The oversight of food packaging in Canada is at a crossroads. In the past two years, the industry has seen significant changes in the way food packaging is reviewed by the Canadian government, particularly with the Canadian Food Inspection Agency’s (CFIA) gutting of its mandatory packaging review program. CFIA’s sister agency, Health Canada, is also contemplating whether to continue with its voluntary review system. What are the legal obligations that apply to food packaging in Canada? What does it take to obtain a voluntary Health Canada “letter of no objection” (LNO)? And, why is Health Canada, like CFIA, thinking about getting out of the LNO business?

FOOD PACKAGING OVERSIGHT HISTORY

Until this summer, two Canadian agencies had historically reviewed packaging used in food contact:

- CFIA, which mandated that packaging used in federally registered facilities (e.g., meat, poultry, dairy, egg, fish facilities) have a CFIA “letter of acceptance” (LOA) prior to use
- Health Canada, which voluntarily reviews the packaging of all other foods

While CFIA continues to have authority to inspect food processing facilities, it no longer mandates LOAs on packaging used in CFIA registered facilities; the last vestige of CFIA oversight of food packaging disappeared with a July 2, 2014 amendment of the Meat Inspection Act to remove the premarket approval requirement for meat packaging materials. Health Canada, for the moment, still conducts its

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FOOD PACKAGING LEGAL STANDARDS

Canada’s Food and Drugs Act prohibits the sale of food that, among other prohibitions, contains any harmful substance, is adulterated, or is manufactured, packaged, or stored under unsanitary conditions. It is this provision of the Act that provides Health Canada its statutory authority over food packaging materials. However, unlike in the U.S., food packaging materials are not considered “food additives” and, as such, are not subject to mandatory premarket clearance.

Section B.23.001 of the Food regulations, “Food Packaging Materials,” further mandates that “no person shall sell any food in a package that may yield to its contents any substance that may be injurious to the health of a consumer of the food.” Health Canada administers the Act and its implementing regulations by setting standards for ensuring the safety of the Canadian food supply and, through its Health Products and Food Branch (HPFB), conducting voluntary health risk assessments regarding packaging materials.

HEALTH CANADA LNOS

Unlike the old CFIA LOAs, Health Canada LNOs are not legally mandated. No “positive” list of permitted food contact materials exists in Canada, and with the exception of some very specific provisions limiting the presence and migration of some nasty actors, the Food Regulations do not address the chemical compositions of food packaging materials. If a company does request an LNO from Health Canada, it will receive an opinion, not an “approval.” While LNOs are voluntary communications, the letters are intended to make it unlikely that specified products and uses will lead to a regulatory violation.

The legal burden to ensure safety of packaged food falls on the food sellers, who in turn frequently try to shift this liability to their packaging suppliers by mandating contractually that they obtain a voluntary Health Canada LNO prior to marketing. LNOs have thus become valuable marketing tools to packaging suppliers and can ease entry into the Canadian food packaging market.

Health Canada will issue LNOs on products that run the gamut of the supply chain—formulated products, films, containers, resins, color concentrates or even single additives. An LNO will:

- Identify the product
- Provide a statement of HPFB’s “no objection” regarding the specified use
- Contain a proviso indicating the package must be technically suitable for the identified use

Health Canada considers LNOs to be valid as long as the package’s composition and intended use do not change; no “expiration date” is identified. However, HPFB mandates that a packaging manufacturer notify Health Canada of any changes made to a substance that has been the subject of an LNO. If not notified, Health Canada reserves the right to rescind the letter.

The complexity of an LNO submission depends on the complexity of the product under consideration, i.e., whether it is a formulated material/structure or a novel chemical that requires a substantial amount of analytical and safety data to support its use.

Health Canada continues to experience very high demand for LNOs and considerable delays can occur in their issuing letters. This, and the severe budget cuts the Agency continually faces, has also caused Health Canada to reevaluate its voluntary LNO process. In a June 26, 2014 teleconference with stakeholders, Health Canada indicated it was considering two possible futures for its packaging review program: Either maintenance of its existing program with the development of positive and negative lists, with a cost recovery or fee for service element, or a cessation of the program in favor of a post market only approach. Health Canada is seeking input from industry on views of the voluntary program, and its future.

About the Author: Catherine Nielsen is a partner at the law offices of Keller and Heckman LLP. She practices in the area of food and drug law, with an emphasis on food additives and food contact materials. Ms. Nielsen advises clients on the regulatory compliance of food contact substances in the U.S., Canada, Europe, Central and South America, and the Pacific Rim. She also assists companies in assessing potential adulteration issues and advising on potential recalls. Additionally, she advises companies on compliance with California Proposition 65 and Coalition on Northeastern Governors “Toxics in Packaging” legislation, and other state legislation dealing with toxic substance exposure issues.