

SPI Canada visit to Health Protection Branch of
Health & Welfare Canada, Ottawa. June 29, 1990

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Summary

Health Protection Branch (HPB) have the responsibility for clearance of materials used in packaging of foodstuffs. They are moving towards a system of preclearance of materials by 1991 - but, do not plan to have a positive listing procedure.

Attempts to harmonize standards between U.S. and Canada are underway, but is proving to be very difficult due to incompatible laws and regulations. It is unlikely that any significant harmonization will occur in the foreseeable future.

HPB have completed the first stage of a study of plasticizer migration into foods. Concerns have been raised about high levels in fatty foods and microwaved foods. New regulations and warning labels are being considered.

The thermal breakdown products of pigments used in packaging materials is coming under scrutiny.

HPB have reacted to FDA's recent concerns about Acrylonitrile.

Consideration is being given to regulating household and retail products used in contact with food, such as utensils and plastic wrap.



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As part of SPI Canada's Health and Welfare Committee, I participated in a meeting with Federal Governments Health Protection Branch with the purpose of updating ourselves on HPB's current and future activities, organization and relationship with U.S. counterparts, such as FDA.

Other members of the SPI Committee attending were:

Jack Soule - DuPont Canada
George Rundans - Monsanto Canada
Bob McPhail - Hoechst Canada
Louise Moelle - BASF U.S.
Basil Darrah - SPI Canada

Health and Welfare attendees:

Dianne Kirkpatrick - Bureau of Chemical Safety
Mike Pelletier - Food Packaging Materials
Bob Piple - Food Packaging Materials
Dennis Page - Food Packaging Materials
Bob Smith - Food Regulatory/Interagency
Don Grant - Toxicological Evaluation Division
B. Huston - Chemical Evaluation Division

BACKGROUND

HPB is in many respects the Canadian equivalent of the FDA in the U.S. as far as plastics packaging is concerned. Its' approval is required for the use of any material used in contact with foodstuffs, it conducts research into the health implications of materials used in contact with food, designs its own test procedures and sets allowable limits. Within the organization, its scientists are constantly looking at the toxicological and carcinogenic properties of established and new materials with a view to establishing Canadian regulations for public health.

It differs from FDA in several ways, the most significant being the absence of a positive listing procedure. HPB will not accept an FDA listing as green light for clearance. They will take into account the scientific basis which led to FDA approval, but will invariably make their decisions based on their own tests and criteria.

NEW POLICIES AND ACTIVITIES

-HPB are moving closer to a system of pre-clearance of new materials or uses, with a target installation date of April 1991. It was stressed that there are no plans for positive listing at this time.

-Toxicity guidelines are to be published in April 1991. Threshold limits are being reviewed and will likely be tightened, based on new, and as yet unpublished toxicological studies.

-Communication of risk to the public will be improved through use of publications written in layman's, rather than scientific language and an improved phone-in inquiry system will be developed to answer questions from the public.

-Canada will continue to promote CODEX as a way of achieving International standardization.

HARMONIZATION UNDER CANADA-US FREE TRADE AGREEMENT

-Discussions are ongoing between representatives of the FDA and Health and Welfare Canada on the subject of additives and contaminants with a view to harmonizing standards between the two countries with the intent of reducing barriers to trade. To date, there has been an identification of differences in policies, regulations and legalities.

-The consensus, so far, is that the inherent legal and regulatory systems are so different between the two countries, that there will be no across-the board harmonization in the foreseeable future. Some of the major laws and regulations which have no equivalent in Canada include:

- The Delaney Clause and Constituents Policy
- De-Minimus approach
- Food irradiation is defined as a food additive in the U.S. and as a process in Canada
- GRAS (addresses use not substances)
- Prior sanctioned substances
- Freedom of Information does not apply in Canadian system, which causes concerns about protection for Canadian data crossing the border.

-In the harmonization process, packaging has a low priority, the top priority is given to trade irritants.

PLASTICS RECYCLING

-No regulations exist, but concerns have arisen over the possibility of contaminated material being used in recycled packages for food contact applications. It seems likely that if this becomes an issue, HPB will regulate if industry does not regulate itself.

HOUSEWARES/FOOD PREPARATION AND STORAGE

-Although housewares are currently beyond the scope of HPB's activities, there is a possibility of regulation down the road if there is sufficient public concern.

PLASTICIZERS

-Reports from ICI and the Mitre report on carcinogenic and Peroxisome proliferation were tabled for discussion, focusing on DEHA, DEHP and other plasticizers. HPB were interested in these and other studies and have been conducting their own work on plasticizers, which they regard as a key area of concern.

-HPB have just completed a major study of plasticizer migration from commercial packaging. Tests were conducted on the following products found in supermarkets and restaurants.

- Foods wrapped in plasticized film at the retail level e.g. sandwiches, cheese, meats, etc.
- Manufactured packages e.g. luncheon meats, cheese, butter, fast foods, etc.
- Foods in contact with cap liners e.g. baby food, water, beer, jams, etc.
- Foods transported through plasticized hoses e.g. maple syrup, juice concentrates, etc.

Analysis by GC/MS, GC/MS and Mass spectroscopy were done to determine plasticizer type and concentration in food.

Results, not surprisingly, showed that the higher the fat content and the higher the surface area of foods wrapped at retail deli and meat counters, the higher the migration, with cheese coming in at levels of 111-310 ppm of DEHA. Meats and other foods wrapped in plasticized films showed a threefold increase in plasticizer content after cooking, compared with cold. Manufactured luncheon meat packages showed very low levels of plasticizer migration. All non-fatty content packages showed low levels of migration.

Cap liners showed very little migration into beer, water or wine. Similarly, baby foods, jams and jellies had low plasticizer migration.

This study is being followed up with a total diet-based lab study. The data developed from both studies will go to the toxicological department for risk assessment and recommendations. It is uncertain what HPB plans to do, but it seems likely that there will be tighter limits on the use of plasticized PVC in contact with high fat foods and cooked foods.

It is almost certain that warning labels or regulations will be required regarding the retail and consumer use of plasticized food wrap for regular and microwave oven use.

PIGMENTS

HPB have a general concern about the toxicity of degradation products of pigments used in plastics. This was highlighted by the

withdrawal of diarylide pigments from the market by Hoechst. It is expected that future testing of pigments will be done with due consideration to chemical changes at processing temperatures.

ACRYLONITRILE

Recent activities in the U.S. related to the FDA's announcement requesting data and instruction on the use of acrylonitrile based packaging has prompted HPB to investigate this area. High nitrile packaging resin is a major concern as are PVC-nitrile blends.

HPB indicated that they welcomed the opportunity to meet with SPI and are interested in further meetings of this type. This would open up the opportunity of providing them with any studies we have on plasticizer extraction.

L.Y.