Safeguard Information

4.7.3 – The methods of protection should include

(a) physical measures, for example, locked filing cabinets and restricted access to offices;

(b) organizational measures, for example, security clearances and limiting access on a "need-to-know basis"; and

(c) technological measures, for example, the use of passwords and encryption.

4.7.4 – Organizations shall make their employees aware of the importance of maintaining the confidentiality of personal information.

Developing a Corporate and Communications Response Plan: Before a breach occurs...

- Establish an incident response team, complete with members, contact information, reporting lines and responsibilities
- Privacy officer should **always** informed in case of privacy breach
- Ensure clear "chain of command" in cases of other crisis and issues (such as product safety and security issue)
- Timelines in breach response plan must be immediate – hours not days
- Ensure incident response team either includes or has access to senior management – access to key personnel and decision makers must be on a 24/7 basis
- Establish specific reporting forms that will govern in the event a breach occurs

Developing a Corporate and Communications Response Plan: Before a breach occurs...

- Predetermine "fixes" that will respond to possible breaches – flag files, further limit access, change codes, change account numbers, account "freeze", media lines
- Ensure immediate ability to contact relevant third parties – suppliers and customers (in case of a product recall)
- "Fixes" may be industry based
- Consider need to notify individuals/regulatory authorities/insurers
- Must have all relevant documents at hand (including insurance policy and key contracts)
- Consider scope of PR response – need for public communication? Qs/As to respond to media queries/internal communications strategy
- Consider all the measures that could be taken to reduce/minimize the impact of a privacy breach or product crisis

Developing a Corporate and Communications Response Plan: Response Plan Template

- Identifies Response Team with contact information
  - Business manager(s)
  - Privacy officer (in the context of a privacy breach)
  - Quality control personnel
  - Business sector personnel
  - Information systems personnel
  - Senior management
  - Public relations/Communications
  - Legal
  - Others?

Developing a Corporate and Communications Response Plan: Response Plan Template

- Identifies "trigger" events
- Identifies reporting protocols and timelines - who to notify (internally) and when
- Provides protocol for initial investigation and report
- Provides escalation measures in the event breach/crisis is confirmed and action required – both immediate and future
- Includes assessment of the nature of the breach (alleged or otherwise) to determine response protocol
- Assesses whether company has lost control of the information and tracks product
- Ensures impact on human safety is assessed immediately even in the absence of proven harm
- Canvasses ability to recover lost/stolen information
- Assesses ability to recall product (i.e. from the chain of distribution?)

Developing a Corporate and Communications Response Plan: Corporate Response Plan

- Limitation/containment measures – short/long-term
- Identifies any "immediate fixes" that must be put in place
- Identifies the need for any future action – system changes
- Considers external notification protocol – regulatory authority/individual
- Provides post-breach review procedure, including system/internal audits if necessary
- Includes communication strategy

Developing a Corporate and Communications Response Plan: Communications Response Plan

- Who should be notified and when?
- Internal communications plan
- Media Qs/As
- "Speaking voice" should already have been determined if possible
- Consider impact on customer service representatives/call centers
- Prepare scripts for public queries
- Press release?
- Press conference?
- Blame allocation of little value

Developing a Corporate and Communications Response Plan: If a breach occurs...

- Breach response plan activates immediately
- Immediate consideration of regulatory notification
- Immediate control and containment are critical
- "Triage" the incident – serious, straightforward, wide-spread, limited in scope
- Ensure **all** incidents are reviewed and investigated – even the most minor
- Ensure immediate containment measures are taken to reduce/limit the breach while investigation is pending
- In the absence of evidence, do not assume a narrow scope of information or products have been affected
- Try to limit possibility of "derivative" recalls or extended/expanding recalls (recent examples: Peanut Corp. of America, Red County Egg/ Hillandale Farms)

Developing a Corporate and Communications Response Plan: After the investigation is completed…

- Identify exactly how the breach occurred – investigation not final until the event chain is known
- What are the lessons learned?
- Does there need to be an apology?
- What are the repercussions?
- Amendments to policies, procedures, contracts, training?
- How could this have been prevented?

CASE STUDY 1: TJX

- December 18, 2006 TJX learned of suspicious software on part of its computer system and immediately initiated an investigation.
- In addition to data accessed concerning US customers (including credit card data), the drivers' license and other provincial identification numbers and names and addresses of approximately 330 individuals in Canada had been accessed – was information that had been provided in connection with unreceipted merchandise-return transactions at TJX stores in the US.
- Privacy Commissioner of Canada and Information and Privacy Commissioner of Alberta conducted a joint investigation into the breach.
- Other investigations conducted by FTC, group of US Attorneys General, the UK Information Commissioner and the Irish Data Protection Commissioner
- Personal information of an estimated 45 million payment cards in Canada, the US, Puerto Rico, the UK and Ireland had potentially been affected

CASE STUDY 1: TJX

- **FINDINGS:**
  - Payment card data, credit card numbers and expiry dates were necessary to the transaction and reasonable. The recording of the ID numbers (i.e. drivers' license) was excessive and contrary to PIPEDA/PIPA.
  - Information retained in contravention of PIPEDA / PIPA and TJX did not meet the safeguard provisions of either PIPEDA or PIPA.
  - Critical that organizations not only consider multiple layers of security but that they keep abreast of technological advances to ensure that security safeguards have not become outdated and easily defeated
  - Once in place, security measures must be actively monitored, audited, tested and updated whenever necessary.

CASE STUDY 1: TJX

- TJX had policies and procedures in place at the time of the breach. It had physical security; administrative measures (behavioural rules and enforcement, policies to restrict the amount and type of data and its retention time, "need-to-know" rules) and technical protection measures (such as encryption, remote access).
- TJX relied on a weak encryption protocol and failed to convert to a stronger encryption standard within a reasonable period of time.
- While TJX took the steps to implement a higher level of encryption, there is no indication that it segregated its data so that cardholder data could be held on a secure service while it undertook its conversion to new encryption technology.
- TJX proposed a reasonable alternative to collecting and retaining drivers' license information – creating a "hash value" through a cryptographic hashing function.

CASE STUDY 2: MONSTER WORLDWIDE, INC.

- In August, 2007, Monster discovered a server in the Ukraine that contained approximately 1.3 million job seekers. The information had been taken from a resume board sponsored by Monster.
- The data was not obtained as result of a security breach; rather, individuals were lured using "malicious tactics" to release or disclose account credentials.
- Even though the incident did not involved credit card, social security or other "sensitive information", Monster voluntarily decided to send notices to 30 million individuals notifying them of the incident. Monster also retained Kroll, a risk consulting company, to provide identity protection and restoration services for any affected individual.
- Highly proactive and detailed policies, procedures and action ensured swift response to consumer issue and facilitated regulatory response.

QUESTIONS?

Martha A. Healey
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Ottawa, Ontario

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Montreal, Quebec

Leadership in Difficult Times

Lynda Kuhn
Senior Vice President, Communications
October 2010

Canada's premier consumer packaged food company

- **Meat, meals and bakery** products
- **$5.2 billion** in sales and EBITDA of **$349 million** in 2009
- **#1 or #2** brands across the board
- **90 facilities** across Canada, USA and UK
- **23,500** dedicated people

What happened?

- **In August/08 Maple Leaf initiated the largest recall in the Company's history**
  - Three SKU's of deli products manufactured at our Bartor Road facility were found contaminated with *Listeria monocytogenes* and linked to illness and death
    - 22 deaths; 57 cases confirmed
  - Products were distributed primarily to health care facilities, where people have a higher risk for contracting listeriosis
  - To contain risk, a decision was made to close the plant and recall ALL products back to January/08
  - This involved a massive recall of 191 products, even though only a small number were affected

Background Information About *Listeria*

- **Six species – only *Listeria monocytogenes* causes human illness**
- **Can be found almost everywhere, including soil, water and foods**
  - Vegetables, fruits, unpasteurized dairy, shellfish and meat
- **1-10% of all ready-to-eat foods contain *Listeria monocytogenes***
  - It is readily destroyed through cooking
- **Listerioisis is the serious infection caused by eating food contaminated by *Listeria monocytogenes***
  - Listeriosis is extremely rare, affecting an average of 1-5 in 1 million people per year
  - Healthy adults and children are at extremely low risk
  - For the immune compromised, pregnant or infants, it can be serious or fatal

Bartor Road Recall Key Timelines and Actions - 2008

Aug. 23rd	Aug.-Sept.	Sept. 5th	Sept. 17th	Current
Match found to strain linked to illness and death. Recall voluntarily expanded (191 products)	Comprehensive investigation launched by MLF with panel of experts; deep sanitization of plant proceeds	Likely source of contamination identified; food safety enhancements implemented	Plant reopened and resumed production under enhanced protocols; positive findings on Oct 8th temporarily suspended distribution	All facilities operating under the highest food safety protocols in North America

Intense Media Coverage – August 2008

Nationwide outbreak spurs massive meat recall; Maple Leaf plant shut after bacterial illness kills one and sickens at least 16 others…*Globe And Mail*

Dozens more cases of the illness are suspected. The damage has been a body blow to Maple Leaf Foods … *Global News*

Killer bug tied to 7 deaths; 38 confirmed or suspected cases as outbreak ripples across province…*Toronto Sun*

Tests verify Maple Leaf meats' link to outbreak. Health, food agencies tie toxic strain to deaths…*Toronto Star*

Intense Media Spotlight

Media	First 10 days	First month
Print	408	1,011
Broadcast	1,959	3,198
Online	233	443

Surveys showed virtually 100% awareness among Canadians of listeriosis crisis

Introducing a New Risk

- While there have been 73 recalls in the US in the past 5 years for *Listeria monocytogenes*, and regular occurrences in Europe, this was a **new risk** introduced to Canadians
- Came at a time when consumers are increasingly concerned about the safety of the food supply
  - Melamine, Bisphenol A, acrylamides, *E. coli* outbreaks
- Maple Leaf had to take a leading role in educating the public

Our Response

Demonstrate the highest level of responsibility possible

- **Take accountability**
- **Put public health and consumer interests first**
- **Lead in open and fact based communication**
- **Implement decisive action plan**

Maple Leaf Values

Do What's Right
Be Performance Driven
Have A Bias For Action
Continuously Improve
Be Externally Focused
Dare To Be Transparent

Values Provide Compass

- Organizational values are clear and deeply entrenched across the organization.
  - Continuously communicated, part of employee orientation and development, integrated into performance reviews
- They provided a well defined "code of behaviour" which made it easier to make quick decisions that everyone supported.
  - ***Do what's right***: It was clear that putting consumers above financial interest was paramount
  - ***Dare to be transparent***: Drove us to be proactive and transparent with communications
  - ***Sharing, trusting and admitting mistakes:*** Required us to immediately and publicly accept responsibility

Take Accountability and Placing Consumers First

- Recognition from the outset that this tragedy was our doing and that we had to immediately take responsibility
  - Being accountable also placed responsibility on us to identify the problem, fix it and then change our food safety practices. This provided the basis for all communications
- Placing consumers and public interests first
  - Our decision to close the plant and recall all products was unprecedented and magnified financial impact, but reduced any potential future risk to the public

Lead in Transparent & Fact Based Communication

- **Communication Team**
  - Led by CEO and small group of staff and advisors
  - Did not over-think strategy, messages, or tactics
  - Lead with information the public wants and fill the void
- **Fact Focused**
  - Critical to quickly and accurately understand the facts to respond to consumer concerns and put risk in context
  - Identified internal and external resources to navigate through the science and provide independent, credible third part perspective

Public Outreach

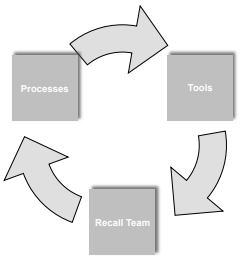
- **Employ a Variety of Mediums**
  - Media tours of plant (before and after outbreak)
  - Recalled product photos on website
  - Photos and footage of plant available on website
  - Five press conferences/news releases
  - Investor conference call
  - Full page ads in national newspapers
  - TV Ads – also used social media (YouTube)
  - Major expansion of consumer hotline response team
  - Food safety microsite developed on mapleleaf.com
  - Technical briefings for customer QA personnel and media
  - *Listeria* Fact Sheet and Food Safety Tips sent to dieticians across Canada; podcast on website
  - Media tour with regional nutritionists/medical experts

Internal Outreach

- Employee impact was significant
  - Shock, grief and remorse
- Fully accept gravity of situation; deliver continuous information to our people and encourage dialogue
  - 2-3 weekly email updates from CEO
  - Weekly all-employee conference calls at height of crisis
  - Ambassador program (Fact Sheets, Q&As and coupons for friends and family)
  - Conference calls for sales force – included presentation from expert on *Listeria* and food safety
  - Employee survey in late March reflects engagement increased to 96% percentile of leading global companies

Be Prepared

- Formalize institutional learning
- Crisis Preparedness Plan
  - Who is on the team?
  - Key contacts – internal, customers, suppliers, media, government
  - Template materials (letters, news release, Q&A, employee notice, customer communications)
- Levels of communication identified based on severity of situation
- Third party experts
- Annual crisis simulations



Implement Decisive Action Plan

- Immediately appointed a Recall Team and Project Manager with accountability for complex and multi-functional Recall Team activities
  - CEO, CFO, Executive business leaders, Communications, Regulatory, Government Relations, Sales, Microbiologists
  - Twice daily calls with all activities mapped and tracked daily
  - Everyone hears the same information at the same time; action items quickly addressed
  - Continuous reporting of test results at all packaged meat plants
  - Daily calls continue as best practice to maintain highest standard of food safety diligence
- Apply the same "crisis team" approach and discipline to other issues, like SARS and H1N1

Lessons Learned

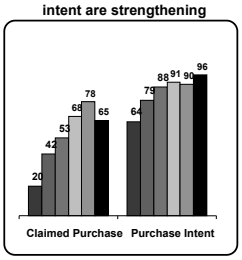
- **Power of having well entrenched values and code of behaviour**
  - Right decisions made quickly and unanimously
  - Employees are watching! Values consistency drove engagement
- **Acting in an ethical manner was instrumental to recovery**
  - Importance of accepting responsibility
  - Lead with the facts and be transparent
- **Have a well prepared crisis management plan in place, and practice it regularly**
- **Deliver on what you promise**
  - Settled class action suits quickly and fairly
  - Established role of Chief Food Safety Officer reporting to CEO to implement global best practices; Food Safety Advisory Council
  - Held first annual Food Safety Symposium with government, industry, customers, scientists
  - Investing in food safety education
  - Advocating for higher standards and sharing knowledge openly with industry

Lessons Learned

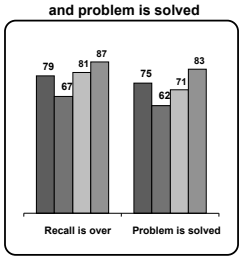
- **Immediacy of communications**
  - Press conferences in ASAP mode (Sat 10:00PM; Sunday afternoon, etc)
  - Don't over think things – get out with information when you have it
- **Ensure bilingual capabilities**
  - No readily accessible qualified internal French spokesperson weakened our response in Quebec
- **Leverage external experts**
  - Identify expert spokespeople in advance of a crisis if possible and ensure they are media trained
  - Build strong relationships with consultants who understand your business and can provide support in times of crisis
- **Maintain communications momentum post-crisis**
  - Once crisis is over, more caution and process takes over communication
  - Continue communications post-crisis to speed recovery

Regaining Consumer Confidence

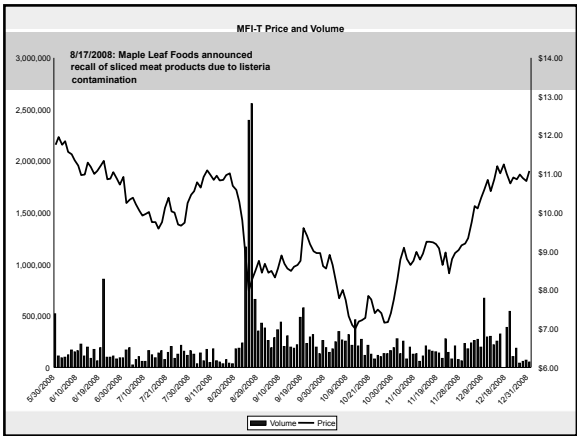
Claimed purchase and purchase intent are strengthening



Consumer Awareness of Recall over and problem is solved



Source: Hotspex Opinion tracker - Based on polling results of Maple Leaf brand users



The Path Forward

- Settled class action lawsuits quickly and fairly
  - Throughout the recall, position of insurers was that the Company needed to own the decisions
  - Viewed as one incident (lump sum payment), with claims consolidated into four provinces
  - $25MM settlement reached by early 2009
- Implemented a food safety program that is best practice in North America
  - Rigorous testing and environmental monitoring program
  - Appointed Dr. Randy Huffman as Chief Food Safety Officer
- Supporting public education on food-borne pathogens & food safety
- Advocating for consistent higher standards across the industry

Summary

- Public face of CEO is critical to accept accountability and maintain public trust
- Actions and communications must be based on strong values – transparent, fact based and proactive
- Be prepared for a crisis, with clear process and responsibilities
- Moving from crisis to leadership in global food safety

Battening Down before the Storm Hits: Recall and Other Crisis Management

RBC's Experience

ACC Meeting

October 2010

Background

RBC and Canadian Banking System

- RBC is Canada's largest financial institution, among top 20 world-wide
- Over 18 million clients worldwide, over half in Canada
- Canadian banking industry is highly regulated and centralized - 6 large Canadian banks
- Uses a centralized national clearing system

May 31-June 7, 2004 – The Disruption

- RBC's technology group discovered an error that affected one day's processing/clearing
- System requirements do not permit backdating by more than one day
- Clearing system requires orderly processing of transactions (ie, deposits before withdrawals)
- Fix required temporary system shut downs, processing recovery took a week (June 7)
- During that period, all RBC clients who had pending transactions were at least one day behind
- Domino effect – impact on other Canadian FI clients who had transactions with RBC

The Crisis

- Millions of Canadian banking transactions affected
- National "front page" press and media attention
- Regulatory scrutiny
- Regional class action, potential for national class action

The Outcome

- Maintained reputation as Canada's premier financial institution
- Sustained negligible client loss and minimal revenue loss
- Paid out less than $2,000,000 in informal claims process
- Settled the only litigation brought against RBC (class action in Quebec) for less than $100,000
- Closed regulatory investigation with satisfactory outcome

How we got there

- Well laid crisis management foundation
- Solid teamwork to identify and resolve issues
- Prompt, proactive and transparent communication with all stakeholders (Board, regulators, competition, clients, employees and general public)
- Accountability
- Rigorous follow through
- Lessons learned – post mortem analysis

Crisis management foundation

- Business Continuity Plans/Crisis Management Practices
  - High level, well tested plans to deal with local, national and global contingencies
  - Enterprise business continuity management team comprised of senior business and functional decision-makers
  - Enterprise crisis management team comprised of business representatives and functional advisors
  - Established roles and accountabilities
- Clearly understood corporate values
  - Set standard for corporate behaviour
- Corporate practice of principled decision-making
  - Basic principles formulated at outset
  - Set priorities
    - Maintain service
    - Communicate transparently and frequently
    - Make it right for all affected parties

Team

Solid teamwork to identify and resolve issues

- Business and key functional representatives
- Clearly understood roles and responsibilities
- Project management approach
- Issue management including accountability
- Escalation processes

Communication

Prompt, proactive and transparent communication with all stakeholders:

- Emergency Board meeting, regular updates
- Proactive contact with regulators
- Daily calls with competitors, clients, suppliers
- Press releases, advertisements, interviews
- Website updates
- Front line staff training

Client messages:

- Your money is safe
- You won't be charged
- You have access to cash

Accountability

Accountability:

- Sincere and timely apology
- Commitment to "make it right"
  - Both from CEO
  - In national press
- Actions as well as words
  - Indemnities
  - Refunds/reversals
  - Claims process

Legal issues

Help achieve business priorities (maintain service, communicate transparently and frequently, make it right for all affected parties) while managing:

- Regulatory interest
  - Internal investigation
- Clearing and processing requirements (ie, the competition)
  - Indemnities
  - Automatic refunds/reversals
- Claims for damages
  - Interest credits/reversals
  - Claims process
  - Indemnities

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Claims process

Options:

1. **Wait for litigation/class action**
- Finality
- Cost
- Timing
- Bad client/public relations – previous negative experience
- Breach of commitment to "make it right"

2. **Pay claims informally**
- Risk/liability – litigation/class action in any event
- Ability to control process and communication
- Quantum unknown
- Living up to our commitment

55

Claims process

- Communicated June 18 (10 days post disruption) via
  - National press advertisements
  - Public website
  - Print material in branches
- Process:
  - RBC client claims for monetary loss up to $100 to branches
    - Authorized to pay them
    - Automated record-keeping process
  - RBC client claims over $100 and all non-RBC client claims to claims administrator
    - Set adjudication parameters for administrator for monetary loss claims under $5,000
    - Claims over $5,000 and/or claims for non-monetary losses adjudicated by internal claims committee with representation from business, risk management and law department

Claims process

Claims adjudication

- Approached as class action claims process
- Developed parameters/grids for claims consideration – same parameters used by branch staff and external claims administrator
- Undertook to decide claims within 40 days of receipt
- Limited time for claim – claimants given 3 months to provide claim and supporting material (though late claims considered)
- Proceeded with claims process notwithstanding class action brought in Quebec before process launched

Claims appeal process

Appeal process

- Appeal from partial or full decline of claim
- To RBC Ombudsman or to any one of an RBC-selected panel of arbitrators (well-known private arbitrators, retired judges, etc)
- RBC did not participate in appeal process – decisions made on basis of claimant's submission only

Battening Down before the Storm Hits: Managing Recalls & Other Crises

Chris Gidez
Senior Vice President
U.S. Director – Risk Management & Crisis Communications

Association of Corporate Counsel
Annual Meeting: October 24 – 27, 2010

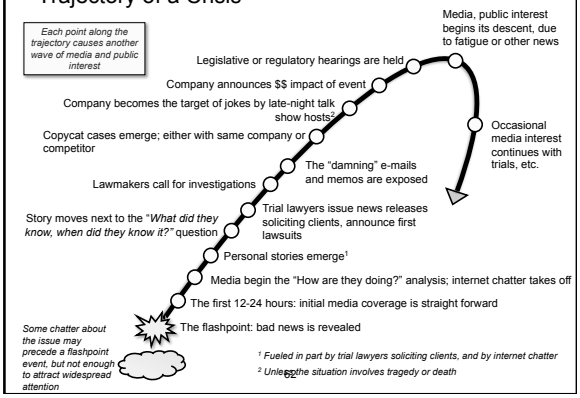
Agenda

- What makes a crisis? Common combustion points
- The trajectory of a crisis
- Navigating the crisis landscape
- Common traps/Essential truths
- Crisis avoidance and survival

Combustion Points

- Spontaneous combustion is rare – there needs to be fuel, someone to light the match, and someone to keep adding fuel to the fire
- Scale
- Clearly defined and measureable risk
- A sympathetic or vulnerable set of victims – children, elderly, the infirm, and animals
- Topicality/Patterns
- Timing
- Compelling images
- Hypocrisy
- Irony
- Deceit
- Engaged web community
- Bad Crisis Management

Trajectory of a Crisis



Navigating the Crisis Landscape

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1. Managing expectations of what communications can do.

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2. The compression of time.

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8. Transparency – like beauty – is in the eye of the beholder.
9. The "*Google Effect*" – What you say or do never goes away.

Google

YAHOO!

YouTube

Common Traps/Essential Truths

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3. Balkanization.
4. When is it too soon/too late to raise your hand?
5. Social media is an early indicator of a problem.
6. "It's a compliance issue, not a safety issue."

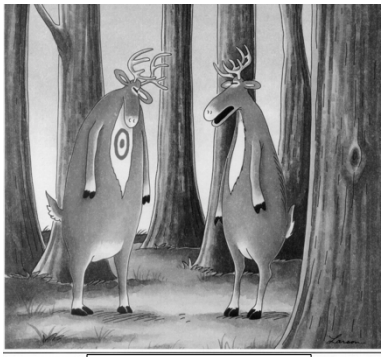
Keys to Success

1. ***Regain Control of the Agenda!!!!!***
2. PR alone cannot solve a crisis; there must be a business fix, with credible communications.
3. Senior leadership must play a role in crisis management.
4. Build goodwill and relationships in advance.
5. Watch the radar (internal and external), stay alert and beware of the shifting sands.
6. Communications cannot be the back-end of the equation.

Keys to Success

7. Values-based messaging is critical; so is clarity and consistency of message.
8. If you can't talk about the solution, talk about the path to the solution.
9. Understand your adversaries.
10. Have mechanisms to measure stakeholder awareness and attitude.
11. If the crisis is prolonged, compartmentalize management of it to prevent distraction.
12. Don't lose focus once the acute phase is over.

Gary Larson Understood "*Crisis*"



"Bummer of a birthmark, Hal."

BATTENING DOWN BEFORE THE STORM HITS:
RECALL AND OTHER CRISIS MANAGEMENT

BREACH REPORTING REQUIREMENTS IN CANADA

Martha A. Healey

Ogilvy Renault LLP

October 2010

BATTENING DOWN BEFORE THE STORM HITS:

RECALL AND OTHER CRISIS MANAGEMENT

INTRODUCTION

When a concern arises relating to the safety of consumer products sold in Canada (including foods, drugs, cosmetics, and other consumer products) or the security of personal information, several key issues arise; namely how to deal with the crisis or issue from a consumer, public relations and legal perspective (including, whether that issue must be reported to regulators by the manufacturer, retailer, importer, distributor or custodian of the information) and, very importantly, the refinement and changes that must be made to information management, manufacturing and/or distribution practices once the crisis has been resolved.

This paper briefly considers Canadian reporting requirements in the context of both data security breaches and in the context of a consumer product problem or recall.

I CANADIAN REPORTING REQUIREMENTS

A. FOOD

Food safety and food recalls in Canada are governed by the federal *Food and Drugs Act* ("FDA"), *Food and Drug Regulations* ("FDR") and *Canadian Food Inspection Agency Act* ("CFIA Act").

(i) Reporting Requirements

The FDA and the FDR establish comprehensive safety standards and mandatory testing, labeling, and packaging requirements for food products. However, there are no statutory obligations on a food manufacturer, importer or distributor to report a food safety incident or safety issue under the FDA, FDR, CFIA Act or otherwise. However, depending on the severity of a particular safety issue, a stakeholder may proactively and voluntarily report safety issues to the Canadian Food Inspection Agency ("CFIA").

(ii) Recall Requirements

It is an offence, punishable by fine or imprisonment or both, to contravene any provision of the FDA or FDR.[1] Section 4 of the FDA provides:

> 4. No person shall sell an article of food that
>
> (a) has in or on it any poisonous or harmful substance;
>
> (b) is unfit for human consumption;
>
> (c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;

[1] FDA at section 31.1.

> (d) is adulterated; or
>
> (e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

Thus, the sale of an unsafe food product is a contravention of the FDA, which effectively imposes an obligation on food manufacturers, importers, distributors and retailers to remove unsafe products from the marketplace when a safety issue becomes known.

The CFIA Act bestows recall powers upon the CFIA in respect of food. Subsection 19(1) provides that the Minister of Agriculture may order a food recall where he or she has reasonable grounds to believe that the food product "poses a risk to public, animal or plant health." Specifically, subsection 19(1) of the CFIA Act provides:

> 19. (1) Where the Minister believes on reasonable grounds that a product regulated under an Act or provision that the Agency enforces or administers by virtue of section 11 poses a risk to public, animal or plant health, the Minister may, by notice served on any person selling, marketing or distributing the product, order that the product be recalled or sent to a place designated by the Minister.

Any person who contravenes a recall order referred to in subsection 19(1) is guilty of an offence and liable on summary conviction to a fine not exceeding $50,000 or to a term of imprisonment not exceeding six months or to both.[2]

The statutory framework governing food products also provides government inspectors with broad investigative powers, including the power to request information. Section 23 of the FDA allows government food inspectors to enter any place where an inspector has reasonable grounds to believe food products are manufactured, prepared, preserved, packaged or stored, and to examine and take samples or copies of the products, books, documents or records found on the premises.[3] During an investigation, the owner, manager and any employees on-site must "give the inspector all reasonable assistance and furnish the inspector with any information he may reasonably require".[4]

To help manufacturers maintain compliance with the FDA during a food safety incident, the CFIA has developed a manufacturer's guide entitled *Food Recall: Make a Plan and Action It!*[5] (the "Manufacturer's Guide"). The Manufacturer's Guide indicates that manufacturers must recall all unsafe or food products otherwise in violation of applicable legislation that have entered the market. Should a manufacturer choose not to recall the product, the Minister of Agriculture may order the manufacturer to do so (as noted above). Although the Manufacturer's Guide is not legally binding, its suggested framework for developing an effective recall plan is nonetheless useful insofar as it is likely to ensure a manufacturer maintains compliance with the

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[2] CFIA Act at subsection 19(2).

[3] FDA at subsection 23(1)(a)-(d).

[4] FDA at subsection 23(3).

[5] *Food Recalls: Make a Plan and Action It! Manufacturers' Guide* is available online at: <http://www.inspection.gc.ca/english/fssa/recarapp/rap/mgguide.shtml>

FDA and FDR. Similar guides are available from CFIA for food distributors, importers and retailers.[6]

B. DRUGS

In Canada, the legislative requirements for the post approval surveillance of drugs (and other health products) are regulated by the FDA and FDR. Health Canada has also established a number of policy documents in connection with reporting and recall obligations for drug products, the details of which are described below.

(i) Reporting Requirements

Under the FDR, drug manufacturers, licensees, distributors, fabricators and importers have various reporting requirements, depending on the type of drug and the particular drug at issue.

Adverse Drug Reaction Reporting

A "manufacturer"[7] must notify the Assistant Deputy Minister, Health Products and Food Branch, of the Department of Health (hereinafter "Health Canada") of any "serious adverse drug reaction" or "serious unexpected adverse drug reaction" that has occurred in Canada by submitting a report to Health Canada within 15 days of becoming aware of the reaction.[8] A serious unexpected adverse drug reaction that has occurred *outside of Canada* must also be reported to Health Canada within 15 days of becoming aware of the reaction. The report must contain all information known to the manufacturer with respect to the adverse reaction.

The FDRs define an "adverse drug reaction" as follows:

> a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function[9]

A "serious adverse drug reaction" is a noxious and unintended response to a drug that occurs at any dose, that requires or prolongs in-patient hospitalization, and causes or results in any one of the following ailments:

- congenital malformation;
- persistent or significant disability;
- persistent or significant incapacity;

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[6] See *Food Recalls: Make a Plan and Action It! Distributors' Guide*, *Food Recalls: Make a Plan and Action It! Importers' Guide*, and *Food Recalls: Make a Plan and Action It! Retailers' Guide*, respectively, also available online on CFIA's website at: <http://www.inspection.gc.ca/english/fssa/recarapp/recarappe.shtml>.

[7] "Manufacturer" or "distributor" is defined in the FDR at A.01.010 as "a person, including an association or partnership, who under their own name, or under a trade-, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug".

[8] FDR at C.01.016.(1).

[9] FDR at C.01.001.(1).

- life-threatening reaction; or
- death.[10]

A "serious unexpected adverse drug reaction" is a serious adverse drug reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the drug.[11]

If, after reviewing any of these reports and other available safety data, Health Canada remains concerned about the safety of a drug, the manufacturer may be requested to submit case reports of all adverse and serious adverse reactions to that drug that are known to the manufacturer. A case report is more detailed than a standard adverse drug reaction report, and must contain a "detailed record of all relevant data associated with the use of a drug in a subject."[12] In addition to case reports, Health Canada may require the manufacturer to submit a summary report, which details all adverse, serious adverse, and serious unexpected adverse reaction reports submitted by the manufacturer to Health Canada during the preceding twelve months.[13] Case reports and summary reports must be submitted within 30 days of the manufacturer receiving a Health Canada request for such report(s).[14]

Additional reporting requirements are prescribed by the FDR in the context of new drugs.[15] Where a notice of compliance has been issued in respect of a new drug submission or abbreviated new drug submission (or a supplement to either), the manufacturer is required to establish and maintain records, in a manner that enables an audit to be made, respecting:

(a) animal or clinical experience, studies, investigations and tests conducted by the manufacturer or reported to him by any person concerning that new drug;

(b) reports from the scientific literature or the bibliography therefrom that are available to him concerning that new drug;

(c) experience, investigations, studies and tests involving the chemical or physical properties or any other properties of that new drug;

(d) any substitution of another substance for that new drug or any mixing of another substance with that new drug;

(e) any error in the labelling of that new drug or in the use of the labels designed for that new drug;

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[10] FDR at C.01.001.(1).

[11] FDR at C.01.001.(1).

[12] FDR at C.01.001.(1).

[13] FDR at C.01.016.(3).

[14] FDR at C.01.016.(4).

[15] A new drug is a drug that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish the safety and effectiveness of that substance for use as a drug; FDR at C.08.001.

(f) any bacteriological or any significant chemical or physical or other change or deterioration in any lot of that new drug;

(g) any failure of one or more distributed lots of the new drug to meet the specifications established for that new drug in the submission or supplement; and

(h) any unusual failure in efficacy of that new drug.[16]

Prior to the sale of that new drug, the manufacturer must, with respect to all the manufacturer's previous sales of that new drug, furnish to the Minister of Health:

- on *request*, reports of all records respecting the information described in paragraphs C.08.007(a) to (c) of the FDR – as described in paragraphs (a) to (c) immediately above;
- immediately on receipt by the manufacturer, reports of all records respecting the information described in paragraphs C.08.007(d) to (f) of the FDR – as described in paragraphs (d) to (f) immediately above; and
- within 15 days after the receipt by the manufacturer of information referred to in paragraphs C.08.007(g) and (h) of the FDR (as described in paragraphs (g) and (h) immediately above), a report on the information received.[17]

Annual Adverse Drug Reaction Reporting

The FDR requires that a manufacturer conduct a "concise, critical analysis of the adverse drug reactions and serious adverse drug reactions" in connection with any of its manufactured drugs during the previous year, and to prepare a summary report of all reports submitted by the manufacturer to Health Canada in the preceding twelve months.[18] The summary report must be prepared on an annual basis (or at any other time interval as requested by Health Canada). There is no obligation on a manufacturer to submit the annual summary report to Health Canada, as subsection C.01.016(2) of the FDR only requires that it be prepared. Nonetheless, as noted above, Health Canada may request a copy of any summary report where there is a continuing concern about the safety of the drug. When requested, summary reports must be submitted to Health Canada within 30 days.[19]

Recall Reporting

Recall reporting requirements apply to manufacturers and importers who sell drugs in Canada in dosage form. If a manufacturer or an importer commences a recall of a drug, the manufacturer or importer must notify Health Canada and submit "forthwith" all of the information specified in subsection C.01.051, including:

[16] FDR at C.08.007.

[17] FDR at C.08.008(a) – (c).

[18] FDR at C.01.016.(2).

[19] FDR at C.01.016.(4).

- the proper name of the drug, the common name of the drug if there is no proper name, the brand name of the drug and the lot number;
- in the case of an imported drug, the names of the manufacturer and importer;
- the quantity of the drug manufactured or imported;
- the quantity of the drug distributed;
- the quantity of the drug remaining on the premises of the manufacturer or importer;
- the reasons for initiating the recall; and
- a description of any other action taken by the manufacturer or importer with respect to the recall.[20]

According to Health Canada's Policy-0016, *Health Products and Food Branch Inspectorate - Recall Policy* (May 18, 2006) (the "Recall Policy"),[21] Health Canada has interpreted the requirement that it be notified "forthwith" as meaning that a manufacturer or importer must notify Health Canada within 24 hours of the decision to recall. The notice may be made in writing or verbally, but must be followed by a written report within three (3) business days of initiating the action and must contain "sufficient information to enable Health Canada to assess the risk to health".[22]

Reporting Requirements Upon Health Canada Request

Health Canada may also require a manufacturer to submit evidence with respect to a drug for Health Canada's review.[23] The evidence must be provided on or before a day specified by Health Canada, and should be sufficient to "establish the safety of the drug under the conditions of use recommended and the effectiveness of the drug for the purposes recommended".[24]

The manufacturer may not make any further sales of the drug until it has submitted the evidence requested by Health Canada.[25] If the evidence submitted is insufficient, Health Canada must notify the manufacturer, and where the manufacturer received such notification, the manufacturer must cease sales until additional evidence is submitted and Health Canada notifies it in writing that the evidence is sufficient.[26]

(ii) Recall Requirements

[20] FDR at C.01.051(a) – (g).

[21] Available at: <http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_recall_policy-politique_retrait_ltr-doc-eng.php>.

[22] Recall Policy at section 6.1, Responsible Parties.

[23] FDR at C.01.013.(1).

[24] FDR at C.01.013.(4).

[25] FDR at C.01.013.(1).

[26] FDR at. C.01.013.(2) and (3)

Applicable legislation does not bestow any clear authority or power on the Minister of Health to order a drug recall or market withdrawal. However, Sections 8 and 9 of the FDA provide as follows:

> 8. No person shall sell any drug that
>
> (*a*) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions; or
>
> (*b*) is adulterated.
>
> 9. (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Accordingly, there is nonetheless a positive obligation on manufacturers to remove unsafe drug products from the marketplace. The Minister of Health, through Health Canada, is well known to attempt to influence the behaviour of drug manufacturers where a marketed drug is believed to be unsafe. For example, Health Canada is known to often threaten to issue press releases, initiate investigations and/or initiate prosecution proceedings under sections 8 and 9 of the FDA, etc., where a manufacturer is not willing to cooperate (i.e. recall the product) where a safety issue is believed to exist.

Any person that contravenes a provision of the FDA or FDR is liable on summary conviction to a fine of $500 (or $1,000 for repeat offenders) or to a term of imprisonment for 6 months or both. An offender may also be liable on conviction on indictment to a fine of $5,000 or to a term of imprisonment for 3 years or to both.[27]

Additionally, section C.02.012 of the FDR requires every fabricator, packager, labeller, and distributor referred to in section C.01A.003[28], and every importer and wholesaler of a drug, to maintain a system of control that would permit a complete and rapid recall of any unsafe lot or batch of drugs on the market. Further, section C.02.022 specifically requires the above-mentioned fabricators, packagers, labellers, distributors, importers and wholesalers to retain records of the sale of each lot or batch of drugs for a period of at least one year after the expiration date of the lot or batch, for the purpose of facilitating any necessary recalls.

Health Canada's Recall Policy sets out further guidance on drug recalls and recall procedures. A "recall" is defined in the Recall Policy as follows:

> Recall: With respect to a health product, other than a medical device, means a responsible party's removal from further sale or use, or correction, of a distributed product that presents a risk to the health of

[27] FDA at section 31.

[28] Subsection C.01A.003 of the FDR refers to the following distributors: (a) a distributor of a drug listed in Schedule C or D to the FDA or in Schedule F to the FDR, a controlled drug as defined in subsection G.01.001(1) or a narcotic as defined in the *Narcotic Control Regulations*, who does not hold the drug identification number ("DIN") for the drug or narcotic; and (b) a distributor of a drug for which that distributor holds the DIN.

> consumers or violates legislation administered by the Health Products and Food Branch.[29]

The definition of "recall" does not include a "product withdrawal" or a "stock recovery". A "product withdrawal" refers to the "…removal from further sale or use, or correction of a distributed product where there is no health and safety risk and no contravention of the legislation…". A "stock recovery" means the "…removal or correction of a product that has not been distributed or that has not left the direct control of the responsible party".[30]

The Recall Policy also sets out the health hazard evaluation and recall classification criteria used by Health Canada. In the event of a safety or health issue with a particular drug, Health Canada will assess the degree of seriousness of the health hazard to which the relevant population at risk would be exposed. Correspondingly, Health Canada will assign a numerical designation, namely Type I, II or III, to a particular drug product to indicate the relative degree of health hazard presented by the drug, as follows:

> Type I**:** a situation in which there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death,
>
> Type II**:** a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote, or
>
> Type III**:** a situation in which the use of, or exposure to, a product is not likely to cause any adverse health consequences.[31]

Type I and II include situations where a product (which does not have generally recognized or scientifically supported therapeutic value) is promoted in such a way that avoidance of recognized therapy occurs and where such avoidance could lead to injury or death.

The criteria used by Health Canada in conducting a health hazard evaluation (and ultimately in determining the appropriate scope of a recall) include whether any disease or injuries have already occurred from the use of the product, whether particular population segments (i.e. children, surgical patients, etc.) who are expected to be exposed to the product are at particular risk, the degree of seriousness of the health hazard, the likelihood of occurrence of the hazard and the potential consequences of the hazard.

C. MEDICAL DEVICES

Reporting requirements and recall obligations in respect of medical devices are set out in the FDA and the *Medical Devices Regulations* (the "MD Regulations"), which were promulgated under the FDA.

[29] Recall Policy at section 4.0 Definitions.

[30] Ibid.

[31] Ibid.

(i) Reporting Requirements

Reporting requirements related to the safety of medical devices are found in the MD Regulations. As noted above, it is an offence to contravene any of the provisions of the FDA or any of the regulations thereto, including the MD Regulations.

Mandatory Problem Procedure and Reporting Requirements

Sections 59 to 62 of the MD Regulations set out the legislative scheme for medical device mandatory problem reporting.

Manufacturers and importers of medical devices must each make a preliminary and final report to the Minister of Health (hereinafter also referred to as "Health Canada") detailing any incident involving a medical device sold in Canada where the incident has led to death, a serious deterioration of health of a patient, user or other person, or would result in one of such reactions upon the failure of the device, a deterioration in its effectiveness, or any inadequacy in its labeling or the directions for use.[32]

However, a manufacturer need not report an incident that has occurred outside Canada if the manufacturer "has indicated, to a regulatory agency of the country in which the incident occurred, the manufacturer's intention to take corrective action, or unless the regulatory agency has required the manufacturer to take corrective action."[33]

For incidents that occur in Canada, the preliminary report must be submitted to Health Canada:

- within 10 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person,[34] or

- within 30 days after the manufacturer or importer of a medical device becomes aware of an incident, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person, but could do so were it to recur.[35]

For incidents that occur outside Canada, and for which a report is necessary, the preliminary report must be submitted to Health Canada as soon as possible after the manufacturer has indicated, to a regulatory agency of the country in which the incident occurred, the manufacturer's intention to take corrective action, or after the regulatory agency has required the manufacturer to take corrective action.[36]

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[32] MD Regulations at subsection 59(1).

[33] MD Regulations at subsection 59(2).

[34] MD Regulations at subsection 60(1)(a)(i).

[35] MD Regulations at subsection 60(1)(a)(ii).

[36] MD Regulations at subsection 60(1)(b).

Subsection 60(2) of the MD Regulations sets out the prescribed information that must be contained in a preliminary report to Health Canada, while subsection 61(2) sets out such information required in a final report.

Health Canada's draft guidance document, *Mandatory and Voluntary Problem Reporting for Medical Devices* (the "MD Reporting Guide")[37], provides further guidance on medical device reporting requirements. The MD Reporting Guide states that Health Canada will generally evaluate the manufacturer's proposed course of action and timetable in a preliminary report on the basis of whether:

- the course of action determines the source of the defect;
- the timetable minimizes risk to patients and users;
- there are unexplained gaps in the timetable;
- the course of action includes an analysis of previous similar incidents;
- the manufacturer's risk assessment is based on sound methodology and reasonable assumptions; and
- if required, whether the manufacturer has arranged for samples of the device to be tested.[38]

Manufacturers and importers must also submit a final report, in accordance with the self-imposed timelines specified in their preliminary report.[39] The final report should contain the following information:

- a description of the incident, including the number of persons who have experienced a serious deterioration in the state of their health or who have died;
- a detailed explanation of the cause of the incident and a justification for the actions taken in respect of the incident; and
- any actions taken as a result of the investigation, which may include
    - increased post-market surveillance of the device,
    - corrective and preventive action respecting the design and manufacture of the device, and
    - recall of the device.[40]

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[37] *Draft Guidance Document – Mandatory and Problem Reporting for Medical Devices*, Health Products and Food Branch Inspectorate, July 6, 2001 (published in draft only). Available at: <http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/mavprfmd-rioevraim_tc-tm-eng.php>.

[38] MD Reporting Guidelines at section 2.7.

[39] MD Regulations at subsection 61(1).

The MD Reporting Guide provides that the explanation given for the cause of the incident should be scientifically sound and consistent with all data provided to Health Canada. Further, the justification for the actions taken in response to the incident should provide evidence to suggest that the manufacturer's proposed course of action is likely to succeed.[41] If the final report indicates that post-market surveillance is required, the manufacturer should include an action plan, detailing the customers that will be monitored, the means for monitoring them, and the period of time for which the surveillance will be in effect.[42] Where the final report indicates that there is a design or manufacturing defect, the report should include a plan of action that addresses, at minimum, whether:

- the company will apply for a new device license;
- the quality system has been updated; and
- the design and manufacturing changes have been validated.[43]

Health Canada provides a problem reporting form that should be used for preliminary reports.[44] Although there is no standardized form for final reports, upon receipt of the preliminary report, Health Canada will provide the manufacturer with an identification number which should be cited on all further correspondence.[45]

Health Canada will determine whether the manufacturer's report is adequate on the basis of whether (i) the incident is described clearly and completely; (ii) the explanation is consistent with the data provided; (iii) the evidence suggests that the course of action will be successful; and (iv) whether the corrective action will also target existing devices.[46]

It is important to note that, where the information that must be submitted in the reports by the manufacturer and the importer is identical, subsection 61.1(1) allows the manufacturer to permit the importer of the device to prepare and file both the preliminary and final reports, provided the manufacturer reports that the importer will do so on its behalf to Health Canada.[47]

Recall Reporting Requirements

Manufacturers and importers are mandated by section 64 of the MD Regulations to each provide Health Canada with the following information on or before undertaking a recall of a medical device:

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[40] MD Regulations at subsection 61(2)(a) –(c).

[41] MD Reporting Guidelines at section 2.09

[42] MD Reporting Guidelines at section 2.10

[43] MD Reporting Guidelines at section 2.12

[44] This form is available online: <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/rep_md_prob-rap_inc_im_e.pdf>.

[45] MD Reporting Guidelines at section 3.6

[46] MD Reporting Guidelines at section 2.14.

[47] MD Regulations at subsection 61.1(2).

- the name of the device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- the name and address of the manufacturer and importer, and the name and address of the establishment where the device was manufactured, if different from that of the manufacturer;
- the reason for the recall, the nature of the defectiveness or possible defectiveness and the date on and circumstances under which the defectiveness or possible defectiveness was discovered;
- an evaluation of the risk associated with the defectiveness or possible defectiveness;
- the number of affected units of the device that the manufacturer or importer:
    - manufactured in Canada,
    - imported into Canada, and
    - sold in Canada;
- the period during which the affected units of the device were distributed in Canada by the manufacturer or importer;
- the name of each person to whom the affected device was sold by the manufacturer or importer and the number of units of the device sold to each person;
- a copy of any communication issued with respect to the recall;
- the proposed strategy for conducting the recall, including the date for beginning the recall, information as to how and when Health Canada will be informed of the progress of the recall and the proposed date for its completion;
- the proposed action to prevent a recurrence of the problem; and
- the name, title and telephone number of the representative of the manufacturer or importer to contact for any information concerning the recall.[48]

According to Health Canada's Recall Policy, a manufacturer will be considered to have reported "on or before" a recall by submitting as much of the recall detail as is known within 24 hours of having made the decision to recall. The initial notice may be made verbally or in writing, but must be followed by a written report containing full information within three (3) business days of initiating the action.[49]

Further, once the recall has been completed, the manufacturer and importer also have follow-up

[48] MD Regulations at section 64(a) – (k).

[49] Recall Policy at section 6.1 Responsible Parties.

reporting obligations. As soon as possible after completion of a recall, section 65 requires each of the manufacturer and importer to report the following information to Health Canada:

- the results of the recall; and
- the action taken to prevent a recurrence of the problem.

As in the case of a pre-recall report, where the information to be submitted by the manufacturer and importer is identical, the manufacturer may also allow the importer to submit a post-recall report on its behalf, if the manufacturer so advises Health Canada.[50]

These reporting requirements do not apply to retailers or health care institutions that distribute the devices.[51]

Annual Reporting Requirements

Medical device manufacturers have an obligation to report to Health Canada annually before November 1, either confirming that all the information and documents supplied by the manufacturer with respect to the device are still correct, or informing Health Canada of any change to the information and documents, other than those changes already submitted pursuant to other provisions in the MD Regulations.[52] Where a manufacturer does not fulfill annual reporting requirements, Health Canada may cancel the manufacturer's medical device license.[53]

Obligation to Submit Additional Information

If Health Canada has reasonable grounds to believe, on the basis of reports or information, that a licensed medical device may not meet the safety and effectiveness requirements, Health Canada may request that the manufacturer provide additional information or samples, on or before a specified day, to assist Health Canada in evaluating whether the device does, in fact, meet the requirements.[54]

Health Care Professional Reporting Requirements

Where a health care professional witnesses an incident involving an authorized medical device that endangers the health or safety of a patient, the health care professional must report the incident to Health Canada and to the manufacturer or importer of the device within 72 hours of the occurrence of the incident.[55] In the report, section 77 requires the health care professional to specify the nature of the incident and the circumstances surrounding it.

(ii) Recall Requirements

[50] MD Regulations at subsections 65.1(1) and (2).

[51] MD Regulations at section 63.

[52] MD Regulations at section 43.

[53] MD Regulations at subsection 43(2).

[54] MD Regulations at section 39.

[55] MD Regulations at section 77.

Section 1 of the MD Regulations defines "recall", in respect of a medical device that has been sold, as

> …any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device
>
> (a) may be hazardous to health;
>
> (b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or
>
> (c) the device may not meet the requirements of the [FDA] or [the MD Regulations].

"Correction" means, in the context of medical devices, "the repair, modification, adjustment, relabelling or inspection (including patient monitoring) of a product without its physical removal to some other location".[56]

The MD Regulations require each manufacturer, importer and distributor of a medical device to establish and implement documented procedures to enable it to carry out effective and timely investigations of safety problems[57], and effective and timely product recalls.[58]

Class II, III, and IV medical devices require a medical device license. An application for a Class III or IV medical device must contain, among other information, a list of the countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries.[59] An application for a medical device establishment license requires, among other information, an attestation by a senior official of the establishment that the establishment has documented procedures in place in respect of distribution records, complaint handling and recalls.[60]

The health hazard evaluation and recall classification criteria set out in Health Canada's Recall Policy also apply to the evaluation of risk associated with medical devices (as described in Part B above).

Health Canada's *Compliance and Enforcement Policy*[61] (the "Compliance and Enforcement Policy") states that the Minister of Health ("MOH") may formally request that a manufacturer

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[56] Recall Policy at section 4.0 Definitions.

[57] MD Regulations at subsection 58(a).

[58] MD Regulations at subsection 58(b).

[59] MD Regulations at subsections 32(3)(c) and 32(4)(c).

[60] MD Regulations at subsections 45(g).

[61] *Compliance and Enforcement Policy* (POL-001), Version 2, May 31, 2005, available online: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/pol_1_e.pdf

recall unsafe medical devices from the marketplace.[62] Where a manufacturer or importer refuses to comply with the MOH's request and allows the unsafe products to remain on the market, the Compliance and Enforcement Policy sets out the following enforcement options:[63]

- Work with Canada Border Services Agency to stop products of non-complying importers from crossing the border;
- Search, seizure, detention and forfeiture pursuant to the investigative powers under the FDA;
- Issue a public advisory warning;
- Refuse, suspend or amend a manufacturer's establishment license;
- Suspend or cancel the manufacturer's marketing authorization;
- Institute a regulatory stop sale; or
- Prosecution pursuant to section 31 of the FDA.

The legislation provides the MOH will specific authority to issue a stop-sale order where the MHO has reasonable grounds to believe that a Class I (lowest risk) medical device is unsafe.[64] The MOH may also suspend a medical device license if he or she has reasonable grounds to believe that the device does not meet the safety and effectiveness requirements. Subsection 40(1) of the MD Regulations provides:

> 40. (1) Subject to subsection (3), the Minister may suspend a medical device licence if the Minister has reasonable grounds to believe that
>
> (a) the licensee has contravened these Regulations or any provision of the Act relating to medical devices;
>
> (b) the licensee has made a false or misleading statement in the application;
>
> (c) the licensee has failed to comply with the terms and conditions of the licence;
>
> (d) the licensee has not complied with a request for information or samples made pursuant to section 39 by the day specified in the request, or the information or samples provided are insufficient to enable the Minister to determine whether the medical device meets the safety and effectiveness requirements;
>
> (e) the medical device no longer meets the safety and effectiveness requirements; or

[62] Compliance and Enforcement Policy at page 7.

[63] Compliance and Enforcement Policy at pages 8-9.

[64] MD Regulations at section 25.

> (f) on the basis of information obtained after the device was licensed, the quality management system under which the device has been designed, in the case of a Class III or IV device, or manufactured, assembled, processed, packaged, refurbished or modified, in the case of a Class II, III or IV device, is inadequate to ensure that the device meets its specifications.

Subsection 40(3) requires the MOH to notify the licensee in writing, with reasons, and to provide the licensee with the opportunity to be heard prior to suspending the license.

A manufacturer may apply to Health Canada's internal appeals procedure if it disagrees with the Minister's decision. An appeal does not stop Health Canada's enforcement procedures.[65]

D. NATURAL HEALTH PRODUCTS

The *Natural Health Products Regulations* ("NHP Regulations"), also enacted under the authority of the FDA, prescribe the mandatory reporting requirements and recall obligations of "licensees" (including manufacturers) of NHPs. The *Guidance Document for Industry – Reporting Adverse Reactions to Marketed Health Products*[66] ("NHP Reporting Guidelines"), published by Health Canada's Natural Health Products Directorate ("NHPD"), also provides guidance on adverse reaction reporting for NHP licensees.

(i) Reporting Requirements

By way of background, an NHP may not be sold in Canada without a NHP license or unless an exemption has been granted.[67] Under the NHP Regulations, a "licensee" (the holder of a NHP license[68]) has certain reporting obligations associated with adverse reactions and recalls arising from the use of its licensed NHPs.

In particular, a licensee must prepare and maintain (i) adverse reaction case reports; (ii) recall reports; and (iii) annual and interim summary reports.[69] The Health Canada may also make requests for safety and other information under sections 16 and 24(3) of the NHP Regulations, which also trigger reporting obligations for licensees.

Adverse Reaction Reporting

Subsection 24(1) of the NHP Regulations requires that a licensee prepare and submit a "case report" as defined in subsection 1(1) to Health Canada in respect of all "serious adverse

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[65] Compliance and Enforcement Policy at page 10.

[66] *Guidance Document for Industry – Reporting Adverse Reactions to Marketed Health Products*, Canada Vigilance Program, August 19, 2009. Available at <http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2009-guidance-directrice_reporting-notification/index-eng.php>.

[67] NHP Regulations at subsection 4(1). See also the *Natural Health Products (Unprocessed Product Licence Applications) Regulations,* SOR/2010-171

[68] A "licensee" for the purpose of the NHP Regulations means the holder of a NHP license issued pursuant to section 7 of the NHP Regulations.

[69] NHP Regulations at sections 24 and 25.

reactions" (domestic) and "serious unexpected adverse reactions" (foreign and domestic[70]) related to the use of its licensed NHP, each within 15 days after the day on which the licensee becomes aware of the reaction. In particular, subsection 24(1) provides as follows:

> 24. (1) A licensee shall provide the Minister with
>
> (a) a case report for each serious adverse reaction to the natural health product that occurs inside Canada, within 15 days after the day on which the licensee becomes aware of the reaction; and
>
> (b) a case report for each serious unexpected adverse reaction to the natural health product that occurs inside or outside Canada, within 15 days after the day on which the licensee becomes aware of the reaction.

A "serious adverse reaction" is a noxious and unintended response to a NHP that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity, that is life-threatening or that results in death.[71] A "serious unexpected adverse reaction" is a serious adverse reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the NHP.[72]

A "case report" is a "detailed record of all relevant data associated with the use of a natural health product".[73] The obligation prescribed by subsection 24(1) will extend to the reporting of every serious adverse reaction and serious unexpected reaction that occurred at any dose of use of the NHP, regardless of whether the person used the NHP according to the recommended conditions of use (as approved by the NHP license) or not (for example, an overdose).[74]

Where complete information required for a case report in relation to an adverse reaction is not obtainable within the 15 days prescribed period for reporting, the licensee may submit an initial report within that time frame containing the following minimum information:

- an identifiable patient (even if not precisely identified by name and date of birth);
- the suspected NHP that may have caused the adverse reaction;
- an identifiable reporting source; and
- the suspect reaction.[75]

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[70] Adverse reactions that occur inside Canada are considered "domestic", while those outside Canada are considered "foreign".

[71] NHP Regulations at subsection 1(1).

[72] NHP Regulations at subsection 1(1).

[73] NHP Regulations at subsection 1(1). See below for the information required in a case report.

[74] NHP Regulations at subsection 24(1) and NHP Reporting Guidelines at section 2.0.

[75] NHP Reporting Guidelines at page 15.

Upon submission of an initial report, the licensee is then required to seek and submit to Health Canada all relevant follow-up information as soon as it becomes available regarding that adverse reaction.[76]

A licensee may "become aware" of an adverse reaction to its NHP in any number of ways. For example, a licensee may become aware of an adverse reaction through a direct customer complaint, through contact with a health care provider or upon receipt of information of individual case reports from published studies that used the licensee's NHP, each of which will trigger an obligation to report under section 24 of the NHP Regulations.[77]

The NHP Reporting Guidelines provide guidance on what information should be included in a case report. In particular, pages 6 and 7 of the NHP Reporting Guidelines state that the "key data elements" required in a case report include:

- the identity of the NHP user;
- the reporter of the adverse reaction and the NHP used;
- information about the adverse reaction and its outcome;
- the NHP user's medical history;
- other medicinal products taken by the patient concurrently with the suspect NHP; and
- certain administrative and licensee details.[78]

Recall Reporting

Upon commencing a recall of a NHP, the NHP Regulations also prescribe certain reporting obligations on the licensee of an NHP. In particular, section 25 of the NHP Regulations requires that every licensee that recalls a NHP shall, within three (3) days after the day on which the recall is commenced, provide Health Canada with all of the information referred to in section 62 of the NHP Regulations, which includes:

- the proper and common name of each medicinal ingredient that it contains and each brand name under which the NHP is sold;

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[76] NHP Reporting Guidelines at section 2.0.

[77] The NHP Reporting Guidelines generally recommend that if a licensee receives a report of an adverse reaction from a consumer or any third party such as a health care provider, that the licensee attempt to obtain as much information as possible from the consumer or third party in respect of the adverse reaction to enable the licensee to prepare and submit a complete adverse reaction report to Health Canada (see sections 4,1 and 4.2 of the NHP Reporting Guidelines).

[78] The NHP Reporting Guidelines suggest that licensees report adverse reactions to the Council for International Organizations of Medical Sciences (CIOMS) I Form at <http://www.cioms.ch/form/frame_form.htm>. Health Canada also provides a form under the Canada Vigilance Reporting Form (HC/SC 4016), which is available at <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/medeff/report-declaration/ar-ei_form-eng.pdf>. The online version of the NHP Reporting Guidelines provides links to the reporting forms.

- the NHP's product number and the number of each lot or batch recalled;
- the name and address of each manufacturer, importer and distributor of the NHP;
- the reasons for commencing the recall;
- the quantity manufactured, imported and distributed into Canada;
- the quantity remaining in the possession of each manufacturer, importer and distributor of the NHP; and
- a description of any other action that the manufacturer is taking in respect of the recall.

Annual and Interim Summary Reports

Subsection 24(2) of the NHP Regulations provides that a licensee who sells a NHP must prepare and maintain an annual summary report of adverse reactions for each of its licensed NHPs. The annual summary report must provide a "concise and critical analysis" of (i) all adverse reactions to the NHP that have occurred inside Canada, and (ii) all adverse reactions for which a case report is required to be provided under subsection 24(1) of the NHP Regulations (for serious adverse reactions and serious unexpected adverse reactions) that have occurred during the preceding 12 months and at a dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying organic functions in humans (at the dose stated on the product label).

There is no obligation on the licensee to submit its annual summary report to Health Canada at any particular time under the NHP Regulations, as the obligation under subsection 24(2) is limited to "prepare and maintain" such report. However, where Health Canada has reasonable grounds to believe that a NHP may no longer be safe when used under the recommended conditions of use, Health Canada may require that, within 30 days after the day on which the request is received, the licensee provide Health Canada with:

- a copy of any annual summary report prepared by the licensee pursuant to its obligations under subsection 24(2) of the NHP Regulations; and/or
- an interim summary report containing a concise and critical analysis of all adverse reactions to the NHP that have occurred inside Canada and all reactions for which a case report is required to be provided under subsection 24(1) of the NHP Regulations that have occurred since the date of the most recent summary report prepared under subsection 24(2), and at a dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying organic functions in humans (at the recommended dose).[79]

The NHP Reporting Guidelines suggest that annual summary reports and interim summary reports should consist of (i) an introduction, (ii) a line listing of all adverse reactions, (iii) a

[79] NHP Regulations at subsection 24(3). Also see the NHP Reporting Guidelines at section 5.

critical analysis of all adverse reactions, and (iv) recommendations.[80] The sources of information for the annual summary report include published and unpublished case reports from studies, direct reports and reports from consumer and health-care providers, in addition to the existing case reports prepared by the licensee.[81]

Health Canada Requests for Safety Information

In addition to the powers of Health Canada to request information under subsection 24(3), section 16 of the NHP Regulations provides that at any time, where Health Canada has reasonable grounds to believe that a NHP may no longer be safe when used under the recommended conditions of use, Health Canada may request that the licensee provide, within 15 days after the day on which the request is received, information and documents demonstrating that "the NHP is safe when used under the recommended conditions of use".

Where the licensee fails to provide Health Canada with the information requested under section 16 within the 15 day time period, or where such information is insufficient to demonstrate the safety of the NHP (among other circumstances), Health Canada may direct the licensee to stop its sale of the NHP in question immediately.[82] Similarly, Health Canada may suspend or cancel a NHP license if Health Canada has reasonable grounds to believe that the licensee has contravened the NHP Regulations or any provision of the FDA related to that NHP, which may include the failure to meet its reporting obligations under the NHP Regulations.[83] Health Canada must give the licensee notice of the suspension in writing. The suspension shall be discontinued if, within 90 days of the notice, the licensee provides information demonstrating that the situation giving rise to the suspension did not exist or has been corrected.[84] Health Canada is not required to provide a notice of suspension to the licensee where "if, as a result of any circumstance, the Minister [of Health] has reasonable grounds to believe that it is necessary to do so to prevent injury to the health of a purchaser or consumer".[85] If the licensee does not respond or provide sufficient information within the 90 day period, the MOH shall cancel the license, and provide notice of the cancellation to the licensee.[86]

(ii) Recall Requirements

Sections 23 of the NHP Regulations requires licensees to maintain records on site "containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale." Pursuant to sections 53 to 57, this obligation applies equally to manufacturers, packagers, labellers, importers and distributors.

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[80] For full particulars of the requirements of annual summary reports, refer to the NHP Reporting Guidelines at section 5..

[81] NHP Reporting Guidelines at sections 3 .0 and 4.0.

[82] NHP Regulations at section 17.

[83] NHP Regulations at section 18.

[84] NHP Regulations at subsection 20(a).

[85] NHP Regulations at section 19.

[86] NHP Regulations at subsection 20(b) and section 21.

Operationally, section 50 provides that every manufacturer, packager, labeller, importer and distributor must maintain a system that enables rapid and complete recalls of NHPs:

> 50. Every manufacturer, packager, labeller, importer and distributor shall establish and maintain a system of control that permits the rapid and complete recall of every lot or batch of the natural health product that has been made available for sale.

Health Canada's *Natural Health Products Compliance Guide* (the "NHP Compliance Guide") provides that all NHPs that pose an unacceptable risk to the safety of Canadians will be removed from sale.[87] Although Health Canada does not specifically have the power to order a recall, it nonetheless has many other enforcement options available to it to ensure compliance with the NHP Regulations. If the manufacturer does not comply with a formal request from the MOH to recall the product, the NHP Compliance Guide indicates that Health Canada will employ the enforcement measures permitted under the FDA and NHP Regulations, such as:

- Stop-sale orders, pursuant to section 17 of the NHP Regulations;
- Suspension of a product license, pursuant to section 18 of the NHP Regulations; and/or
- Prosecution by way of summary judgment or indictment, pursuant to section 31 of the FDA.

Further, the NHP Compliance Guide indicates that Health Canada will also enforce compliance by way of any of the measures outlined in the Compliance and Enforcement Policy (as described below).

E. COSMETICS

Cosmetics are also regulated under the FDA and the regulations thereto. The FDA and the *Cosmetic Regulations* prescribe safety requirements for cosmetics in Canada, including marketing and labeling requirements and requirements for the manufacture, labeling, distribution, and sale of cosmetic products. Additionally, Health Canada's *Guidelines for Cosmetics Manufacturers, Importers and Distributors*[88] (the "Cosmetics Guidelines") provides guidance to industry on all aspects of cosmetics regulation, including compliance and enforcement. As well, Health Canada's policy document *Recalling Consumer Products – A Guide for Industry, April 2005*[89] (the "General Recall Guide") provides guidance on recalls of all types of consumer products, including cosmetics.

(i) Reporting Requirements

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[87] *Natural Health Products Compliance Guide*, Health Canada, Version 2.1, January 2007 at page 2. Available at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/complian-conform_guide-eng.php>.

[88] *Guidelines for Cosmetics Manufacturers, Importers and Distributors*, Health Canada, 2005. Available at: <http://www.hc-sc.gc.ca/cps-spc/pubs/indust/cosmet_guide/index-eng.php>.

[89] Available at: <http://www.hc-sc.gc.ca/cps-spc/advisories-avis/child-enfant/recalling-guide-2005-04-rappel-eng.php>.

Neither the FDA nor the Cosmetic Regulations provide a specific reporting or recall regime for cosmetics. That being said, as with other consumer products, it is always the responsibility of the "manufacturer" to ensure that a cosmetic product complies with the FDA and Cosmetic Regulations, including that the cosmetic is safe when used by a consumer as intended.[90] For the purposes of the Cosmetic Regulations, "manufacturer" is defined as:

> "manufacturer" means a person, a partnership or an unincorporated association that sells, or manufactures and sells, a cosmetic under its own name or under a trade-mark, design, trade name or other name or mark owned or controlled by it.

Although there is no statutory obligation on a manufacturer to report safety incidents, subsection 29(1) of the Cosmetic Regulations provides that Health Canada may request the manufacturer to submit, on or before a specified day, evidence to establish the safety of a cosmetic under its recommended conditions of use. Where the manufacturer is requested to submit such information, the manufacturer must cease from selling that cosmetic after the day specified in the request unless the manufacturer has duly submitted the evidence requested.[91] If Health Canada is of the opinion that the evidence submitted by the manufacturer is insufficient, Health Canada must notify the manufacturer in writing to that effect and the manufacturer shall not thereafter sell that cosmetic unless (i) the manufacturer has submitted further evidence to Health Canada; and (ii) the manufacturer has been notified in writing by Health Canada that the additional evidence is sufficient.[92]

Health Canada's General Recall Guide, which provides a step-by-step guide to planning and implementing product recalls, states that a manufacturer must notify Health Canada upon the completion of a recall of a consumer product (which includes a cosmetic), of the number of recalled units identified by its accounts and include in that report a summary of the actions taken to return, repair, or destroy all of the recalled products.[93]

(ii) Recall Requirements

As noted, the Minister of Health is not provided any specific authority under the FDA or the Cosmetic Regulations to order a recall of a cosmetic. However, section 16 of the FDA provides that no person shall sell any cosmetic in Canada that, most notably, "has in or on it any substance that may cause injury to the health of the user when the cosmetic is used".[94] In addition, subsection 24(1) of the Cosmetic Regulations prohibits the sale of a cosmetic that presents an "avoidable hazard" to users unless the label carries "adequate directions for safe use" in English

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[90] See FDA at section 16 and Cosmetic Regulations at section 24.

[91] Cosmetic Regulations at subsection 29(2).

[92] Cosmetic Regulations at subsection 29(3).

[93] *Recalling Consumer Products – A Guide for Industry, April 2005* ("General Recall Guide") at "Step 10". Available at: <http://www.hc-sc.gc.ca/cps-spc/advisories-avis/child-enfant/recalling-guide-2005-04-rappel-eng.php>.

[94] The FDA also prohibits the sale of cosmetics that consist in whole or in part of any filthy or decomposed substance or of any foreign matter (section 16), that has been manufactured, prepared, preserved, packaged or stored under unsanitary conditions (section 16) or that has not been notified with Health Canada (section 30 of the Cosmetic Regulations).

and French. An "avoidable hazard" is defined under subsection 24(2) of the Cosmetic Regulations as:

> …a threat of injury to the health of the user of a cosmetic that can be
>
> (a) predicted from the composition of the cosmetic, the toxicology of the ingredients and the site of application thereof;
>
> (b) reasonably anticipated during normal use; and
>
> (c) eliminated by specified limitations on the usage of the cosmetic.

As such, where a manufacturer has reason to believe that a cosmetic presents a hazard (other than an "avoidable hazard") that *may* cause injury to the health of users, the manufacturer is prohibited from selling that cosmetic in Canada. Where a cosmetic is already in the marketplace and it is determined that it presents a hazard (other than an "avoidable hazard") that may cause injury to the health of users, given the above noted provisions and obligations, the manufacture will likely have a positive obligation to recall such unsafe cosmetic from the market or to otherwise take such action so as to prevent the sale of the cosmetic to prevent any unsafe use of the cosmetic. From a product liability perspective, recall in such a situation is also usually advisable.

According to the General Recall Guide, Health Canada may also *request* that a manufacturer initiate a recall of a cosmetic (or other consumer product) when that product does not comply with the applicable legislation or where that product poses "an unacceptable risk to the health and safety of the consumer or user".[95] A manufacturer that does not comply with Health Canada's request runs the risk of being subject to prosecution, among other enforcement action.

The General Recall Guide also states that a manufacturer of consumer products should generally initiate a product recall when it becomes aware of (i) a defect that makes a product unsafe; (ii) an injury or death to consumers caused by an unsafe product; or (iii) that a product does not comply with legislative requirements.[96] Health Canada takes the position that the General Recall Guide is intended to apply to cosmetics, among other products.

Accordingly, where a manufacturer believes that its cosmetic presents an unavoidable hazard that *may* cause injury to the health of a user, or where that cosmetic presents an "avoidable hazard" but is not properly labeled in accordance with the Cosmetic Regulations, the manufacturer must not only stop selling the cosmetic in Canada, but should in most circumstances commence an immediate recall of that cosmetic. The failure by a manufacturer to ensure that a cosmetic is safe when sold (and when used as intended) or the untimely recall of an unsafe cosmetic or a cosmetic presenting an avoidable hazard that is improperly labeled may expose that manufacturer to Health Canada enforcement action and liability under Part II of the FDA (in addition to potential civil liability for product liability claims (i.e. negligence) from users of the cosmetic and other stakeholders).

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[95] General Recall Guide at page 2.

[96] According to the General Recall Guide, Health Canada may *request* that a manufacturer initiate a recall of a cosmetic (or other consumer product) when that product does not comply with the applicable legislation or where that product poses "an unacceptable risk to the health and safety of the consumer or user".

Pursuant to section 23 of the FDA, inspectors have equally broad powers of investigation with respect to cosmetic products. The Cosmetic Guidelines indicate that, where a product safety inspector suspects that a product may be contaminated, the inspector may examine and take samples as required.[97] Where a cosmetic is found to be unsafe the inspector will contact the manufacturer or distributor and discuss corrective actions, which may include voluntary removal, recall, or seizure. As with other products regulated by the FDA, a failure to comply with either the FDA or the Cosmetic Regulations may result in prosecution by way of summary conviction or indictment.[98]

F. OTHER CONSUMER PRODUCTS

Consumer products that do not fall within the above noted categories are not generally subject to legislated reporting requirements or recall procedures. However, some product safety incidents may trigger reporting and other obligations imposed on manufacturers pursuant to other relevant legislation, including under the *Canadian Environmental Protection Act, 1999*.[99] As well, the General Recall Guide provides guidance for industry on Health Canada's approach to recalls of all categories of consumer products.

It is also worth noting that consumer products may be subject to reporting and/or recall obligations in connection with the manufacturer's contractual relationship with the Canadian Standards Association (or equivalent product standard accreditation bodies).

Health Canada – The General Recall Guide

The General Recall Guide provide a step-by-step guide to planning and implementing consumer product recalls, including that a manufacturer of a consumer product should generally initiate a product recall when it becomes aware of (i) a defect that makes a product unsafe; (ii) an injury or death to consumers caused by an unsafe product; or (iii) that a product does not comply with legislative requirements.

The General Recall Guide notes that Health Canada may *request* that a manufacturer initiate a recall of a consumer product when that product does not comply with the applicable legislation or where that product poses "an unacceptable risk to the health and safety of the consumer or user". The General Recall Guide also indicates that a manufacturer must notify Health Canada, upon the completion of a recall of a consumer product, of the number of recalled units identified by its accounts and include in that report a summary of the actions taken to return, repair, or destroy all of the recalled products.[100]

Transport Canada - Motor Vehicle Safety Act

[97] Cosmetics Guidelines at page 20.

[98] FDA at section 31.

[99] Additional mandatory obligations to provide information in respect of consumer products in response to an information request for such information from a regulatory authority exist in several bodies of legislation. A detailed overview of these requirements is outside the scope of this memorandum.

[100] General Recall Guide at "Step 10".

Section 10(1) of the federal *Motor Vehicle Safety Act* (the "MVSA") provides that a company that manufactures, sells or imports any vehicle or equipment of a class for which standards are prescribed shall, on becoming aware of a defect in the design, construction or functioning of the vehicle or equipment that affects or is likely to affect the safety of any person, cause notice of the defect to be given in the prescribed manner to:

> (a) the federal Minister of Transport;
>
> (b) each person who has obtained such a vehicle or equipment from the company; and
>
> (c) each current owner of such a vehicle or equipment as determined
>
> > (i) from any warranty issued by the company with respect to the functioning of the vehicle or equipment that has, to its knowledge, been given, sold or transferred to the current owner,
> >
> > (ii) in the case of a vehicle, from provincial motor vehicle registration records, or
> >
> > (iii) in the case of equipment, from a registration system referred to in paragraph 5(1)(h).[101]

As can be seen, the reporting requirements will apply where a safety issue exists in respect of any vehicle or equipment of a class for which standards are prescribed. "Vehicle" is defined in section 2 of the MVSA as "any vehicle that is capable of being driven or drawn on roads by any means other than muscular power exclusively, but does not include any vehicle designed to run exclusively on rails". "Equipment" is defined as "any equipment set out in Schedule I that is designed for use in or on a vehicle". Schedule I to the MVSA sets out "tires" and "equipment for use in the restraint of children and disabled persons" as "equipment" for the purposes of the MVSA.

The MVSA and related *Motor Vehicle Safety Regulations* ("MVSR") prescribe standards for a wide variety of classes of vehicles and equipment, including vehicles such as busses, cars, trucks, motorcycles and all-terrain vehicles, as well as vehicle parts and equipment such as seat belts and child restrain systems.

Although "safety" or "safety related defect" are not defined terms in the legislation, it is interesting to note that Transport Canada's website describes a "safety-related defect" as follows:

> A safety-related defect is generally one that is common to a group of vehicles, tires or child restraints of the same design or manufacturer. These defects are likely to affect the safe operation of a vehicle, tire or child restraint without providing any prior warning to the vehicle

[101] Paragraph 5(1)(h) of the MVSA requires that any company that (i) applies a national safety mark to any vehicle or equipment, (ii) sells a vehicle or equipment to which a national safety mark has been applied, or (iii) imports into Canada any vehicle or equipment of a prescribed class must, in the case of equipment, maintain a registration system in the prescribed form and manner by which any person who has purchased such equipment from the company and who wishes to be identified may be identified.

> operator or user. Therefore, the defect poses a risk to the vehicle operator, occupants and others.[102]

The Transport Canada website provides a list of examples of safety-related defects as follows:

- Steering components that may break suddenly, causing loss of vehicle control;
- Problems with fuel system components that may cause fuel leaks and possibly vehicle fires;
- Improperly designed or constructed tires that may blow out unexpectedly;
- Accelerator controls that may break or stick;
- Wheels that may crack or break, resulting in loss of vehicle control;
- Windshield wiper arms that may fall off while in operation;
- Seats and/or seat backs that fail unexpectedly during normal use;
- Critical vehicle components that may break, fall apart, or separate from the vehicle, causing loss of vehicle control, or injury to people inside or outside the vehicle;
- Wiring problems that may lead to a fire or loss of lighting;
- Air bags that deploy when they shouldn't; and
- Child restraints with defective harness systems, buckles or components.

Examples of non-safety-related problems are also listed as follows:

- Ordinary wear of equipment that has to be inspected, maintained and replaced periodically by the consumer. Such equipment includes shock absorbers, batteries, brake pads and shoes, and exhaust systems;
- Air conditioners and radios that do not operate properly;
- Non-structural or body panel rust; and
- Poor quality of paint or cosmetic blemishes.

Canadian Environmental Protection Act, 1999

Under the *Canadian Environmental Protection Act, 1999* ("CEPA"), any manufacturer that becomes aware of an incident in which a designated toxic substance was released, or is likely to be released, into the environment is required to notify an enforcement officer (of Environment Canada) of the incident as soon as possible, and to provide a written report.[103] This notification

[102] Available at: <http://www.tc.gc.ca/eng/roadsafety/tp-tp2822-page2_e-250.htm>.

[103] CEPA at subsection 95(1)(a).

requirement applies to anyone that owns or has management and control of the substance before it is released into the environment, or anyone who causes or contributes to its release.[104] Further, any person whose property is affected by the release of the toxic substance must notify an enforcement officer.[105] It is also worthy of note that the list of toxic substances includes lead, mercury, and asbestos.[106]

G. LOSS OR UNAUTHORIZED ACCESS TO PERSONAL INFORMATION

In Canada, two jurisdictions presently require notification in the event personal information in the hands of a private sector organization has been lost or inappropriately accessed – Ontario and Alberta.

In Ontario, the *Personal Health Information Protection Act, 2004* a health information custodian to take steps that are reasonable in the circumstances to ensure that personal health information in the custodian's custody or control is protected against theft, loss and unauthorized use or disclosure and to ensure that the records containing the information are protected against unauthorized copying, modification or disposal. Subject to limited exceptions, a health information custodian that has custody or control of personal health information about an individual shall notify the individual at the first reasonable opportunity if the information is stolen, lost, or accessed by unauthorized persons.[107] Apart from personal health information, however, there is no obligation to report a breach of security in respect of other types of personal information.

Alberta's *Personal Information Protection Act* was recently amended to require that an organization having *any* personal information under its control must, without unreasonable delay, provide notice to Alberta's Information and Privacy Commissioner of any incident involving the loss of or unauthorized access to or disclosure of the personal information. This notice must be given where a reasonable person would consider that there exists a real risk of significant harm to an individual as a result of the loss or unauthorized access or disclosure.[108] The notice must be in writing and must include:

(a) a description of the circumstances of the loss or unauthorized access or disclosure;

(b) the date on which or time period during which the loss or unauthorized access or disclosure occurred;

(c) a description of the personal information involved in the loss or unauthorized access or disclosure;

(d) an assessment of the risk of harm to individuals as a result of the loss or unauthorized access or disclosure;

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[104] CEPA at subsections 95(2)(a) and (b).

[105] CEPA at subsection 95(3).

[106] CEPA at Schedule I.

[107] *Personal Health Information Protection Act, 2004*, S.O. 2004, c. 3, Sched A, s. 12

[108] *Personal Information Protection Act*, S.A. 2003, c. P-6.5, s. 34.1

(e) an estimate of the number of individuals to whom there is a real risk of significant harm as a result of the loss or unauthorized access or disclosure;

(f) a description of any steps the organization has taken to reduce the risk of harm to individuals;

(g) a description of any steps the organization has taken to notify individuals of the loss or unauthorized access or disclosure; and

(h) the name of and contact information for a person who can answer, on behalf of the organization, the Commissioner's questions about the loss or unauthorized access or disclosure

In a situation where the organization is required to notice an individual to whom there is a "real risk of significant harm" as a result of a loss of or unauthorized access to or disclosure of personal information, the notification must be given directly to the individual and must include

(a) a description of the circumstances of the loss or unauthorized access or disclosure,

(b) the date on which or time period during which the loss or unauthorized access or disclosure occurred,

(a) a description of the personal information involved in the loss or unauthorized access or disclosure,

(b) a description of any steps the organization has taken to reduce the risk of harm, and

(c) contact information for a person who can answer, on behalf of the organization, questions about the loss or unauthorized access or disclosure.[109]

It is, however, possible that notification may be given indirectly to the individual if the Commissioner determines that direct notification would be unreasonable in the circumstances.

In practice, and despite the limited number of jurisdictions that require mandatory notification to either the individual concerned or to the data protection authority in that jurisdiction, organizations will usually notify the applicable data protection authority and/or the individual(s) concerned in the event of a breach. Voluntary notification would be made in an effort to resolve the data breach and/or to allow affected individuals to take actions and precautions in order to minimize the impact of such a breach.

H. PENDING LEGISLATIVE AMENDMENTS

Two pending legislative amendments at the federal level should be noted: Canada's proposed *Canada Consumer Product Safety Act* (Bill C-36) will, if enacted as proposed, implement a comprehensive regulatory regime for all consumer products other than those regulated under certain federal statutes (such as food, drugs, motor vehicles). The new legislative proposal represents a sea change that will subject hundreds of thousands of consumer products to direct government regulation for the first time. The proposed legislation reaches beyond manufacturers and importers to sellers, testers, packagers and advertisers. Bill C-36 provides that no manufacturer or importer may manufacture, import, advertise or sell a consumer product that is a

[109] *Personal Information Protection Act Regulations*, Alta. Reg. 366/2003, s. 19.1(1) and (2)

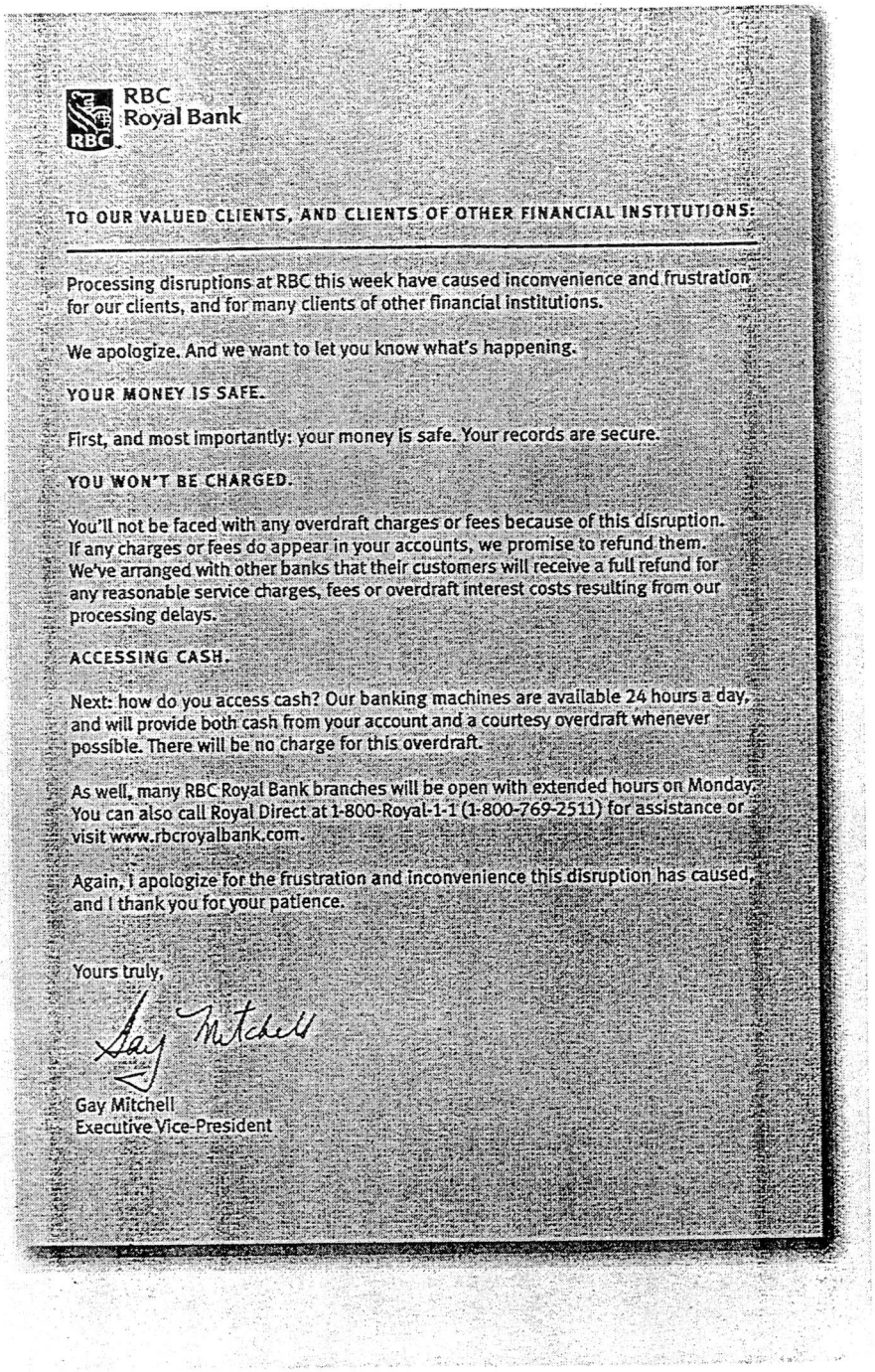
danger to human health or safety, is the subject of a recall or is the subject of a remedial order that has not been complied with. The proposed legislation includes sweeping powers for inspectors appointed under the draft legislation and the ability for mandatory recall orders to be issued.

Proposed amendments to the *Personal Information Protection and Electronic Documents Act* (Bill C-29), Canada's federal legislation governing the protection of personal information in the private sector, will require an organization to report any material breach of security safeguards involving personal information under the organization's control to Canada's Privacy Commissioner. In order to determine whether a breach was "material", the organization would consider the sensitivity of the personal information, the number of individuals whose personal information was involved, and an assessment by the organization that the cause of the breach or a pattern of breaches indicates a systemic problem. The amendments proposed would also require the organization to notify the individual of any breach of security safeguards involving the individual's personal information under the organization's control if it is reasonable in the circumstances to believe that the breach creates a real risk of significant harm to the individual (unless such notification would be otherwise prohibited by law). "Significant harm" is defined to include bodily harm, humiliation, damage to reputation or relationships, loss of employment, business or professional opportunities, financial loss, identity theft, negative effects on the credit record and damage to or loss of property. In certain circumstances, broader notification to other organizations or government institutions may be required (i.e. if such other organization or institution may be able to reduce the risk of the harm that could result from the breach or mitigate that harm.

It is expected that both Bill C-36 and C-29 will move quickly through the legislative process once Parliament resumes after the summer recess.

Processing Disruption
Overview of Paid Advertising Communications

Fri., June 4	Phase 1 -	Radio advertising nationally English & French Began between 5 – 7 pm, E & F
Sat., June 5	Phase 1 -	Radio advertising continued, English & French National and major daily newspapers, E & F
Sun., June 6	Phase 1 -	Radio advertising continued, English & French Some major Sunday newspaper editions, English only (The Sun newspapers)
Mon., June 7	Phase 2 -	New Radio advertising, English & French
Tues., June 8	Phase 2 -	Radio advertising continued, English & French National and major daily newspapers, E & F
Wed., June 9	Phase 2 -	Balance of major daily newspapers
Sat., June 19	Phase 3 -	National and Major daily newspapers, E & F
Sun., June 20	Phase 3 -	Some major Sunday newspaper editions
Week of June 21	Phase 3 -	Extended list of community newspapers, E & F
Week of June 28	Phase 3 -	Chinese and South Asian community newspapers Balance of extended list of community newspapers, E & F



RBC Royal Bank

TO OUR VALUED CLIENTS, AND CLIENTS OF OTHER FINANCIAL INSTITUTIONS:

Processing disruptions at RBC this week have caused inconvenience and frustration for our clients, and for many clients of other financial institutions.

We apologize. And we want to let you know what's happening.

YOUR MONEY IS SAFE.

First, and most importantly: your money is safe. Your records are secure.

YOU WON'T BE CHARGED.

You'll not be faced with any overdraft charges or fees because of this disruption. If any charges or fees do appear in your accounts, we promise to refund them. We've arranged with other banks that their customers will receive a full refund for any reasonable service charges, fees or overdraft interest costs resulting from our processing delays.

ACCESSING CASH.

Next: how do you access cash? Our banking machines are available 24 hours a day, and will provide both cash from your account and a courtesy overdraft whenever possible. There will be no charge for this overdraft.

As well, many RBC Royal Bank branches will be open with extended hours on Monday. You can also call Royal Direct at 1-800-Royal-1-1 (1-800-769-2511) for assistance or visit www.rbcroyalbank.com.

Again, I apologize for the frustration and inconvenience this disruption has caused, and I thank you for your patience.

Yours truly,

Gay Mitchell

Gay Mitchell
Executive Vice-President

RBC Royal Bank

RBC PROCESSING DISRUPTION UPDATE

TORONTO, June 2, 2004 — A processing disruption, which resulted in some RBC Financial Group client transactions not being reflected in account balances, is being resolved.

As of 2:30 p.m. EDT, account balances for RBC clients in Canada have been updated to reflect all transactions as of May 31. The bank is currently completing a verification of all June 1 transactions and expects to have these transactions reflected in client balances by tomorrow morning. Transactions that took place today will be processed to client accounts later this evening and will also be available tomorrow morning.

"We recognize this has caused not only our own clients but also clients of some other institutions considerable inconvenience and for this we sincerely apologize. We want to assure all those affected that their money is safe and secure," said Rod Pennycook, executive vice-president, RBC Royal Bank. "We are now completing the process of rechecking and verifying transactions that took place between May 31 and June 2. We process tens of millions of transactions a day and we are being painstakingly thorough in order to minimize any further inconvenience to all those affected."

Any service fees or overdraft interest charges that clients experience due to the processing delay will be reversed. Should any service charges, fees, or interest costs be incurred from other financial institutions as a result of this processing delay, RBC Financial Group clients will receive a full refund of any charges. Other reasonable costs incurred as a result of this delay will be handled on an individual basis.

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RBC PROCESSING DISRUPTION STATUS UPDATE

TORONTO, June 3, 2004 — Accounts for RBC Royal Bank have been updated and reflect all transactions made through June 1, 2004. Verification of all June 2 transactions is continuing and the bank expects to have these transactions reflected in client balances tomorrow. Transactions that take place today will be processed to client accounts this weekend.

"We appreciate that our clients have been extremely patient and want to assure them that their money is safe and secure," said Rod Pennycook, executive vice-president, RBC Royal Bank. "Our systems are running well and we are making good progress. In addition, we are continuing to be extremely thorough to ensure that all transactions are correctly reflected in client account balances."

We do not expect any service fees or overdraft interest charges to appear in clients' accounts as a result of the processing delay. However, should any materialize they will be refunded. Other reasonable costs incurred as a result of this delay will be handled on an individual basis.

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For further information, please contact:
Judi Levita, Media Relations, (416) 974-8810
Chris Pepper, Media Relations, (416) 974-2124

RBC EXTENDS BUSINESS HOURS

TORONTO, June 4, 2004 — In order to be as accessible as possible to clients who may be experiencing difficulties as a result of this disruption, many RBC Royal Bank branches will be operating under extended hours today. In addition, the bank will open an increased number of branches throughout Canada on Saturday to ensure clients have ready access to our services. A listing of the Saturday opening branches will be available this evening at www.rbcroyalbank.com. Branches not open on Saturday will have signage directing clients to the nearest open location.

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For further information, please contact:
Judi Levita, Media Relations, (416) 974-8810
Chris Pepper, Media Relations, (416) 974-2124

RBC PROCESSING RETURNS TO NORMAL

TORONTO, June 6, 2004 — RBC Financial Group today said that by opening of business on Monday morning, its clients' accounts will reflect virtually all transactions processed up to and including Friday, June 4 and it expects that client transactions completed over the weekend will be reflected in their account balances on a normal basis.

"Our transaction processing is essentially up to date and we are finally back to a more normal schedule. However, the delays we experienced throughout much of last week have prevented some other financial institutions from updating their own client accounts," said Marty Lippert, vice-chairman and RBC's chief information officer. "Now that those institutions have the information they need, they will be able to update their records according to their own processing schedules."

"Our clients and a great many other Canadians have shown incredible patience and understanding and we apologize for the inconvenience and hardship this disruption has caused them," said Gordon Nixon, president & chief executive officer of RBC Financial Group. "We will not consider this disruption behind us until its consequences have been resolved for every client regardless of the institution with which they bank. While there may be some isolated instances where the effects of the disruption will impact clients over the next few days, I want to assure them that their money is safe and secure and that we will continue to do whatever we can to assist them," said Nixon.

RBC has communicated in both print and radio advertising messages over the weekend the steps it is taking to help offset the impact of the disruption on clients, including its commitment to refund any overdraft charges or fees incurred as a result of this disruption.

- more -

RBC FINANCIAL GROUP ANNOUNCES STEPS TO "MAKE IT RIGHT" FOR CLIENTS AFFECTED BY PROCESSING DISRUPTION

TORONTO, June 18, 2004 — RBC Financial Group today announced it has established a formal process to review claims for costs or losses incurred as a result of its recent processing disruption. This is in addition to steps RBC is currently taking to minimize the impact for those affected during the processing disruption, including the reversal of bank service charges and interest fees caused by the disruption, and the refunding of certain other charges and fees.

"With the processing disruption behind us, our primary objective now is to make it right for those who were directly impacted," said Gordon Nixon, president and chief executive officer of RBC Financial Group. "I want to thank those who were inconvenienced for their patience and understanding, and once again offer them my sincere apology."

RBC has begun to automatically reverse, wherever possible, banking service charges, fees and overdraft interest that RBC clients may have been charged as a result of the recent processing disruption. RBC expects the vast majority of necessary adjustments will be completed by June 30. After June 30, if clients see a charge due to the processing disruption that has not been corrected, they should contact their branch, business centre or call 1-800-ROYAL 1-1 (1-800- 769-2511).

RBC has agreed to reimburse other Canadian financial institutions for certain banking charges their clients have incurred as a result of the processing disruption and appreciates the cooperation provided. These clients should contact their own financial institution if they have any questions or concerns about reversal of banking charges or to address any other issues they may have.

- more -

"We believe the steps we are taking to reimburse all banking related charges that resulted from the processing disruption will address the concerns of the vast majority of those who have been affected," said Nixon. "However, we recognize that these measures may not address all circumstances and we want to ensure that special situations are dealt with in a fair and timely manner."

To manage such situations, RBC has retained the services of Crawford Adjusters Canada, a wholly owned subsidiary of Crawford & Company, one of the world's largest providers of claims management solutions. Crawford will act as claims administrator for non-banking related costs and losses that may have been incurred by clients of RBC and other financial institutions as a result of RBC's processing disruption of May 31 to June 4, 2004.

Effective June 21, 2004, clients of RBC or other financial institutions can obtain a Claim Form from any RBC Royal Bank branch, business centre or by calling 1-800-ROYAL 1-1 (1-800-769-2511). A Claim Form can also be downloaded in PDF format from www.rbc.com/clientnews/.

RBC clients with claims up to $100 can present their completed Claim Form and supporting documentation to any RBC Royal Bank branch for processing there.

RBC clients with claims of more than $100, and clients of other financial institutions for all claim amounts, should mail their completed Claim Form and supporting documentation to:

RBC Processing Service Disruption: Redress and Claims Process
Claims Administrator
P.O. Box 517
Waterloo, Ontario,
N2J 4A9

Alternatively, completed Claim Forms and supporting documentation may be delivered to any RBC Royal Bank branch or business centre for forwarding to the claims administrator.

Further information regarding the RBC Processing Disruption Redress and Claims Process is available at www.rbc.com/clientnews/ and will be further communicated through advertisements in selected Canadian and community newspapers over the next week.

About RBC Financial Group

Royal Bank of Canada (RY: TSX, NYSE) uses the initials RBC as a prefix for its businesses and operating subsidiaries, which operate under the master brand name of RBC Financial Group. Royal Bank of Canada is Canada's largest bank as measured by market capitalization and assets, and is one of North America's leading diversified financial services companies. It provides personal and commercial banking, wealth management services, insurance, corporate and investment banking, and transaction processing services on a global basis. The company employs 60,000 people who serve more than 12 million personal, business and public sector clients through offices in North America and some 30 countries around the world. For more information, please visit www.rbc.com.

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Media contact:
Beja Rodeck, Media Relations, (416) 974-5506

RBC Financial Group

RBC Financial Group

Information About RBC's Processing Delay

Making it right - Client Q&As
June 18, 2004; 1:30 p.m. EDT

1. What is RBC doing to make it right for those who were affected by the processing disruption?
2. What happens if another charge, like a late payment fee, comes through on my account a month from now? Will you still reimburse me?
3. I incurred costs as a result of RBC's processing disruption that are not directly banking related. How will I be reimbursed?
4. Should I use the claims process for the reversal of bank service fees, charges or overdraft interest?
5. How do I submit a claim?
6. How can I get a Claim Form?
7. How long is it going to take for my claim to be processed?
8. Why are you using an outside company to manage the claims process?
9. What type of claims will you consider?
10. Are there any types of claims RBC will not consider?
11. How long will the claims process be in effect?
12. It seems that you're making me do a lot of work. Why couldn't you make it a little easier for me?
13. Are you paying interest on claims? If so, how much?
14. Do I need to submit receipts for the claim that I am filing? What happens if I don't have all my receipts?
15. What happens if I don't agree with the decision made about how much I will be reimbursed?
16. You are asking clients to submit a claim for all amounts. Wouldn't it be easier to pay small amounts on the spot?

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3. I incurred costs as a result of RBC's processing disruption that are not directly banking related. How will I be reimbursed?

We have established a formal review process to ensure that clients of RBC and other financial institutions who can substantiate additional costs or losses incurred as a direct result of the processing disruption are reimbursed fairly.

If you incurred such costs or losses as a direct result of our processing disruption, you may be eligible to participate in *RBC's Processing Disruption Redress and Claims Process*. If you consider that you qualify, you must submit your completed Claim Form and supporting documentation no later than September 30, 2004.

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4. Should I use the claims process for the reversal of bank service fees, charges or overdraft interest?

No, the claims process should not be used for this purpose. We will automatically reverse, wherever possible, banking service charges, fees and overdraft interest that may have been incorrectly charged to accounts as a result of the processing disruption that occurred between May 31, 2004 and June 4, 2004. We expect the vast majority of these adjustments will be completed by June 30.

After June 30, if you find that a charge from this time period has not been reversed, please bring it to our attention by contacting your branch, business centre or calling 1 800 ROYAL 1-1™ (1-800-769-2511) and we will make it right for you.

If you are a client of another Canadian financial institution, please bring any such charges to their attention. We have made arrangements with most Canadian financial institutions to correct the problem and we will reimburse them. For clients of financial institutions outside of Canada, please submit a Claim Form.

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5. How do I submit a claim?

If you incurred costs or losses other than banking charges as a direct result of our processing disruption that occurred

between May 31 and June 4, 2004, you must submit a completed Claim Form and supporting documentation by no later than September 30, 2004.

If you are an RBC client with a claim up to $100, please present your completed Claim Form and supporting documentation to any RBC Royal Bank branch. You can also file claims of up to $100 by calling 1 800 ROYAL 1-1™ (1-800-769-2511) and then mailing us your supporting documentation.

If you are an RBC client with a claim of more than $100, or a client of another financial institution, please mail your completed Claim Form and supporting documentation to:

RBC Processing Disruption Redress and Claims Process
Claims Administrator
P.O. Box 517
Waterloo, ON
N2J 4A9

Alternatively, completed Claim Forms and supporting documentation may be delivered to any RBC Royal Bank branch or business centre for forwarding to the claims administrator.

If you need help in completing your Claim Form, please call us at 1 800 ROYAL 1-1™ (1-800-769-2511).

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6. How can I get a Claim Form?

Effective Monday, June 21, Claim Forms will be available through any RBC Royal Bank branch, business centre or by calling 1 800 ROYAL 1-1™ (1-800-769-2511). A Claim Form can also be downloaded in PDF format.

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7. How long is it going to take for my claim to be processed?

Approved claims will be paid within 40 days of receipt of your completed Claim Form and supporting documentation.

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8. Why are you using an outside company to manage the

claims process?

We want to make sure this process is fair and equitable to everyone filing a claim. Engaging the services of an external specialist will help ensure the process we are implementing is consistently applied and responsive to your needs. Crawford Adjusters Canada is a division of one of the world's largest providers of claims management solutions, with an outstanding reputation for fairness, impartiality and responsiveness.

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9. What type of claims will you consider?

We will reimburse substantiated costs and losses directly resulting from the processing disruption that occurred between **May 31 and June 4, 2004**. Examples of such costs might include transportation costs, telephone charges, childcare costs, etc. that were necessitated by the processing disruption.

To be eligible, claims must clearly establish the reason for the reimbursement claim, the connection between the amount claimed and the processing disruption, the amount requested and the efforts you made to minimize your costs or losses.

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10. Are there any types of claims RBC will not consider?

We will provide reimbursement for substantiated costs and losses directly resulting from the processing disruption that occurred between **May 31 and June 4, 2004**. Claims for reimbursement of other costs or losses would not generally be considered payable.

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11. How long will the claims process be in effect?

Completed Claim Forms and supporting documentation must be submitted no later than September 30, 2004.

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12. It seems that you're making me do a lot of work. Why couldn't you make it a little easier for me?

We have tried to design our process to minimize inconvenience for those making claims, while ensuring that it is is fair and equitable to everyone as well. Engaging the services of an external specialist will help ensure the process we are implementing is consistently applied and responsive to your needs. Crawford Adjusters Canada is a division of one of the world's largest providers of claims management solutions. Crawford has an outstanding reputation for fairness, impartiality and responsiveness, and these standards will be applied to every claim that is submitted.

If you need help in completing your Claim Form, please call 1 800 ROYAL 1-1™ (1-800-769-2511)

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13. Are you paying interest on claims? If so, how much?

Yes, we will pay interest on approved claim settlements at the rate of 2%, calculated from the date costs or losses were incurred.

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14. Do I need to submit receipts for the claim that I am filing? What happens if I don't have all my receipts?

All claims are expected to include receipts or supporting documentation. If you can't attach supporting documentation, an explanation should be provided for each missing document in your claim. If you aren't able to provide supporting documentation, your claim may be denied.

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15. What happens if I don't agree with the decision made about how much I will be reimbursed?

If your claim is denied in whole or in part, you may submit your claim to RBC's Office of the Ombudsman for further consideration, or submit the claim to an Arbitrator for final and binding arbitration. Further information regarding the arbitration process will be provided to you in the event you choose that process.

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16. You are asking clients to submit a claim for all amounts. Wouldn't it be easier to pay small amounts on

the spot?

To make the process easier, RBC clients with claims for up to $100 will be reviewed by your branch. RBC clients may also file claims of up to $100 by calling 1 800 ROYAL 1-1™ (1-800-769-2511), and then mail us your supporting documentation.

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17. RBC clients can deal directly with their branch or through your telephone banking service. Why do clients of other financial institutions have to deal with Crawford?

Many of those affected by the processing delay are clients of RBC Financial Group. The relationships we have with our clients and our understanding of their banking history will enable us to resolve most of their claims most effectively at our branches or telephone banking centres. Because we do not have the same relationship with clients of other financial institutions and the same access to their banking records and history, we have engaged the services of an external specialist to help ensure the process we are implementing is consistently applied and responsive to their needs.

In addition to this review process, RBC has agreed to reimburse other Canadian financial institutions for certain banking charges their clients have incurred as a result of the processing disruption. If you are a client of another financial institution, please bring any such charges to their attention.

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18. Who has final approval of claims? Crawford Adjusters Canada or RBC?

Claims up to $5,000 will be adjudicated by Crawford Adjusters Canada and the claims decision for these is Crawford's. Claims for more than this amount will be referred to the RBC Processing Disruption Claims Committee, as required.

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19. What is the RBC Processing Disruption Committee?

This is a committee comprised of representatives from RBC Financial Group's various business divisions and legal counsel.

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20. I am a corporate or institutional client of RBC. What's the process for making a claim?

We recognize that some corporate and institutional clients were affected by the disruption and sincerely apologize for the frustration and inconvenience. In an effort to make things right, we will have a process in place to ensure that these clients are fairly reimbursed for their costs and losses. If you believe you have a claim, please contact your relationship manager for more information.

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RBC® Processing Disruption Redress and Claims Process

Royal Bank of Canada apologizes for the inconvenience and frustration caused during our processing disruption. Our first priority was to fix the problem. The problem is solved, but we will not consider this issue behind us until we have resolved the consequences for you, no matter where you bank.

In most cases, the banking service charges, fees or overdraft interest you may have incurred as a result of the disruption have already been reversed. For RBC clients, if you see such a charge that has not been reversed, please bring it to our attention.

If you are a client of another financial institution you should bring any such charges to their attention. Your financial institution will correct the problem and be reimbursed by RBC. In this case, there is no need to complete a Claim Form.

We believe these steps will address the concerns of the vast majority of those who have been affected. However, in some cases you may consider that the steps outlined above may not fully address your situation.

Until September 30, 2004, the following process will be in place to ensure these isolated situations are addressed in a fair and consistent manner. This process is intended to ensure that clients of RBC and other financial institutions who incurred **additional costs or losses as a direct result of the processing disruption that occurred between May 31, and June 4, 2004** are compensated fairly. For RBC clients, most claims for less than $100 can be processed by your branch. For larger claims and claims by clients of other financial institutions, we have retained Crawford Adjusters Canada to act as administrator of the claims process ("Claims Administrator").

Please complete the attached Claim Form if you consider your situation eligible for the **RBC Processing Disruption Redress and Claims Process.**

CLAIM PERIOD DEADLINE

To qualify for compensation you must submit your **completed** Claim Form and supporting documentation **no later than September 30, 2004.**

RBC clients with claims for up to $100, please present your completed Claim Form and supporting documentation to any RBC Banking branch.

RBC clients with claims of more than $100, and clients of all other financial institutions, please mail your completed Claim Form and supporting documentation to:

RBC Processing Disruption Redress and Claims Process
Claims Administrator
P.O. Box 517
Waterloo, ON
N2J 4A9

Alternatively, completed Claim Forms and supporting documentation may be presented to any RBC Royal Bank branch or business centre for forwarding to the Claims Administrator.

Approved claims will be paid within 40 days of receipt of your completed Claim Form. You are required to complete the Claim Form and provide the relevant supporting documents. If you require assistance regarding completion of your Claim Form, you are encouraged to contact RBC at 1 800 ROYAL® 1-1 (1-800-769-2511).

CLAIMS ELIGIBLE FOR COMPENSATION

RBC will provide compensation only for substantiated costs and monetary losses directly resulting from the processing disruption that occurred between May 31, 2004 and June 4, 2004. To be considered eligible, your completed Claim Form and supporting documentation must clearly establish:

1) the reason for your claim for compensation,
2) the connection between the compensation claimed and the processing disruption,
3) the amount of compensation requested, and
4) the efforts you made to minimize your costs or losses.

CLAIMS PROCESS

After your claim is received, it will be reviewed to ensure that it is complete. If it is not complete, you will be contacted.

Your claim will be processed in one of the following ways:

> RBC clients with claims for up to $100 will be reviewed by your branch

> RBC clients with claims between $101 and $5,000 and clients of other financial institutions with claims up to $5,000 will be reviewed by the Claims Administrator

> Any claim for more than $5,000 and/or any claims for non-monetary losses will be reviewed by the RBC Processing Disruption Claims Committee

You will be notified of the decision within 30 days of receipt of your completed Claim Form and supporting documentation. If approved, you will receive payment by direct deposit within 10 days following the notice.

If your claim is denied in whole or in part, you may submit your claim to RBC's Office of the Ombudsman for further consideration, or submit the claim to an Arbitrator for final and binding arbitration. Further information regarding the arbitration process will be provided to you in the event you choose that process.

PRIVACY STATEMENT

Information you provide to RBC and the Claims Administrator with your Claim Form will be used only:

> To implement and administer the RBC Processing Disruption Redress and Claims Process and

> To evaluate and consider your eligibility status under the RBC Processing Disruption Redress and Claims Process

Your information will be kept strictly private and confidential and will not be disclosed to anyone else without your consent except as required by law or as provided in the RBC Processing Disruption Redress and Claims Process.

CLAIM FORM
RBC Processing Disruption Redress and Claims Process

RBC Financial Group

Note: Please complete either Section A (for Individual Claimants) or Section B (for Business Claimants). All Claimants must also complete Section C. PLEASE PRINT OR TYPE

SECTION A – INDIVIDUAL CLAIMANTS		
Surname	First Name	Initial(s)
Suite/Apt. #		
Street Address		
City	Province	Postal Code
Home Telephone ( )	Work Telephone ( )	
E-mail address		
IDENTIFY THE FINANCIAL INSTITUTION(S) INVOLVED		
Are you an RBC Client? ☐ Yes ☐ No	RBC Client Card # 4519 – – –	
Branch Address		
City	Province	Postal Code
Account #	Transit	Attach a cheque marked as "void" to assist processing
If your claim relates to a relationship with another financial institution:		
Your Financial Institution's Name		
Branch Address		
City	Province	Postal Code
Account #	Transit	Attach a cheque marked as "void" to assist processing

SECTION B – BUSINESS CLAIMANTS		
Claimant's Name		
Name of contact: Surname	First name	
Title of contact		
Claimant's Address		
City	Province	Postal Code
Telephone ( )	Fax ( )	
E-mail address		
IDENTIFY THE FINANCIAL INSTITUTION(S) INVOLVED		
Is claimant an RBC Client? ☐ Yes ☐ No	RBC Client Card # 4519 – – –	
RBC Account Manager's Name		
Branch Address		
City	Province	Postal Code
Account #	Transit	Attach a cheque marked as "void" to assist processing
If your claim relates to a relationship with another financial institution:		
Your Financial Institution Name		
Branch Address		
City	Province	Postal Code
Account #	Transit	Attach a cheque marked as "void" to assist processing

SECTION C – NATURE OF CLAIM

Check the appropriate box:

☐ Claim for up to $100.00

☐ Claim between $101.00 and $5,000.00

☐ Claim for more than $5,000.00

List the items that you are seeking compensation for and how they are related to the processing disruption (please attach a separate page if required). Attach original receipts or other supporting documentation. **Failure to provide original receipts or other supporting documentation may result in your claim being denied.** If you cannot attach supporting documentation, provide an explanation for each missing document.

List the items that you are seeking compensation for.	How are the claimed items related to the processing disruption?	Supporting Documentation (if none, explain why)	Amount Claimed
1.			
2.			
3.			

Did you obtain or attempt to obtain funds from another source or otherwise take steps to minimize any loss arising from the processing disruption? If so, please provide details of the steps you took or tried to take and the result obtained.

Funds obtained/received or attempted to obtain	Identify the sources where you obtained or attempted to obtain funds and/or steps taken to minimize your loss.	Results of your efforts	Amount Received
1.			
2.			
3.			

Have you applied for compensation from RBC or any other source relating to the processing disruption? ☐ Yes ☐ No

If yes, please provide the following details:

Amount Sought: From:

Date of Application (please attach supporting documentation):

Result (including amount obtained):

DECLARATION

I hereby declare that the information provided above is complete and accurate.

Date Signature

RBC Financial Group

HOW WE'RE MAKING THINGS RIGHT AFTER OUR RECENT PROCESSING DISRUPTION.

We're glad to say that normal business has resumed at RBC. Here are answers to the questions you're asking.

ARE MOST CHARGES REVERSED AUTOMATICALLY?

Yes. On June 8, we began to automatically reverse, wherever possible, banking service charges, fees and overdraft interest that our RBC clients may have been charged as a result of our recent processing disruption. The vast majority of necessary adjustments will likely be completed by June 30. After June 30, if you see a charge due to the processing disruption that has not been corrected, please bring it to our attention. Contact your branch, business centre or call **1-800-ROYAL* 1-1 (1-800-769-2511)**. Other financial institutions are following similar procedures for their clients. If you think you've been affected, please contact your financial institution.

I INCURRED OTHER COSTS. WILL I BE REIMBURSED?

We will provide reimbursement for substantiated costs and losses directly resulting from the processing disruption.

Here's the process: starting June 21, 2004, clients of RBC and clients of other financial institutions can obtain a Claim Form from any RBC Royal Bank branch, business centre or by calling **1-800-ROYAL* 1-1 (1-800-769-2511)**. A Claim Form can also be downloaded in PDF format from **www.rbc.com/clientnews**

Claim Forms for up to $100 with supporting documentation delivered by RBC clients to their branch will be processed by the branch. Our employees will provide you with any assistance you require in submitting your claim.

All other completed Claim Forms and supporting documentation can be returned to any RBC Royal Bank branch or business centre for forwarding or can be mailed directly to:

RBC Processing Service Disruption: Redress and Claims Process
Claims Administrator
P. O. Box 517
Waterloo, Ontario
N2J 4A9

To ensure that you have adequate time to assemble the required information, **the deadline for submitting claims is September 30, 2004.**

Again, we at RBC Financial Group express our appreciation for your patience and understanding throughout the disruption. And we acknowledge the efforts of our employees and the staff of other financial institutions who continue to work so hard to make things right.

RBC Financial Group

RBC Groupe Financier

Processus d'arbitrage

Si vous n'êtes pas satisfait de la décision prise au sujet de votre demande de remboursement, vous pouvez soumettre celle-ci à un arbitre. L'arbitre, dont les services sont retenus par RBC, prend des **décisions** indépendantes. Il examinera votre demande et rendra une décision finale et exécutoire. Si vous souhaitez qu'un arbitre examine votre demande, vous pouvez choisir une des options suivantes :

1. L'arbitre examinera la demande de remboursement et toutes les autres pièces présentées par vous à l'administrateur des demandes de remboursement ainsi que tous les documents supplémentaires que vous aimeriez y joindre pour son analyse ; ou

2. L'arbitre examinera la demande de remboursement et toutes les pièces présentées par vous et vous aurez l'occasion de lui présenter votre cas. Vous pouvez présenter vos arguments par téléphone en utilisant un numéro local ou sans frais ou en personne. Si vous souhaitez exposer votre cas en personne, vous devrez assumer vous-même vos frais de déplacement et autres dépenses. RBC ne paiera aucun des frais juridiques engagés par vous si vous retenez un avocat pour vous représenter dans l'arbitrage. RBC ne présentera aucune argumentation et ne fournira des documents complémentaires qu'à la demande de l'arbitre.

Si vous souhaitez faire appel à un arbitre, veuillez remplir la formule ci-dessous et l'envoyer à l'adresse indiquée. Vous devez le faire **dans les 30 jours** de la réception d'une décision concernant votre demande. L'arbitre prendra une décision au sujet de votre demande dans les **30 jours** de la réception de votre dossier et, le cas échéant, de l'audition de vos arguments.

La décision de l'arbitre est finale et exécutoire et ne peut pas faire l'objet d'un autre appel, d'une réévaluation ou d'une révision.

☐ Je souhaite soumettre ma demande à l'arbitrage sur la base des documents présentés initialement et de tout document additionnel inclus dans cette demande.

☐ Je souhaite soumettre ma demande à l'arbitrage sur la base des documents présentés initialement et de tout document additionnel inclus dans cette demande. J'aimerais aussi présenter mon cas à l'arbitre.

_____

[Nom en caractères d'imprimerie]

Envoyer à :

Administrateur des demandes de remboursement
Processus de demande de remboursement et de dédommagement à la suite de l'interruption de traitement
C.P. 517, Succursale Waterloo
Waterloo (Ontario)
N2J 9Z9

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RBC Financial Group

Arbitration Process

If you are dissatisfied with the disposition of your claim, you can have your claim referred to an Arbitrator. The Arbitrator is an independent **decision-maker** appointed by RBC. The Arbitrator will review your claim and render a final and binding decision. If you wish an Arbitrator to review your claim, you may choose one of the following options:

1. The Arbitrator will review the Claim Form and any other documentation submitted by you to the Claims Administrator and any additional documentation that you wish to be included in the Arbitrator's review; or

2. The Arbitrator will review the Claim Form and any documentation submitted by you and you will have an opportunity to tell your story to the Arbitrator. You can make your submissions by telephone using a local or toll free number or in person. If you wish to tell your story in person, you must pay your own travel costs and other expenses. RBC will not pay any legal expenses incurred by you if you retain a lawyer to represent you in the arbitration. RBC will not be making any submissions and will only provide additional materials at the request of the Arbitrator

If you wish to proceed with an arbitration, please complete the form below and mail to the address indicated. You must make this request **within 30 days** of your receipt of the decision regarding your claim. The Arbitrator will make a decision about your claim within **30 days** of receiving your file and, if applicable, hearing your submissions.

The decision of the Arbitrator is final and binding and shall not be the subject of any further appeal, reconsideration, review or revision.

☐ I wish to submit my claim to arbitration based upon the materials originally submitted and any additional materials included with this request.

☐ I wish to submit my claim to arbitration based upon the materials originally submitted and any additional materials included with this request. I also want to tell my story to the Arbitrator.

_____

[Print Name]

Submit Claim to:

Claims Administrator
Service Disruption and Re-dress Claim Process
PO Box 517 Station Waterloo
Waterloo, Ontario
N2J 9Z9

RBC Financial Group

AN APOLOGY FROM RBC FINANCIAL GROUP TO OUR CLIENTS, AND CLIENTS OF OTHER FINANCIAL INSTITUTIONS

On behalf of RBC Financial Group, I apologize for the inconvenience and frustration we caused during RBC's processing disruptions last week. Our first priority was to fix the problem. The problem is solved, but we will not consider this issue behind us until we have resolved the consequences for you, no matter where you bank.

We promise to refund banking service charges, fees, overdraft interest or associated past due fees you may have incurred as a result of our disruption. For RBC clients, if you see such a charge that has not been reversed, please bring it to our attention. Clients of other financial institutions should bring any such charges to the attention of their institution. Your financial institution will correct the problem and be reimbursed by RBC.

I would like to thank our clients and clients of other financial institutions for your patience and understanding. I would also like to thank all the other financial institutions in Canada for their cooperation. And I would like to thank every one of our employees for their hard work and commitment.

Yours truly,

Gordon M. Nixon
President & C.E.O.

For more information, please contact your branch, business centre, or Royal Direct at 1-800-ROYAL-1-1 (1-800-769-2511) or visit www.rbcroyalbank.com

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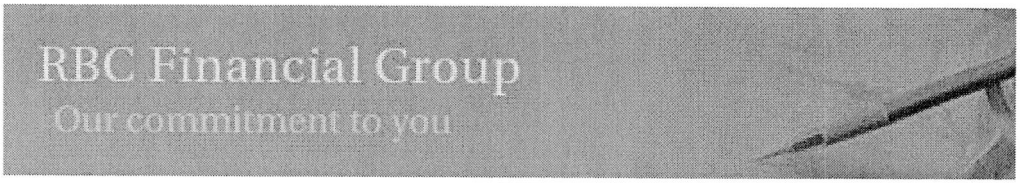

Information About RBC's Processing Delay

Status

RBC resumed normal business activities on June 7, 2004 following the processing delay of the preceding week.

Our primary objective from the very beginning of the disruption has been to minimize the inconvenience for clients of both RBC and all financial institutions, including providing immediate access to cash.

Now that the disruption is behind us, we have begun to reverse banking service charges, fees and overdraft interest that RBC clients may have been charged as a result of the processing disruption. We expect the vast majority of necessary adjustments will be completed by June 30. After that date, if you still see a charge from this time period which was incurred due to the processing disruption and that has not been reversed, please bring it to our attention by contacting your branch, business centre or by calling 1-800-ROYAL™ 1-1 (769-2511).

Other financial institutions will be following similar procedures for their clients who may have been affected as a result of the processing disruption. Those clients are asked to contact their own financial institution if they have any questions or concerns about reversal of fees.

RBC clients with questions or concerns regarding late payments, returned cheques, or past due fees should contact us. You can call our telephone banking centre 1-800-ROYAL™ 1-1 (769-2511) or contact your branch or business centre. Clients of other financial institutions are asked to contact their own financial institution.

We believe these steps will address the concerns of the vast majority of those who have been affected. Some clients may consider that the steps outlined above do not address their situation. To manage such situations, we have established a formal process to review claims for costs or losses incurred as a result of the processing disruption. Please see the

Claim Process for more information.

Extras from ACC

We are providing you with an index of all our InfoPAKs, Leading Practices Profiles, QuickCounsels and Top Tens, by substantive areas. We have also indexed for you those resources that are applicable to Canada and Europe.

Click on the link to index above or visit http://www.acc.com/annualmeetingextras.

The resources listed are just the tip of the iceberg! We have many more, including ACC Docket articles, sample forms and policies, and webcasts at http://www.acc.com/LegalResources.