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Scientific Evaluator Discusses Regulation of Food-Contact Materials in Canada

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Canada is reviewing its voluntary letter of no objection (LONO) program for food packaging materials, while continuing to process existing and new requests for assessments, said Elena Emelianova, Ph.D., Health Canada. Speaking on the regulation of food-contact materials in Canada, she explained that the triggers behind the review are:

- Amendments to the *Canadian Fish Inspection Regulations*, *Egg Regulations*, and *Meat Inspection Regulations*, which repealed the requirement in Canada for pre-market authorization of food packaging materials in federally registered facilities, and
- A call by Health Canada's Health Products and Food Branch for a review of existing operations to find efficiencies in program delivery.

Currently, under the Canadian Food and Drugs Act and related regulations, premarket clearance of food packaging materials is not mandatory, except for packaging for infant formula and certain novel processes. Nevertheless, packaging materials (both finished products and components of packaging) intended for use in contact with food may be submitted voluntarily to the Food Directorate in the Health Products and Food Branch (HPFB) for a safety evaluation. If HPFB considers the material to be acceptable for its intended use, it will issue a LONO.

A LONO is not equivalent to an "approval" by Health Canada, emphasized Dr. Emelianova, adding that the food seller (*i.e.*, manufacturer, packager, distributor, etc.) is responsible for ensuring that materials used in contact with food are safe for their intended use. Once Health Canada receives a request for a LONO, it will send an acknowledgement letter with a file (KS) number to the petitioner typically within two to four weeks. The timeframe for receiving a substantive response from Canada depends on the workload of the reviewers when the submission is received. A first response can take roughly two to four months after the acknowledgement is sent. Dr. Emelianova further explained that, while safety opinions are generally issued on a first-come first-served basis, priority is given to materials that are: 1) used for infant formula packaging; 2) associated with certain novel processes; and 3) intended to replace bisphenol A (BPA).

Noting that confidentiality is very important, Dr. Emelianova pointed out that, under Canada's *Access*

to Information Act, “information provided to Health Canada is used in confidence for evaluation purposes only and is not divulged to any third party, without express written consent of the person or company that originally provided the information.” [add “Emphasis added” note?]

The Canadian Food Inspection Agency (CFIA) is responsible for inspection of federally registered food facilities. Before July 2014, a federally-registered meat, fish, or egg processing plant could not use a food packaging material unless it had received a letter of acceptance (LOA) from CFIA, and it appeared in CFIA’s *Reference Listing of Accepted Construction Materials, Packaging Materials, and Non-Food Chemical Products* database (which has now been archived and is no longer being updated). CFIA generally required an opinion from Health Canada on the safety of food packaging materials before CFIA could complete its review of an application for an LOA.

Despite the elimination of the premarket registration requirement for food packaging materials used in federally registered food establishments, operators are still responsible for demonstrating to CFIA inspectors that the materials used in these facilities are safe under Canada’s Hazard Analysis and Critical Control Point (HACCP) program. Dr. Emelianova said this can generally be accomplished through a LOA and listing on the archived Reference Listing, a LONO from Health Canada, or a third party letter in the form of a Letter of Guarantee (LOG) asserting that the food packaging material meets federal safety requirements.

(The third party letter may not be used for antimicrobials used on meat and poultry products, which must be the subject of a LONO or interim LONO (iLONO)).

Dr. Emelianova also provided an update on Canada’s Chemicals Management Plan (Plan) as it relates to food. Launched in 2006, the objective of the Plan is to prevent or manage any environmental and human health risks posed by chemical substances. She told attendees that for substances defined as toxic under the Canadian Environmental Protection Act (CEPA) for which there are food implications, the Food Directorate has several options, ranging from regulatory or policy changes to surveillance to enforcement action.

Finally, Dr. Emelianova indicated that Canada is considering various approaches for regulating food packaging materials in the future, and did not rule out the possibility that the law may be changed to mandate their premarket approval. The considerations being taken into account with respect to a potential shift in the regulatory framework for packaging materials in Canada include the following:

- Any process dealing with oversight of food packaging materials must be based on sound scientific principles;
- Any new “approach” should lead to a predictable and effective program;
- To the greatest extent possible, any changes should align with approaches adopted by Canada’s major trading partners;
- Stakeholder requirements and perspectives must be considered; and
- Any new approach should be sustainable.

Once developed, consultation documents outlining proposed options will be posted for broader stakeholder comment and consultation, Dr. Emelianova told attendees.

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