NOTE FROM THE CHAIRS

These are heady times for a food lawyer, as the FDA overhauls its regulations to implement the Food Safety Modernization Act. But a perhaps even more extensive overhaul is taking place in Canada. Our lead article summarizes the Safe Food for Canadians Act, and how it will affect food producers who import into Canada. Our second feature highlights a different kind of regulatory change—a cautionary story about unintended consequences. Many modern cosmetics contain plastic “microbeads.” But mounting concern over environmental consequences is leading numerous jurisdictions to ban or limit their use. Our final article reminds us that even as the world changes, the fundamentals of good lawyering remain vital. As food litigation proliferates, the value of clear and enforceable indemnification clauses is becoming increasingly evident; we are therefore presenting concrete guidance on how to write them. We also add a brief comment on news as we publish this issue—the release of the FSMA Final Rule on Sanitary Transportation of foods.

Enjoy!

Laurie A. Henry, Jonathan Berman, John Fuson

The Safe Food for Canadians Act—Major Changes Coming for U.S. Based Food Exporters

By Christopher Oates, Associate, Gowling Lafleur Henderson, LLP

Originally passed in 2012, the Safe Food for Canadians Act (SFCA) came into force in 2015, and will, when the final rulemaking process is complete, present major changes for U.S. based companies that import food products into Canada, including a licensing requirement, and mandatory product traceability requirements. The SFCA will consolidate and replace the Meat Inspection Act (MIA), the Fish Inspection Act (FIA), the Canadian Agricultural Products Act (CAPA), and the food related provisions of the
Microbeads Legislation

By Gabriella Baki,* Andrew Hartman†, Mark Chandler,‡

Microbeads are commonly used in a variety of cosmetic and personal care products, including facial cleansers, shower gels, shampoos, hand soaps, and toothpaste. Microbeads, also known as microplastics, either are fragments of larger macroplastic items, or are originally manufactured as micro-sized plastic particles smaller than 5 mm in diameter. They are solid materials that are insoluble in water, and are non-biodegradable. Microbeads are present in various products at a variety of concentrations. The functions clearly go beyond their well-known scrubbing effect. Depending on the polymer type, composition, hardness, size and shape, microbeads can fulfill a variety of functions in products, including exfoliating agents, abrasives, viscosity regulators, aesthetic agents, and glitters. It was found that a typical exfoliating shower gel can contain roughly as much microplastic as is used to make the plastic packaging it comes in.

The most common microplastics used in cosmetics and personal care products are composed of polyethylene (PE), however, they can also be made of polypropylene (PP), polyethylene terephthalate (PET), polymethyl methacrylate (PMMA), and nylon. Today, most microbeads in cosmetics and personal care products are 500 μm or smaller.

Whereas plastics have distinct benefits, there are downsides to the "plastic age" we live in. Durability and inappropriate waste management cause their extensive accumulation in the environment, including oceans, bays, lakes, rivers, and streams. Further, plastics in aquatic environments affect numerous species that become entangled in or ingest them.

In the last decade there has been a major change in potential for microplastic pollution in the aquatic environment. Microplastic-containing products first were recognized as a minor source of plastic pollution in the 1990s. However, due to their widespread use today, the average consumer now uses microbead-containing products in the home, often on a daily basis. Many consumers are not aware they are using microbead-containing products unless they check the ingredient list and know what to look for, since the term "microbead" or "microplastic" is not disclosed on most labels. Every time a microbead-containing product gets washed off the skin, microplastics are released into wastewater. A study found that a single facial wash use can release from 4,594 to 94,500 microbeads.

A major concern is that, due to their small size, a significant portion of released microbeads pass through filters at water treatment facilities and enter the aquatic environment. Because of their widespread and frequent use, some allege these plastic particles now constitute a significant source of microplastic pollution in rivers, lakes, seas and oceans. Ingestion of microplastics has been reported for a variety of organisms—ranging from plankton and fish to birds and even mammals. Additional concerns are that their non-biodegradable nature allows them to easily accumulate. In addition, plastics contain a number of chemical additives, and they can adsorb organic contaminants from the surrounding media. Since these compounds can transfer to organisms upon ingestion, microplastics may act as vectors for other organic pollutants and are, therefore, a source of exposure to these chemicals. As plastic microbeads can be replaced with biodegradable alternatives, it is a better solution to remove them from products and replace them with alternatives than installing expensive upgrades to wastewater treatment plans throughout the country.

Given the associated potential risks of microplastics, several US states started to regulate and ban the sale and manufacture of personal care products containing microbeads in 2014 and 2015. Some of the world’s largest cosmetics companies, including Procter & Gamble, Johnson & Johnson, and L’Oréal voluntarily started phasing out microbeads in 2014 and 2015. The manufacture or the introduction or delivery for introduction into interstate commerce of rinse-off cosmetics containing intentionally-added plastic microbeads. The Federal Food, Drug and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

"(dd) The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.

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If you are a food lawyer, you are probably too busy to read a long-winded article on indemnification provisions. As you know, the industry is facing an unprecedented number of lawsuits—both for alleged food safety violations and for mislabeling. And your clients are probably looking to you more than ever to limit their risk. One way to do that is by drafting and negotiating clear-cut, enforceable indemnification clauses in their agreements with suppliers.

This article walks through the basic principles of indemnity clauses and how parties to a supply agreement may structure a balanced provision that is valuable to both sides. I will keep it short.

**Basic Terms**

In supply agreements, indemnity clauses dictate the degree of each party’s liability and the extent that each takes on or shifts risk. The terms “indemnify,” “hold harmless,” and “defend” are often used interchangeably, but actually have distinct meanings:

- **“Indemnify.”** Indemnification is a contractual obligation by one party (the indemnitor) to pay or compensate for the losses, damages or liabilities incurred by another party (the indemnitee).
- **“Hold Harmless.”** In some states, this term only releases the indemnitee from liability to the indemnitor, not third parties.
- **“Defend.”** In many states, the obligation to indemnify does not occur until resolution of the case, when the indemnitee has had a judgment entered against it for damages, or has made payments or suffered actual loss—unless the contract requires such a defense. Also, in some states (like California and New York), the right to indemnity includes the reasonable costs of defense, but in other states (like Illinois); it does not, unless expressly stated.

To avoid ambiguity, the terms should be used purposefully. And for an indemnitee to obtain full protection, the three terms should be used collectively, e.g., “A agrees to fully indemnify, hold harmless, and defend (collectively, "indemnify") B…”

- **“Damages,” vs. “Liabilities.”** An indemnity for “damages,” or “losses” or similar terms is generally considered different from an indemnity for “liabilities.” In general, “damages” are not payable by the indemnitor until the indemnitee is compelled to pay the claim, whereas an indemnity for "liabilities" requires the indemnitor to pay as soon as the indemnitee becomes liable.

**Delineating Areas of Control and Fault**

Common types of losses subject to indemnification include: breach of representation or warranty; breach of agreement; losses incurred under specified conditions; and third party claims for product defects or personal injury.

Parties should beware of overbroad or ambiguous indemnification clauses, which put the indemnitor on the hook even where it has not breached the contract or otherwise been at fault, e.g. "any liability arising out of or connected to with the services under this agreement…”

In a balanced contract, parties should only warrant and indemnify for things under their control. Each party’s obligations should be clear in the supply agreement. Likewise, in the indemnification provision, the types of fault that could reasonably occur should be defined and spelled out as attributable to a certain party.

A party may not be in a position or want to take on certain responsibilities—suppliers may have "riskier" duties under a supply agreement, although the brand may have the "deeper pocket." When reviewing indemnification language, each party should consider the worse possible scenario under the agreement and determine the level of risk.

Obviously each party wants to minimize their risk under the agreement. Factors to consider in allocating risk are as follows:

- Who would be at fault for the loss? Who is in the best position to control/mitigate the risk? If the indemnities are delineated by areas of control and fault, as a practical matter, they should be easy for each party to accept.
- What is the customary industry practice?
- Who has the bargaining power?
- Who is in the best position to insure against the risk?
On April 6, 2016, FDA published the Sanitary Transportation Final Rules in the Federal Register as industry stakeholders awaited clarification on certain issues that were actively discussed by industry stakeholders during the Comment Period.

These rules—the last of the “Big Eight” FSMA Rules—will require those who transport human and animal food in the USA via ground transportation to use specific sanitary transportation practices to ensure the safety of food. Committee members who want a “refresher course” on the FSMA Rules can access my 2014 article through their Science & Technology Law section membership access—Woodhouse, “Preparing for FSMA”, SciTech Lawyer, Summer 2014.

I comment that this topic is of particular interest to me since my family owns a trucking company and, as truckers, we always like to remind you that, “If you bought it, a trucker brought it.” Americans spend $2 Trillion annually on food and it all reaches the consumer on a truck as it moves from “farm to fork.” Thus, FDA estimates that compliance with the Sanitary Transportation Rules will involve some 84,000 domestic businesses including shippers, carriers, and receivers of food products.

The scope of the Sanitary Transportation Rules extends over substantially all of US ground transportation industry:

- **Vehicles and transportation equipment**: The design and maintenance of vehicles and transportation equipment to ensure that it does not cause the food that it transports to become contaminated.

- **Transportation operations**: The measures taken during transportation to ensure food is not contaminated, such as adequate temperature controls and separation of food from non-food items in the same load.

- **Information exchange**: Procedures for exchange of information about prior cargos, cleaning of transportation equipment, and temperature control between the shipper, carrier, and receiver, as appropriate to the situation. For example, a carrier transporting bulk liquid non-dairy foods would want to ensure that vehicles that have previously hauled milk will not introduce allergens into non-dairy foods through cross contact.

- **Training**: Training of carrier personnel in sanitary transportation practices and documentation of the training.

- **Records**: Maintenance of written procedures and records by carriers and shippers related to transportation equipment cleaning, prior cargos, and temperature control.

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm

*Charles Woodhouse is a partner in Woodhouse Shanahan PA. He received his BA from Dartmouth, MBA from Wharton, JD from Rutgers, and MS Food Safety from Michigan State where he is Adjunct Professor of Law and is currently pursuing an additional graduate degree in Packaging (Materials Science and Engineering) at MSU.*
The Sanitary Transportation Final Rules will present particularly serious challenges to those US Importers who “cause” international shipment of food (and thus the domestic ground portion of transport) and the overseas Suppliers who “initiate” these same shipments.

Nearly every significant US participant in the food business (there are certain de minimis exceptions) will be required to prepare a Sanitary Transportation Plan—but Importers will have the additional challenge of assisting their Suppliers in preparation of Sanitary Transportation Plans.

To this end, the below FSMA documentation chart illustrates the relationship between Importer and Exporter and the relationship between the FSMA mandated RBPC (Risk-Based Preventative Controls) Plans and Sanitary Transportation Plans.

At this point practitioners should not become overly concerned—there will be adequate time for domestic compliance. As anticipated, the Rule will become effective in 60-days and the compliance date for large companies will be June 2017. Smaller businesses should be aware that major Retail Grocery and Food Service operators will begin requesting the required Supplier Sanitary Transportation Plans in the relatively near future as part of their vendor documentation packages. Thus, even Importers that meet the small business requirements may have a relatively unforgiving timetable for assisting their overseas Suppliers on compliance issues.

We will publish a more detailed guide to the preparation of Sanitary Transportation Plans in our next FCN issue. However, practitioners should also be aware that the supply of Qualified Individuals (FDA definition) available to prepare RBPC (Risk-Based Preventative Controls) Plans and Sanitary Transportation Plans is limited and the timelines for compliance are short. Readers who are interested in earning professional qualifications in this area should consider one of the MS Food Science and LLM Food Law programs offered at a number of American research universities. For a general discussion of these programs please see the “Food Law Education” article by Michigan State University Professor Neal Fortin in our Fall 2014 issue.

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Consumer Packaging and Labelling Act, and is intended to improve Canada’s food safety system by implementing stronger food safety rules, allowing more effective inspection, and providing more information to consumers. This article is intended to provide an overview of the key changes expected under the SFCA, with a particular focus on their impact on U.S. based food companies importing food into Canada.

Licensing and Registration

Subject to limited exceptions, the proposed regulations under the SFCA will require all persons that import foods into Canada to have a licence. The licensing process is intended to provide the Canadian Food Inspection Agency (CFIA) with a more complete picture of the importation of food into Canada, and to allow the collection of data for the oversight of the food safety system. To this end, the regulations would require applicants to import food to have either a fixed place of business in Canada, or in a foreign state that has a food safety system in place that affords a similar level of protection to that of Canada (U.S. based importers should note that Canada is engaged in a reciprocal assessment of our respective food safety systems with the U.S. Food and Drug Administration).

The licensing process is expected to require importers to disclose information regarding the products they import, their intended use and processing, the annual volume of imported goods, and their typical country of origin. The licence would indentify both the food products the licensee is authorized in respect of, and the activities they are authorized to conduct (e.g. manufacturing, processing, treating, preserving, grading, packaging, or labelling food). Licensees may choose whether to have one or multiple licences to cover their operations. While holding multiple licences may increase the costs associated with licensing, it may also present an opportunity to prepare separate ‘preventative control plans’ targeted to the activities stated in each licence, and may address some risk, given the potential for licence suspension. Licences are proposed to be valid for a period of two years, and applications or renewals would be subject to a proposed $250 CAD fee.

The licensing system would provide increased regulatory oversight by allowing the Minister of Agriculture and Agri-Food broad powers to suspend a licence where its holder failed to comply with a requirement of the SFCA or the Food and Drugs Act (FDA). Where the cause of the suspension does not pose a risk to human health, prior to the suspension of the licence, its holder would be provided with a notice of the grounds for suspension and corrective measures that must be implemented to avoid it. In cases where there is a risk of injury to human health, the Minister may suspend the licence immediately. If a licence is suspended twice, or if its holder is convicted of an offence under the SFCA or FDA, the licence may be cancelled.

Proposed exceptions to the licensing requirements include the importation of food additives and beverages that contain over 0.5% alcohol by volume.

Traceability

The draft regulations will create a standard for food product traceability that requires importers to retain documents that identify the person from whom they received food, their address, the food received, and the date on which it was received. When food is sent to another person, the importer must retain the name of the person to whom it was sent, along with their address, and the food sent, and the date. The CFIA has summarized this proposal as requiring "one step forward and one step back" traceability- food must be tracked forward to the immediate customer, and back to the immediate supplier. To facilitate recall situations, these records would need to be maintained for a period of three years, (regardless of whether the food product is perishable on a shorter timeframe), and would need to be provided to the Minister on request in electronic format in English or French, in plain text that can be manipulated using standard commercial software. The records would be required to be accessible in Canada. These records would be supplemented by a requirement for foods to be labelled with a identifier such as a lot identifier, bar code, or universal product code.

Prohibitions and Offences

The SFCA includes a number of new prohibitions and offences in relation to food products. These include a prohibition on tampering with a food, or its labelling/packaging, with intent to render it injurious to human health, or to create a reasonable apprehension the food is injurious to human health. Further provisions prohibit selling a food that is subject to a recall order, and strengthening the existing prohibitions on selling, labelling, or advertising food in a manner that is false, misleading, or deceptive as to its quality, composition, merit, safety, origin, or method of manufacture.

The legislation will also significantly increase the potential penalties associated with violations associated with food. Minor violations of the SFCA that proceed by summary conviction will be punishable by a fine of up to $250,000 and/or imprisonment for up to six months, increasing to a fine of up to $500,000 and/or imprisonment for up to
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18 months on a subsequent offence. Major violations could be subject to a fine of up to $5 million, and/or imprisonment for up to two years. Higher penalties, including a fine at the discretion of the court and up to five years imprisonment, are possible for tampering with food or knowingly or recklessly creating a risk of injury to human health.

Food Safety Requirements

The regulations are proposed to include minimum requirements for operators of establishments where food is manufactured, prepared, stored, packaged or labelled. These will include baseline requirements with respect to sanitation and pest control, hygiene, and the physical structure and maintenance of food establishments.

Licence holders will also be subject to new notification requirements, including an obligation to conduct an investigation when they learn that a food may present a risk of injury to human health, and a requirement to notify the Minister without delay if the investigation confirms such a risk exists. The licensee will be required to have an effective recall procedure, and conduct a recall simulation at least once a year. If the licensee recalls a food product, it must notify the Minister, and maintain records identifying the date of the recall and how it was carried out, for a period of three years.

Preventative Control Plans

All applicants for the issuance or renewal of a licence to import food would be required to have a Preventative Control Plan (PCP) in place as part of a system-based approach to food safety and prevention management. Such plans would be required to identify the hazards that would need to be prevented, eliminated, or reduced in the respect of the licensee’s food or processes, and demonstrate how those hazards will be controlled. The PCP would need to identify critical control points and limits that are supported by evidence to demonstrate that the hazard control measures adequately address the identified hazards, and must include monitoring and corrective action procedures. In addition to preparing a PCP, the licensee would be required to implement it, and to prepare and retain documents to evidence their compliance with both the PCP and the SFCA more broadly.

The CFIA intends that the PCP may be used as a tool for inspectors in assessing licensee compliance with the SFCA.

Inspection

A major element of the SFCA is the centralization of food inspection authority, consolidating the powers currently available under the MIA, FIA, and CAPA. Under the SFCA, inspectors are permitted to enter places and conveyances to verify compliance (or prevent non-compliance), and may exercise a variety of investigatory powers, including examining or taking samples of anything found, including documents and computer systems and devices, opening packages, taking photographs, limiting access to all or part of the location, and removing anything from it for further examination, testing, or sampling. Inspectors are permitted to seize and detain anything they have reasonable grounds to believe was used in contravention of the Act.

Labelling

The SFCA and the regulations under it are not intended to drastically change the requirements for food labelling in Canada, nor the standards of identity prescribed for many food products. However, they are intended to consolidate and streamline the duplication and differing requirements that are currently found in a variety of statutes such as the MIA and the CAPA. The more extensive labelling requirements in respect of foods in Canada would remain those found under the FDA and its regulations, and are not being amended as part of the implementation of the SFCA. However, importers should be aware that Health Canada and the CFIA continue to consider changes to food labelling in Canada as part of the ongoing Food Labelling Modernization Initiative.

Conclusion

Final coming into force dates for all SFCA regulations are not yet known, since the final versions of the regulations have not yet been published and it is anticipated that draft regulations will continue to be published in the Canada Gazette during 2016. Similarly to FSMA in the United States, SFCA regulations are expected to be supported by extensive guidelines and interpretive documents which have currently not been fully issued by the CFIA. While the final form of the regulations, guidelines, and the coming into force dates are not yet available, entities that are involved in the import of food products into Canada must be aware that major changes are on the horizon.

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Insurance

Indemnification provisions should reflect the parties’ insurance coverage. In other words, the indemnitor for a type of loss should be the one to obtain insurance for that loss and should name the indemnitee as an additional insured. An indemnity may only be as strong as the insurance the party has to back it up—especially where the indemnitor is a small company with limited assets. Additional insured status gives the indemnitee the right to claim directly against the indemnitor’s insurer, which can include the right to immediate defense and avoid a recovery dispute between the parties. Although general liability policies provide coverage for claims by consumers alleging “bodily injury” or “property damage,” they will likely cover very few, if any, of the costs associated with a food recall. There are a variety of specialty policies available, however, that will provide coverage for recall-related losses.

Practical Considerations

Finally, for ease of enforceability, an indemnification section should include provisions for how a claim will be handled, including: notification, right to control the defense, right of the other party to participate with its own counsel, and the obligation to advance or reimburse legal fees and costs.

ABOUT THE AUTHOR:

Rebecca Cross is a partner with BraunHagey & Borden LLP, a San Francisco-based litigation boutique. She has served as outside general counsel to a number of food product clients, advising them on regulatory and litigation risk regarding labeling, advertising, supply chain management, product safety and recalls.
Canada and Australia have also joined the U.S. and the EU in their efforts to ban the manufacture and selling of products containing microbeads.

Microscopy image of microplastics (microbeads) extracted from shower gel.
Endnotes


Editor’s Notes:

(1) Because of the ongoing regulatory actions, readers are encouraged to keep up-to-date on the CFIA's web-pages on the Safe Food for Canadians Action Plan at: http://www.inspection.gc.ca/food/actionplan/eng/1366921334607/1366921368545
(2) The complete text of the SFCA is available on the Canada Justice website which includes links to all amendments and coming into force dates at: http://laws-lois.justice.gc.ca/eng/acts/S-1.1/
(3) Michigan State University's Institute for Food Laws and Regulations offers a full-semester online course—Food Regulation in Canada at: http://www.iflr.msu.edu