AN 6970

MEMORANDUM

Date: November 9, 1992

To: R. Hinderer OTM-3

From: W. Ban OTM-3

Subject: Canada HPB methyl tin issue

Bob, I have reviewed the materials you provided, the Keller & Heckman letter dated November 3, 1992, the sheet on Division 23 Food Packaging Materials, and the text of the speech presented by Robert A. Ripley on Canadian Food Packaging Regulations.

[redacted]

cc: Larson

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November 3, 1992

(202) 434-4164

Robert Hinderer, Ph.D.
Director of Health, Toxicology
and Product Safety
The BFGoodrich Company
Geon Vinyl Division
6100 Oak Tree Boulevard
Cleveland, Ohio 44131

Re: Canadian Food Packaging Requirements; Our File No. BF4159

Dear Bob:

Dr. Lester Borodinsky and I certainly enjoyed our telephone conversation with you last Friday regarding the regulation of food-contact materials, particularly polyvinyl chloride (PVC), in Canada. The purpose of this letter is simply to provide you with the additional information you requested regarding the Canadian regulatory system for food packaging materials.

As I indicated, Canada does not regulate indirect food additives in the same way as the United States. This is because, under Section B01.001 of the Canadian Food and Drug Regulations, a food additive is defined as "a substance, including any source of radiation, the use of which results, or may reasonably be expected to result in it or its byproducts becoming part of or affecting the characteristics of the food, but does not include . . . (e) food packaging materials and components thereof . . . (emphasis supplied). Thus, food packaging materials do not require preclearance by the Health Protection Branch (HPB) before being sold in Canada.

[redacted] See Division 23 of Canada's Food and Drug Regulations (copy enclosed). [redacted]

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the range of a [redacted]). As requested, a copy of the official analytical method for the determination of vinyl chloride in food is enclosed. Furthermore, you will notice several regulations that either limit or ban the use of an octyltin chemical in PVC formulations intended for use in food packaging.

Finally, there is a "good manufacturing practices regulation," Section B.23.001, which states that "[n]o 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." This regulation places the burden on the food processor to ensure the safety of any packaging materials it uses. In turn, this all too often prompts the food processor to request that his packaging supplier(s) obtain a "no-objection" letter from Canada's HPB.

In considering such requests, HPB does take into consideration the U.S. Food and Drug Administration (FDA) status of the packaging material at issue, but is by no means willing to rely on FDA status alone. In fact, it has come to show less and less respect for FDA decisions since 1977 when there arose a difference of opinion regarding some toxicology concerns. Thus, the Canadians require that compositional information and use conditions of a packaging material be provided in detail before it will issue any "no-objection" letter. We deal with the proper Canadian officials regularly and cordially in these types of matters, should you like our assistance in getting something in writing from HPB to show that it has no objection to the use of a given BFGoodrich material in Canada.

For a more complete discussion of the Canadian status of food packaging materials, enclosed are two additional items. The first is a letter from Dr. Robert Ripley, the Director of HPB's Food Packaging Materials and Incidental Additives Section, Chemical Evaluation Division; this letter outlines the basic legal requirements for food packaging materials in Canada. The second item is a copy of a speech Dr. Ripley presented on Canadian Food Packaging Regulations to The Society of the Plastics Industry, Inc.'s (SPI) Food, Drug, and Cosmetic Packaging Materials Committee at its December, 1990 meeting in Palm Springs, California.

* * *

We trust that this letter and the enclosures will give you some helpful background in this area. If you have any questions about the material, or if we can be of assistance in submitting

to HPB a request for a no-objection letter for a particular packaging component, please do not hesitate to let us know.

Cordially yours,

T. Phillips Beck

Enclosures

cc: Robert C. Campbell (w/encls)

Food Packaging Materials

B.23.001. 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.

B.23.002. Subject to section B.23.003 no person shall sell any food in a package that has been manufactured from a polyvinyl chloride formulation containing an octyltin chemical.

B.23.003. A person may sell food, other than milk, skim milk, partly skimmed milk, sterilized milk, malt beverages and carbonated non-alcoholic beverage products, in a package that has been manufactured from a polyvinyl chloride formulation containing any or all of the octyltin
4-12-86 chemicals, namely, di (*n*-octyl)tin S,S'-bis(isooctylmercaptoacetate), di (*n*-octyl)tin maleate polymer and (*n*-octyl)tin S,S',S"-tris (isooctylmercaptoacetate) if the proportion of such chemicals, either singly or in combination, does not exceed a total of 3 per cent of the resin, and the food in contact with the package contains not more than 1 part per million total octyltin.

B.23.004. (1) Di (*n*-octyl)tin S,S'-bis (isooctylmercaptoacetate) shall be the octyltin chemical made from di (*n*-octyl)tin dichloride and shall contain 15.1 to 16.4 per cent of tin and 8.1 to 8.9 per cent of mercapto sulfur.

(2) For the purposes of this Division, di (*n*-octyl)tin dichloride shall be the chemical having an organotin composition of not less than 95 per cent di (*n*-octyl)tin dichloride and shall contain not more than

4-12-86

(a) 5 per cent total of *n*-octyltin trichloride or tri (*n*-octyl)tin chloride or both;
(b) 0.2 per cent total of other eight (8) carbon isomeric alkyltin derivatives; and
(c) 0.1 per cent total of the higher and lower homologous alkyltin derivatives.

B.23.005. Di (*n*-octyl)tin maleate polymer shall be the octyltin chemical made from di (*n*-octyl)tin dichloride and shall have the formula $((C_8H_{17})_2SnC_4H_2O_4)n$ (where *n* is between 2 and 4 inclusive), and a saponification number of 225 and 255, and shall contain 25.2 to 26.6 per cent of tin.

B.23.006. (1) (*n*-octyl)tin S,S',S"-tris (isooctylmercaptoacetate), being an octyltin chemical having the formula $n\text{-}C_8H_{17}Sn(SCH_2CO_2C_8H_{17})_3$, shall be made from (*n*-octyl)tin trichloride and shall contain 13.4 to 14.8 per cent of tin and 10.9 to 11.9 per cent of mercapto sulfur.

(2) For the purposes of this Division, (*n*-octyl)tin trichloride shall be the chemical having an organotin composition of not less than 95 per cent (*n*-octyl)tin trichloride and shall contain not more than

4-12-86

(a) 5 per cent total of di (*n*-octyl)tin dichloride, tri (*n*-octyl)tin chloride or the higher (more than eight (8) carbons) alkyltin chlorides or any combination of the foregoing.
(b) 0.2 per cent total of alkyl tin derivatives; and
(c) 0.1 per cent of the lower (less than eight carbons) homologous alkyltin derivatives.

5-8-82 **B.23.007.** No person shall sell a food in a package that may yield to its contents any amount of vinyl chloride, as determined by official method FO-40, Determination of Vinyl Chloride in Food, October 15, 1981, in respect of that food.

27-5-82 **B.23.008.** No person shall sell a food in a package that may yield to its contents any amount of acrylonitrile as determined by official method, FO-41, Determination of Acrylonitrile in Food, February 16, 1982, in respect of that food.

Official Method

FO-40
October 15, 1981

HEALTH PROTECTION BRANCH

OTTAWA

DETERMINATION OF VINYL CHLORIDE IN FOOD

I. APPLICATION

This method shall be used for the determination of vinyl chloride in such foods as vegetable oils, oil based products, and vinegars under Section B.23.007 of the Food and Drug Regulations.

II. PRINCIPLE

The vegetable oil or vinegar is heated in a constant temperature water bath and a one mL sample of the head space gas is injected into the gas chromatograph. The vinyl chloride is identified and quantitated by gas chromatography at levels greater than 50 µg/kg.

III. APPARATUS

(1) Gas chromatograph, Varian Model 2100 or equivalent, equipped with:

(a) flame ionization detector;

(b) 6' x 1/4" o.d. or 6' x 2 mm i.d. glass column packed with 5% OV-101 on Chromosorb W, HP, 100-120 mesh (Note 1);

(c) operating parameters — temperatures (°C)

detector	265
injection port	150
column	room temperature

room temperature implies the temperature when the oven door is left open and no oven heat supplied; the actual temperature is slightly above room temperature due to heat from detector and injection port.

carrier gas — nitrogen.

(I) Use 5 µL injections of standard vinyl chloride to adjust carrier gas flow rate to give a retention time of approximately (ca) 80 sec by stop watch for vinyl chloride.

(II) Adjust H_2 and air flow rates to obtain maximum peak height from injection of standard vinyl chloride to determine the maximum sensitivity for vinyl chloride detection.

(III) Determine instrument attenuation which will give a 90% full scale deflection with 5 µL injection of standard vinyl chloride or maximum sensitivity possible.

(IV) Peaks can be caused by insertion and removal of syringe from septum. Leave syringe in septum 40 seconds, after all injections, to avoid interference.

(V) After vinyl chloride peak has eluted, (vinyl chloride elutes before the solvent peak) flush out the solvent, aqueous ethanol, using the following procedure:

(a) close oven door;

(b) set oven temperature dial to 180°C;

(c) ten min after setting dial, open oven door;

(d) set temperature dial to room temperature;

(e) allow oven to cool for 30 min.

(VI) Replace septa frequently.

(VII) Determine all retention times with the stopwatch as measured from time of injection.

(2) Recorder, one mv.

(a) chart speed ≈ 2/3" (1.7 cm) per minute.

(3) Stop watch.

(4) Syringes, Hamilton, 10 µl size.

(5) Syringe, gas-tight, 2.5 mL size.

(6) Reacti-flasks, 25 mL size.

(a) equipped with screw caps and teflon faced septa.

(7) Water bath, shaker type.

(a) equipped with temperature control capable of maintaining temperature of bath to within 1°C.

IV. REAGENTS

(1) Gas cylinder of vinyl chloride.

(2) Ethanol, reagent grade.

(3) Mercury.

(4) Standard solutions of vinyl chloride.

(a) weigh a known volume of ethanol into a tared septum sealed vial containing 1-2 mL of mercury;

(b) bubble vinyl chloride slowly into the ethanol through a syringe barrel and needle;

(c) vent the vial with a second syringe needle;

(d) after 5-10 min remove the needles;

(e) invert the vial to form a mercury seal;

(f) weigh vial and contents;

(g) determine the weight of vinyl chloride;

(h) dilute aliquots of this stock solution to prepare working solutions;

(i) confirm their concentration by comparison with the stock solution (Note 2).

V. PROCEDURE

The test shall be carried out in accordance with the following instructions:

1. Preparation of samples

(1) invert the sample bottle several times to mix the contents;

(2) place Reacti-flask and cap on balance;

(3) record weight (W_1);

(4) open sample bottle and quickly transfer by pipette (Note 3) ca 10 g of the sample to the flask (Note 4);

(5) seal both Reacti-flask and sample bottle as quickly as possible;

(6) weigh Reacti-flask and contents (W_2);

(7) determine quantity of sample transferred by subtracting W_1 from W_2;

(8) shake the vial 20 min in the constant temperature water bath at 75 ± 1°C for edible oils and at 23 ± 1°C for vinegars.

2. GLC analysis

(1) withdraw a 1 mL sample of the head-space (Note 5) and inject into the gas chromatograph;

(2) compare retention time of peak obtained from unknown sample with that obtained from a control sample spiked with an ethanol solution of vinyl chloride;

(3) determine the amount of vinyl chloride present in the sample by comparing the peak height or area obtained from the unknown sample with those obtained from a control sample spiked with an ethanol solution of vinyl chloride.

VI. NOTES

(1) Purge column overnight at 250°C.

(2) Ethanol solutions of vinyl chloride stored in a mercury sealed vial are stable for at least 8 weeks when stored in the dark.

(3) Wipe off pipette before all additions of sample to Reacti-flask to avoid transfer of adhering sample to neck of flasks.

(4) Speed of transfer is of much greater importance than the transferring of exactly 10 g of the sample to the Reacti-flask.

(5) Exercise care when piercing septum so that needle does not become plugged with septum.

The method described above, being comprised of five pages and identified as FO-40, DETERMINATION OF VINYL CHLORIDE IN FOOD and dated October 15, 1981, is hereby designated the "Official Method" for the purposes of Section B.23.007 of the Food and Drug Regulations.

Acting Assistant Deputy Minister

Health and Canada / Santé et Bien-être social Canada

Health Protection Branch / Direction générale de la protection de la santé

Bureau of Chemical Safety
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November 30, 1987

Your file:

Mr. Jerome H. Heckman
KELLER AND HECKMAN
1150 17th Street N.W.
Suite 1000
WASHINGTON, D.C. 20036
USA

Dear Mr. Heckman:

RE: Canadian Status of Food Packaging Materials

This is in reply to your letter of September 2, 1987 on the above subject.

As you have noted, under Section B01.001 of the Food and Drug Regulations a "food additive" means any substance, including any source of radiation, the use of which results, or may reasonably be expected to result in it or its by-products becoming part of or affecting the characteristics of a food, but does not include.....

(e) food packaging materials and components thereof....

Since food packaging materials are not considered to be food additives, they are therefore not subject to the statutory preclearance and other requirements which food additives must meet under the provisions of the Regulations.

Instead, food packaging materials are regulated as such under Division 23 (Food Packaging Materials) of the Regulations Section B.23.001 of Division 23 reads as follows:

> "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".

This general prohibition clearly places the legal responsibility on the food seller i.e. food packager for ensuring the safety of any packaging materials which be uses.

Unlike the U.S. Food and drug Administration's Indirect Food Additive Regulations, Division 23 does not list permitted food packaging materials to which packaging suppliers can refer to establish compliance of their products. As a consequence, the Health Protection Branch receives several hundred submissions annually from packaging suppliers seeking the Branch's opinion on the safety of products which they wish to sell to the food industry. If the Branch is satisfied that a given product poses no health risk to consumers, a no objection letter is issued for that product for some specified end-use.

A no objection letter represents only an opinion by the Branch and does not relieve food packagers from their legal responsibilities respecting Section B.23.001.

I trust this is a satisfactory response to your enquiry.

Yours truly,

Robert A. Ripley, Ph.D.,
Head,
Food Packaging Materials and
Incidental Additives Section,
Chemical Evaluation Division.

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"CANADIAN FOOD PACKAGING REGULATIONS"

TO BE PRESENTED AT THE SPI INC. FOOD, DRUG AND COSMETIC PACKAGING MATERIALS COMMITTEE MEETING AT PALM SPRINGS, CALIFORNIA, DECEMBER 6-7, 1990

BY

ROBERT A. RIPLEY, PH.D
HEAD, FOOD PACKAGING MATERIALS AND INCIDENTAL ADDITIVES SECTION
CHEMICAL EVALUATION DIVISION
BUREAU OF CHEMICAL SAFETY
FOOD DIRECTORATE
HEALTH PROTECTION BRANCH
HEALTH AND WELFARE CANADA
OTTAWA, ONTARIO, K1A 0L2

CANADIAN FOOD PACKAGING REGULATIONS INTRODUCTION

GOOD AFTERNOON LADIES AND GENTLEMEN. LET ME BEGIN BY THANKING YOU FOR YOUR INVITATION TO ADDRESS THE SPI FOOD, DRUG AND COSMETIC PACKAGING MATERIALS COMMITTEE.

I'M PLEASED TO HAVE THIS OPPORTUNITY TO SHARE WITH YOU AN OVERVIEW OF THE REGULATORY CONTROL OF FOOD PACKAGING MATERIALS IN CANADA. IN THIS ENDEAVOUR I'LL BE COVERING THE PERTINENT LEGISLATION AND IT'S ADMINISTRATION BY THE HEALTH PROTECTION BRANCH (HPB) OF THE FEDERAL DEPARTMENT OF HEALTH AND WELFARE, PARTICULARLY AS IT RELATES TO THE SUBMISSION EVALUATION PROCESS AND THE ISSUANCE OF NO OBJECTION LETTERS FOR FOOD PACKAGING MATERIALS.

LEGISLATION

WHILE THERE WERE CERTAIN FOOD LAWS IN FORCE IN CANADA PRIOR TO CONFEDERATION IN 1867, THE FIRST FEDERAL LEGISLATION DEALING WITH THE ADULTERATION OF FOODS WAS ENACTED 115 YEARS AGO WHEN THE CANADIAN PARLIAMENT PASSED THE INLAND REVENUE ACT OF 1875, THEN CITED AS "AN ACT TO IMPOSE LICENCE DUTIES ON COMPOUNDERS OF SPIRITS, TO AMEND THE ACT RESPECTING INLAND REVENUE; AND TO PREVENT THE ADULTERATION OF FOOD, DRINK AND DRUGS".

SINCE THEN THERE HAVE BEEN SEVERAL AMENDMENTS TO THAT ACT. IN 1920, IT'S NAME WAS CHANGED TO THE FOOD AND DRUGS ACT, WHICH WAS

SUBSEQUENTLY AMENDED IN 1939 TO INCLUDE COSMETICS, AND AGAIN AND FINALLY IN 1954 TO INCLUDE MEDICAL DEVICES, AND IT IS THAT ACT WHICH IS CURRENTLY IN FORCE, ACCOMPANIED OF COURSE BY THE MANY AMENDMENTS OF THE REGULATIONS TO THE ACT THAT HAVE BEEN PROMULGATED IN THE INTERIM.

THE FOOD AND DRUGS ACT

THE FOOD AND DRUGS ACT IS CONSIDERED TO BE A CONSUMERS ACT INTENDED TO PROTECT CANADIAN CONSUMERS FROM HEALTH HAZARD AND FRAUD IN THE SALE AND USE OF FOODS, DRUGS, COSMETICS AND MEDICAL DEVICES. SINCE THE ACT MAKES THE OMISSION OR COMMISSION OF SPECIFIC ACTS A CRIME, IT IS CONSIDERED TO BE PART OF CRIMINAL LAW, AND AS SUCH, FALLS WITHIN THE AUTHORITY OF THE FEDERAL GOVERNMENT OF CANADA.

THE TASK OF ADMINISTERING THE FOOD AND DRUGS ACT RESTS WITH THE HEALTH PROTECTION BRANCH (HPB) OF THE FEDERAL DEPARTMENT OF HEALTH AND WELFARE, AND THIS ACT IS THE PRINCIPAL PIECE OF LEGISLATION ADMINISTERED BY HPB.

HEALTH PROTECTION BRANCH

BY WAY OF BACKGROUND, THE FIRST SLIDE (SLIDE 1) SHOWS THE ORGANISATION OF HPB, WHICH AS WE CAN SEE IS MADE UP OF SEVERAL DIRECTORATES, ONLY 2 OF WHICH, HOWEVER, THE FOOD DIRECTORATE AND FIELD OPERATIONS DIRECTORATE ARE DIRECTLY INVOLVED IN THE

REGULATORY CONTROL OF THE SALE OF FOODS AND HENCE, OF FOOD PACKAGING MATERIALS.

FOOD DIRECTORATE

THE PRIME RESPONSIBILITY OF THE FOOD DIRECTORATE UNDER THE FOOD AND DRUGS ACT IS TO ENSURE THE SAFETY, NUTRITIONAL QUALITY AND WHOLESOMENESS OF THE CANADIAN FOOD SUPPLY.

FOR THIS TASK, THE FOOD DIRECTORATE IS ORGANIZED INTO THE 3 BUREAUX SHOWN ON THE SLIDE, I.E. CHEMICAL SAFETY, NUTRITIONAL SCIENCES AND MICROBIAL HAZARDS, ONLY THE FIRST OF WHICH WILL CONCERN US HERE TODAY. THEN, AS WE CAN SEE WITHIN THE BUREAU OF CHEMICAL SAFETY WE HAVE 4 ACTIVITY ORIENTED DIVISIONS, CHEMICAL EVALUATION, TOXICOLOGICAL EVALUATION, FOOD RESEARCH AND TOXICOLOGICAL RESEARCH DIVISION, EACH OF WHICH IS FURTHER BROKEN DOWN INTO SECTIONS, ONE OF WHICH, IN THE CHEMICAL EVALUATION DIVISION IS THE FOOD PACKAGING MATERIALS AND INCIDENTAL ADDITIVES SECTION, WHICH IS RESPONSIBLE AMONG OTHER THINGS FOR INTERPRETING AND DEVELOPING REGULATIONS AND FOR LIAISING WITH AND PROVIDING ADVICE TO INDUSTRY AND OTHER DEPARTMENTS ON MATTERS CONCERNING THE SAFETY OF FOOD PACKAGING MATERIALS.

THE FOOD AND DRUG REGULATIONS

THE RELEVANT PARTS OF THE FOOD AND DRUGS ACT RELATING TO FOOD PACKAGING SAFETY ARE (SLIDE 2).

SECTION 4(a), WHICH PROHIBITS THE SALE OF AN ARTICLE OF FOOD THAT HAS IN OR UPON IT ANY POISONOUS OR HARMFUL SUBSTANCE. AND SECTION 30, WHICH GIVES AUTHORITY TO THE GOVERNOR-IN-COUNCIL TO PASS INTO LAW REGULATIONS TO CARRY THE PURPOSES AND PROVISIONS OF THE ACT RESPECTING FOOD PACKAGING MATERIALS INTO EFFECT.

<u>DIVISION 23 (FOOD PACKAGING MATERIALS) OF THE FOOD AND DRUG REGULATIONS</u>

IT IS THESE SECTIONS OF THE ACT WHICH PROVIDE THE BASIS FOR DIVISION 23 OF THE FOOD AND DRUG REGULATIONS ENTITLED "FOOD PACKAGING MATERIALS", WHICH IS THE ONLY DIVISION OF THE REGULATIONS THAT IS SPECIFICALLY CONCERNED WITH THE CHEMICAL SAFETY OF FOOD PACKAGING MATERIALS (SLIDE 3).

AS WE CAN SEE, DIVISION 23 COMPRISES ONLY 8 SECTIONS, THE MOST IMPORTANT OF WHICH IS

- SECTION B23.001 - A GENERAL PROHIBITION AGAINST THE SALE OF FOOD IN A PACKAGE THAT MAY IMPART HARMFUL SUBSTANCES TO THE FOOD.
- NEXT WE HAVE SECTIONS B23.002 TO .006 WHICH PERMIT THE USE OF ONLY SPECIFIED OCTYLTIN STABILIZERS IN PVC COMPOUNDS AND WHICH SET A USE LEVEL LIMIT OF 3% BY WEIGHT AND A 1 PPM MIGRATION LIMIT TO FOODS FOR THESE STABILIZERS
- AND FINALLY, WE HAVE SECTIONS B23.007 AND 8, WHICH PROHIBIT THE SALE OF FOODS IN A PACKAGE WHICH IMPARTS DETECTABLE AMOUNTS

OF VINYL CHLORIDE AND ACRYLONITRILE RESPECTIVELY TO THOSE FOODS, AS DETERMINED BY OFFICIAL ANALYTICAL METHODS.

PACKAGE - DEFINITION

BEFORE PROCEEDING WITH THE ADMINISTRATION OF DIVISION 23, WE SHOULD DEFINE THE TERM PACKAGE (SLIDE 4).

"PACKAGE" IS DEFINED IN THE INTERPRETATION SECTION OF THE FOOD AND DRUGS ACT TO INCLUDE "ANYTHING IN WHICH ANY FOOD, COSMETIC OR DEVICE IS WHOLLY ON PARTLY CONTAINED, PLACED OR PACKED."

THEREFORE, AS DEFINED IN THE ACT, IN ITS BROADEST TERMS A PACKAGE MAY BE REGARDED AS ANY ARTICLE THAT A FOOD CONTACTS DURING PROCESSING AND DISTRIBUTION FOR SALE, AND THUS WOULD INCLUDE THE VARIOUS CONTAINERS USED AT THE FOOD RETAIL LEVEL, AS WELL AS BULK FOOD HANDLING ARTICLES SUCH AS FOOD PROCESSING EQUIPMENT, DRUMS, PAILS, AND TRANSPORTATION VEHICLES LIKE TANKER TRUCKS, ROLLING STOCK, BARGES AND FISHING VESSEL HOLDS.

SECTION B23.001

RETURNING NOW TO SECTION B23.001 OF THE REGULATIONS (SLIDE 5).

THIS REGULATION CLEARLY MAKES THE FOOD SELLER LEGALLY RESPONSIBLE FOR THE SAFETY OF ANY PACKAGING MATERIALS WHICH HE USES IN THE SALE OF HIS FOOD PRODUCTS.

AN IMPORTANT POINT WORTH NOTING HERE IS THAT, CONSISTENT WITH SECTION 4(a) OF THE ACT, DIVISION 23 IS CONCERNED WITH REGULATING THE

SAFETY OF ONLY THOSE FOOD PACKAGING MATERIALS THAT ARE USED IN THE SALE OF FOODS. CONSUMER PRODUCTS SUCH AS KITCHEN UTENSILS, HOUSEHOLD WRAP AND MICROWAVE COOKWARE THEREFORE FALL OUTSIDE THE PURVIEW OF THE CANADIAN FOOD AND DRUG REGULATIONS. I UNDERSTAND THAT A SIMILAR SITUATION EXISTS IN YOUR COUNTRY UNDER THE HOUSEWARES EXEMPTION INTERPRETATION OF THE 1958 FOOD ADDITIVES AMENDMENT TO THE FEDERAL FOOD, DRUG AND COSMETIC ACT.

ANOTHER VERY IMPORTANT POINT TO NOTE IN REFERENCE TO THE LATTER US LEGISLATION RESPECTING THE INDIRECT FOOD ADDITIVE REGULATIONS, IS THE FACT THAT UNDER SECTION B01.001 OF THE CANADIAN FOOD AND DRUG REGULATIONS (SLIDE 6), FOOD PACKAGING MATERIALS AND COMPONENTS THEREOF ARE NOT CONSIDERED TO BE FOOD ADDITIVES. THEY ARE THEREFORE NOT SUBJECT TO THE STATUTORY PRECLEARANCE REQUIREMENTS THAT FOOD ADDITIVES MUST MEET UNDER SECTION B16.002 OF THE REGULATIONS (SLIDE 7). INSTEAD, THEY ARE REGULATED IN THEIR OWN RIGHT AS FOOD PACKAGING MATERIALS UNDER DIVISION 23, WHICH, AS WE HAVE SEEN, DOES NOT AT PRESENT DELINEATE STATUTORY PRECLEARANCE REQUIREMENTS OTHER THAN THE FEW I HAVE DESCRIBED.

WE CAN SEE HERE THEREFORE MAJOR DIFFERENCES IN THE REGULATORY STATUS OF FOOD PACKAGING MATERIALS UNDER THE FOOD LAWS OF CANADA AND THE UNITED STATES.

SUBMISSIONS AND NO OBJECTION LETTERS

GIVEN THE LEGAL RESPONSIBILITY PLACED UPON THEM BY REGULATION B23.001, IT'S ENTIRELY REASONABLE TO EXPECT THAT FOOD MANUFACTURERS WILL SEEK ASSURANCE FROM THEIR PACKAGING SUPPLIERS REGARDING THE SAFETY OF ANY PACKAGING MATERIALS THEY MAY BE CONSIDERING PURCHASING.

THAT IS WHY THOSE OF YOU WHO ARE DIRECTLY OR INDIRECTLY INVOLVED IN SUPPLYING PACKAGING PRODUCTS TO THE CANADIAN FOOD INDUSTRY MAY BE FACED WITH THE QUESTION "DO YOU HAVE AN HPB NO OBJECTION LETTER FOR YOUR PRODUCT?", AND WHY, AS A RESULT HPB, AND MORE PARTICULARLY THE CHEMICAL EVALUATION DIVISION OF THE BUREAU OF CHEMICAL SAFETY OF THE FOOD DIRECTORATE RECEIVES SEVERAL HUNDRED SUBMISSIONS ANNUALLY FROM FOOD PACKAGING AND RELATED SUPPLIERS REQUESTING SAFETY EVALUATIONS AND NO OBJECTION LETTERS ON PRODUCTS THEY WISH TO SELL TO THE FOOD INDUSTRY.

WELL, WHAT IS A NO OBJECTION LETTER? A NO OBJECTION LETTER IS A MECHANISM WHEREBY HPB, IN THE ABSENCE OF COMPREHENSIVE POSITIVE LIST REGULATIONS, PROVIDES A SERVICE TO PACKAGING SUPPLIERS AND RELATED COMPANIES TO ASSIST THEM IN SUPPLYING PRODUCTS TO THE CANADIAN FOOD INDUSTRY WHICH ARE LIKELY TO BE ACCEPTABLE UNDER DIVISION 23 OF THE FOOD AND DRUG REGULATIONS.

A TYPICAL EXAMPLE OF A NO OBJECTION LETTER IS SHOWN IN THE NEXT SLIDE (SLIDE 8). AS YOU CAN SEE, THESE LETTERS ARE FAIRLY SIMPLE AND STRAIGHTFORWARD - BASICALLY, SPECIFIC IDENTIFICATION OF THE PRODUCT AND A STATEMENT OF NO OBJECTION TO SPECIFIED FOOD CONTACT END USES, BASED UPON SUPPORTING DATA SUBMITTED BY THE PETITIONER, FOLLOWED USUALLY BY A TECHNICAL SUITABILITY PROVISO.

THOSE OF YOU WHO ARE FAMILIAR WITH THE WAY IN WHICH THE FDA HANDLED FOOD CONTACT ARTICLES PRIOR TO THE 1958 FOOD ADDITIVES AMENDMENT TO THE FEDERAL FOOD, DRUG AND COSMETIC ACT, ESTABLISHING STATUTORY PRECLEARANCE REQUIREMENTS FOR SUCH ARTICLES, WILL RECOGNIZE THE CLOSE SIMILARITY BETWEEN THE NO OBJECTION LETTERS ISSUED BY DR. LEHMAN'S OFFICE THIRTY ODD YEARS AGO AND THOSE ISSUED BY HPB TODAY. AS A MATTER OF INTEREST, HPB (WHICH WAS THEN KNOWN AS FDD - THE FOOD AND DRUG DIRECTORATE) BEGAN THE PRACTICE OF ISSUING NO OBJECTION LETTERS ABOUT THE SAME TIME THAT THE FDA PRECLEARANCE REGULATIONS BEGAN TO BE PROMULGATED IN THE EARLY 1960s.

ONCE A NO OBJECTION LETTER HAS BEEN ISSUED BY HPB ON A PARTICULAR PRODUCT, THE RECIPIENT IS FREE TO PRESENT IT TO PROSPECTIVE CUSTOMERS. IT'S IMPORTANT TO NOTE HOWEVER THAT A NO OBJECTION LETTER EXPRESSES ONLY AN OPINION BY HPB ON THE ACCEPTABILITY OF THE PRODUCT. IT DOES NOT CONSTITUTE AN APPROVAL

OF THE PRODUCT IN A LEGAL SENSE, NOR DOES IT RELIEVE THE FOOD MANUFACTURER FROM THE ULTIMATE RESPONSIBILITY FOR THE PRODUCT'S SAFETY UNDER DIVISION 23. HOWEVER, THE INTENT OF THE LETTER IS TO MAKE IT HIGHLY UNLIKELY THAT THE SPECIFIED USE OF THE PRODUCT IN QUESTION WOULD LEAD TO A CONTRAVENTION OF THIS REGULATION.

BECAUSE SUBMISSIONS BY PACKAGING SUPPLIERS ARE MADE TO HPB ON A VOLUNTARY BASIS, AT LEAST INSOFAR AS THE FOOD AND DRUGS ACT AND REGULATIONS ARE CONCERNED, A LETTER REFLECTING AN HPB OBJECTION RATHER THAN A NO OBJECTION WOULD NOT NECESSARILY PREVENT THE SUPPLIER FROM SELLING THAT PRODUCT TO A FOOD MANUFACTURER WHO WISHED TO USE IT. IN THE FINAL ANALYSIS, THE DECISION TO USE THAT PRODUCT RESTS WITH THE FOOD MANUFACTURER. HOWEVER, WE BELIEVE THAT MOST FOOD MANUFACTURERS ARE FULLY AWARE OF THAT STATUTORY RESPONSIBILITY, AND WOULD NOT LIKELY PROCEED TO USE A PRODUCT WHOSE SAFETY WAS IN QUESTION.

<u>TYPES OF SUBMISSIONS</u>

WHILE MANY OF THE SUBMISSIONS RECEIVED BY HPB ORIGINATE WITH COMPANIES WHICH DIRECTLY SUPPLY FINISHED PACKAGING MATERIALS TO THE FOOD INDUSTRY, A LARGE PROPORTION ARE INITIATED BY COMPANIES LIKE PLASTIC RESIN MANUFACTURERS, COMPOUNDERS, ADDITIVE AND COLOUR CONCENTRATE SUPPLIERS. AS A CONSEQUENCE, NO OBJECTION LETTERS RUN THE GAMUT OF ALL OF THEIR PRODUCTS, SO THAT IN THE IDEAL

SCHEME OF THINGS, EACH COMPANY IN THE SUPPLY CHAIN SHOULD BE IN A POSITION TO SATISFY ITS RESPECTIVE CUSTOMER'S REQUESTS FOR NO OBJECTION LETTERS.

WHILE WE RECOGNIZE THAT THERE ARE DIFFERENCES IN THE PRESENT REGULATORY APPROACHES TO CONTROLLING FOOD PACKAGING MATERIALS IN CANADA AND THE UNITED STATES, WE BELIEVE THAT THE SCIENTIFIC PRINCIPLES AND CRITERIA USED BY HPB AND FDA IN ASSESSING THEIR SAFETY ARE SIMILAR. CONSEQUENTLY, GENERALLY SPEAKING, PACKAGING MATERIALS PERMITTED FOR USE IN THE US UNDER FDA REGULATIONS WOULD ALSO LIKELY BE DEEMED ACCEPTABLE IN PRINCIPLE FOR USE IN CANADA. THERE ARE EXCEPTIONS OF COURSE, AND I WISH TO STRESS THAT ANY DECISIONS REACHED BY HPB REGARDING THE ACCEPTABILITY OF ANY PACKAGING MATERIALS ARE NEVER BASED ON SANCTIONS MADE BY ANOTHER AGENCY, BUT RATHER ON HPB EVALUATION OF AT LEAST THE SUPPORTING DATA UPON WHICH THOSE SANCTIONS WERE BASED. IT FOLLOWS THAT STATEMENTS MADE IN HPB SUBMISSIONS ATTESTING TO THE COMPLIANCE STATUS OF A PRODUCT WITH FDA REGULATIONS, IS NOT CONSIDERED BY HPB TO BE DEFINITIVE EVIDENCE PER SE OF THE ACCEPTABILITY OF THAT PRODUCT FOR USE IN CANADA - WE REQUIRE SUPPORTING DATA TO BACK UP SUCH STATEMENTS.

WHICH BRINGS US TO THE QUESTION OF WHAT TYPE OF DATA DO WE REQUIRE FOR OUR EVALUATION PURPOSES.

SUBMISSION REQUIREMENTS

AN HPB NO OBJECTION LETTER IS THE END RESULT OF A SAFETY EVALUATION OF A PARTICULAR PACKAGING MATERIAL IN CONSIDERATION OF BASICALLY 4 ELEMENTS OF INFORMATION (SLIDE 9).

PRODUCT IDENTITY - TO CHEMICALLY AND OTHERWISE CHARACTERIZE THE MATERIAL AND THUS IDENTIFY CHEMICAL CONSTITUENTS THAT MAY BE POTENTIALLY EXTRACTABLE BY FOODS COMING INTO CONTACT WITH THE MATERIAL.

PROPOSED USAGE OF PACKAGING MATERIAL - TO ESTIMATE THE DIETARY INTAKE OF THE FOODS INVOLVED AND ALSO TO ESTABLISH APPROPRIATE EXTRACTION TEST PROTOCOLS.

FOOD EXTRACTABILITY CHARACTERISTICS OF PACKAGING MATERIAL - TO IDENTIFY AND QUANTIFY THOSE OF ITS CONSTITUENTS THAT ARE LIKELY TO BE EXTRACTED BY FOODS. EVALUATION OF THIS INFORMATION IN CONJUNCTION WITH USAGE INFORMATION PERMITS THE ESTIMATION OF THE PDI (PROBABLE DAILY INTAKE) MG/KG B.W./DAY OF EXTRACTED CONSTITUENTS IN THE AVERAGE DIET OF THE CONSUMER.

TOXICOLOGICAL DATA ON EXTRACTABLE CONSTITUENTS - TO PERMIT THE ESTABLISHMENT OF AN ADI (ACCEPTABLE DAILY INTAKE) MG/KG B.W./DAY FOR HUMANS FOR EXTRACTED CONSTITUENTS.

SUBMISSIONS TO HPB FALL INTO 2 GENERAL CATEGORIES FROM AN EVALUATION VIEWPOINT: THOSE CONCERNING INDIVIDUAL CONSTITUENTS OF

PACKAGING MATERIALS AND THOSE CONCERNING FORMULATED OR FINISHED PRODUCTS. WHILE THE SAME PRINCIPLES ARE USED IN EVALUATING BOTH TYPES, GENERALLY SPEAKING THE INFORMATION PACKAGE REQUIREMENTS AND THE EVALUATION PROCESS ARE MORE DEMANDING FOR INDIVIDUAL CONSTITUENTS. FORTUNATELY FOR MY OFFICE FROM A RESOURCE PERSPECTIVE, MOST SUBMISSIONS FALL INTO THE FORMULATED OR FINISHED PRODUCT CATEGORY.

THE INITIAL SUBMISSION REQUIREMENTS FOR A FORMULATED OR FINISHED PRODUCT ARE LISTED ON THE NEXT SLIDE (SLIDE 10) AND ARE SELF EXPLANATORY.

THESE ARE ONLY BASIC INITIAL REQUIREMENTS BECAUSE EVALUATION OF THIS INFORMATION MAY REVEAL DATA GAPS REGARDING EXTRACTION STUDY DATA OR TOXICOLOGICAL DATA ON CERTAIN CONSTITUENTS, THUS REQUIRING FOLLOW-UP CORRESPONDENCE WITH THE PETITIONER OR PERHAPS HIS CONSTITUENT SUPPLIERS TO PROVIDE THE MISSING INFORMATION.

IT'S PERHAPS WORTH MENTIONING IN THAT REGARD THAT WE HAVE SUCCESSFULLY ENCOURAGED SEVERAL COMPANIES, NOTABLY PLASTIC RESIN MANUFACTURERS TO ESTABLISH MASTER LISTINGS WITH HPB COVERING ALL THEIR RESIN PRODUCTS DESTINED FOR FOOD PACKAGING APPLICATIONS IN CANADA. THESE MASTER LISTINGS, WHICH CONTAIN DETAILED CONFIDENTIAL COMPOSITIONAL INFORMATION ON EACH RESIN PRODUCT ALONG WITH

INTENDED END USE INFORMATION AND PERTINENT DOCUMENTATION IN SUPPORT OF THEIR SAFETY, AND WHICH CAN BE UPDATED ON A REGULAR BASIS, HAVE PROVED TO BE MOST USEFUL IN EXPEDITING OUR EVALUATION OF SUBMISSIONS FROM CUSTOMERS WISHING TO USE THESE COMPANIES' PARTICULAR RESINS. THE MARKETING ADVANTAGES TO COMPANIES WHO SUBMIT MASTER LISTS ARE THUS SELF EVIDENT.

THE NEXT SLIDE LISTS THE REQUIREMENTS FOR A SPECIFIC PACKAGING CONSTITUENT SUCH AS A BASE RESIN OR AN ANTIOXIDANT (SLIDE 11). THIS, AS YOU CAN SEE IS MUCH MORE DETAILED AND IS SIMILAR TO THE TYPE OF INFORMATION THAT IS SUBMITTED TO FDA BY PETITIONERS SEEKING TO AMEND THE INDIRECT FOOD ADDITIVE REGULATIONS - AND INDEED, QUITE OFTEN, WHAT HPB RECEIVES IN SUBMISSIONS TO FULFILL OUR REQUIREMENTS, IS A DUPLICATE COPY OF THE FULL FDA PETITION, WHICH OFTEN SUFFICES FOR OUR EVALUATION PURPOSES.

<u>EXTRACTION STUDIES</u>

AS REGARDS EXTRACTION STUDIES, HPB RECOGNIZES THE DIFFICULTIES INHERENT IN ANALYZING FOODS FOR PACKAGING MIGRANTS AND ACCEPTS THE USE OF FOOD SIMULANTS OR SURROGATES FOR SUCH STUDIES. THOSE SIMULANTS WHICH ARE CONSIDERED ACCEPTABLE ARE LISTED IN THE NEXT SLIDE (SLIDE 12). HOWEVER, WE ARE REASONABLY FLEXIBLE, AND DEPENDING UPON THE PARTICULAR CIRCUMSTANCES WE MAY ACCEPT THE USE OF OTHER SIMULANTS SUCH AS N-HEPTANE AND ETHANOL FOR FATTY FOODS.

ON THE NEXT SLIDE (SLIDE 13) ARE LISTED THE RECOMMENDED EXTRACTION TEST TEMPERATURES CORRESPONDING TO THE INDICATED INTENDED END USES TO BE OBSERVED IN CONDUCTING THE TESTS, AND GENERALLY SPEAKING, WE RECOMMEND THAT THEY BE RUN TO EQUILIBRIUM CONCENTRATIONS OF THE EXTRACTED CONSTITUENT IN EACH SIMULANT.

THE WHOLE PURPOSE OF THIS EXERCISE IS OF COURSE TO ALLOW US TO ESTIMATE THE PDI (PROBABLE DAILY INTAKE) OF THE MIGRATING FOOD PACKAGING CONSTITUENT, AND HOW WE DO IT IS ILLUSTRATED IN THE NEXT SLIDE (SLIDE 14). THIS IS SIMILAR TO THE APPROACH USED BY FDA, WITH ONE MAJOR DIFFERENCE - AS YOU CAN SEE, IT DOES NOT EMPLOY A PACKAGING USE DISTRIBUTION FACTOR FOR EACH FOOD TYPE - AND THE REASON FOR THIS IS SIMPLE - WE LACK USE DISTRIBUTION DATA FOR THE CANADIAN FOOD INDUSTRY. THIS IS NOT AN ENTIRELY SATISFACTORY SITUATION, BUT IN THE ABSENCE OF SUCH DATA, IT DOES ALLOW US TO ARRIVE AT A CONSERVATIVE PDI WHICH INCORPORATES AN ADDED SAFETY FACTOR. WE DO HOWEVER TRY TO INCORPORATE USE DISTRIBUTION FACTORS IN THOSE CIRCUMSTANCES WHICH PERMIT IT.

THE FOLLOWING SLIDE INDICATES THE TYPES OF TOXICOLOGICAL TESTING WHICH MAY BE REQUIRED TO ASSESS THE SAFETY OF A GIVEN PACKAGING CONSTITUENT (SLIDE 15). I DO STRESS MAY, BECAUSE THE SPECIFIC TESTING REQUIREMENTS FOR A PARTICULAR CONSTITUENT WILL BE DEPENDENT UPON CONSIDERATION OF SEVERAL FACTORS,INCLUDING LEVEL

OF EXPOSURE (PDI), CHEMICAL STRUCTURAL SIMILARITY BETWEEN THE CONSTITUENT AND THOSE OF OTHER CHEMICALS OF KNOWN TOXICOLOGICAL PROFILE AND THE EXISTING TOXICOLOGICAL DATA BASE ON THE CONSTITUENT. BEFORE EMBARKING ON ANY TESTING, I WOULD RECOMMEND THAT PETITIONERS DISCUSS REQUIREMENT DETAILS WITH STAFF TOXICOLOGISTS IN OUR TOXICOLOGICAL EVALUATION DIVISION.

SUBMISSION OF THE APPROPRIATE TOXICOLOGICAL STUDY DATA WILL ALLOW OUR TOXICOLOGISTS TO ASCERTAIN A NOAEL (NO OBSERVABLE ADVERSE EFFECT LEVEL) MG/KG B.W./DAY FOR THE PACKAGING CONSTITUENT IN THE TEST ANIMALS, WHICH BY THE APPLICATION OF ESTABLISHED SAFETY FACTORS WILL PERMIT THEM TO CALCULATE AN ACCEPTABLE DAILY INTAKE (ADI) IN HUMANS.

BEFORE MOVING ON FROM THE SUBJECT OF SUBMISSION EVALUATION, I WOULD LIKE TO STRESS THAT HPB RECOGNIZES THE NEED TO GUARD THE CONFIDENTIALITY OF INFORMATION CONTAINED IN SUBMISSIONS. WE THEREFORE WISH TO ASSURE PETITIONERS THAT ALL SUBMISSION INFORMATION IS USED SOLELY FOR OUR EVALUATION PURPOSES, AND WOULD NOT BE RELEASED TO A THIRD PARTY WITHOUT THE EXPRESS WRITTEN CONSENT OF THE ORIGINATOR.

IT'S UNDERSTANDABLE THAT COMPANIES CONTACTING HPB FOR THE FIRST TIME MAY HAVE SOME CONCERNS ABOUT THE CONFIDENTIALITY OF PROPRIETARY INFORMATION THEY ARE SENDING TO US - SO I HOPE THAT MY

ASSURANCE AND THE FACT THAT WE HAVE INFORMATION ON FILE FROM OVER 4,000 DOMESTIC AND FOREIGN COMPANIES, WITHOUT A SINGLE COMPLAINT REGARDING CONFIDENTIALITY OVER THE MANY YEARS WE'VE BEEN IN BUSINESS, WILL ALLAY ANY CONCERNS YOU MAY HAVE IN THAT REGARD.

ONE POINT WORTH MENTIONING - ANY CHANGES IN THE CHEMICAL COMPOSITION OF A PRODUCT AUTOMATICALLY INVALIDATE THE NO OBJECTION LETTER ISSUED FOR THAT PRODUCT. FOR THE LETTER TO REMAIN IN EFFECT, WE REQUIRE PRE-NOTIFICATION OF ANY SUCH CHANGES, SO THAT WE CAN ASSESS THEIR IMPACT ON THE ORIGINAL EVALUATION.

HPB AND OTHER ORGANIZATIONS

AND NOW I'D LIKE TO SAY A FEW WORDS ABOUT HPB'S INTERACTION WITH OTHER REGULATORY AGENCIES AND ORGANIZATIONS ON MATTERS INVOLVING FOOD PACKAGING MATERIALS SAFETY.

AS PART OF ITS RESPONSIBILITIES IN ADMINISTERING THE FOOD AND DRUGS ACT AND REGULATIONS, HPB HAS FOR MANY YEARS PROVIDED ADVICE (I.E. EVALUATED PRODUCTS) TO SEVERAL OTHER FEDERAL GOVERNMENT DEPARTMENTS IN THIS AREA, SOME OF WHICH ARE LISTED IN THE NEXT SLIDE (SLIDE 16) PERHAPS THE MOST IMPORTANT FEDERAL AGENCY FROM A REFERRAL WORK VOLUME PERSPECTIVE IS THE

- AGRI-FOOD SAFETY DIVISION/FOOD INSPECTION DIRECTORATE/AGRICULTURE CANADA - REGARDING THE PRECLEARANCE SAFETY EVALUATION OF PRODUCTS USED IN FOOD PROCESSING ESTABLISHMENTS REGISTERED UNDER THE MEAT INSPECTION ACT AND OTHER ACTS ADMINISTERED BY THAT DEPARTMENT.

- PRODUCT MANAGEMENT DIVISION/PESTICIDES DIRECTORATE/AGRICULTURE CANADA - REGARDING THE SAFETY EVALUATION OF FOOD PACKAGING CONSTITUENTS SUCH AS PAPER PULP SLIMICIDES AND PAPER COATING PRESERVATIVES WHICH ARE SUBJECT TO REGISTRATION UNDER THE PEST CONTROL PRODUCTS ACT.

- INSPECTION SERVICES DIRECTORATE/FISHERIES AND OCEANS - ON THE SAFETY EVALUATION OF MATERIALS USED ON FISHING VESSELS AND FISH

PROCESSING PLANTS SUBJECT TO CONTROL UNDER THE FISH INSPECTION ACT.

- SUPPLY AND SERVICES CANADA AND THE DEPARTMENT OF NATIONAL DEFENCE - REGARDING SPECIFICATIONS FOR PROCUREMENT OF FOOD PACKAGING MATERIALS BY THESE DEPARTMENTS.

I'VE ALSO INCLUDED SOME EXTERNAL AGENCIES SUCH AS:

- CODEX COMMITTEE ON FOOD ADDITIVES OF FAO/WHO CODEX ALIMENTARIUS COMMISSION - REGARDING INTERNATIONAL GUIDELINE STANDARDS FOR FOOD PACKAGING MATERIALS.

- BUREAU OF FOODS/FDA - IN CONNECTION WITH THE IMPACT OF THE RECENTLY SIGNED CANADA-US FREE TRADE AGREEMENT ON THE REGULATION OF FOOD PACKAGING MATERIALS IN OUR TWO COUNTRIES

AND LAST, BUT CERTAINLY NOT LEAST

- COMMITTEE FOR INDUSTRIAL AND CONSUMER HEALTH/SPI OF CANADA - WITH WHOM WE'VE BEEN MEETING ON AN ANNUAL BASIS FOR 8 YEARS NOW TO DISCUSS ISSUES OF MUTUAL INTEREST CONCERNING THE SAFETY OF PLASTICS USED IN CANADA IN FOOD PACKAGING APPLICATIONS. IN ADDITION TO FACILITATING AN INFORMAL EXCHANGE OF INFORMATION, THESE MEETINGS GIVE THE CANADIAN PLASTICS INDUSTRY AN OPPORTUNITY TO PROVIDE INPUT TO ASSIST HPB IN ITS DELIBERATIONS ON BOTH SHORT TERM REGULATORY ACTIONS AND LONG TERM REGULATORY POLICY.

POSSIBLE CHANGES IN REGULATIONS

- WHICH BRINGS US TO ONE OF THE SUBJECTS DISCUSSED AT THE LAST MEETING - POSSIBLE FUTURE CHANGES IN THE REGULATORY CONTROL OF FOOD PACKAGING MATERIALS IN CANADA.

THE PRESENT VOLUNTARY SUBMISSION/NO OBJECTION LETTER SYSTEM HAS FOR ALMOST 3 DECADES NOW PROVIDED A REASONABLY EFFECTIVE MEASURE OF PROTECTION TO CANADIAN CONSUMERS AGAINST THE LIKELIHOOD OF HARMFUL SUBSTANCES ENTERING THE FOOD SUPPLY FROM PACKAGING MATERIAL SOURCES. NO SYSTEM IS PERFECT HOWEVER, AND WE HAVE FOR SOME TIME RECOGNIZED SOME DEFICIENCIES IN THE PRESENT REGULATIONS. ONE OF THEM IS THE ENFORCEMENT OF THE GENERAL PROHIBITION B 23.001, FOR WHILE IT DOES INDEED MAKE THE FOOD SELLER LEGALLY RESPONSIBLE FOR THE SAFETY OF THE PACKAGING MATERIALS HE USES, THE BURDEN OF PROOF OF COMPLIANCE FALLS ON HPB.

THIS REQUIRES ANALYTICAL IDENTIFICATION AND QUANTITATION OF LOW LEVELS OF PACKAGING MIGRANTS IN FOODS - A TASK WHICH OFTEN POSES ANALYTICAL DIFFICULTIES. FURTHERMORE, ENFORCEMENT OF THIS REGULATION CONSTITUTES AN AFTER THE FACT SYSTEM OF CONTROL. THIS, COUPLED WITH THE PROLIFERATION OF NEW TYPES AND USES OF FOOD PACKAGING MATERIALS, AND THE ATTENDANT INCREASED POTENTIAL FOR ADDED DIETARY EXPOSURE OF CONSUMERS TO MIGRATING PACKAGING CONSTITUENTS, HAS PROMPTED HPB TO LOOK INTO THE FEASIBILITY OF

DEVELOPING A STRENGTHENED, MORE FORMALIZED SYSTEM OF PRE-MARKET REVIEW AND CLEARANCE OF FOOD PACKAGING MATERIALS. WE'RE PRESENTLY LOOKING AT SEVERAL OPTIONS SUCH AS PRE-MARKET PRODUCT REGISTRATION AND POSITIVE LIST CONTROL SYSTEMS - AND WE EXPECT TO HAVE A DRAFT PROPOSAL READY FOR INTERNAL DISCUSSION SOMETIME NEXT YEAR. I DO WISH TO ASSURE YOU HOWEVER, THAT WHATEVER STRATEGY EMERGES, THE PLASTICS INDUSTRY WILL HAVE AMPLE OPPORTUNITY TO PROVIDE INPUT INTO OUR DELIBERATIONS ON ANY PROPOSED CHANGES, SO THAT WE CAN WORK TOGETHER TO DEVELOP EFFECTIVE REGULATIONS THAT WE CAN ALL LIVE WITH.

CANADA - US FREE TRADE AGREEMENT

IT IS PERHAPS APROPOS THAT HPB IS EXAMINING REGULATORY REVIEW IN THIS AREA AT THIS TIME, IN VIEW OF THE RECENTLY INITIATED ONGOING DISCUSSIONS BETWEEN HPB AND FDA OFFICIALS REGARDING THE HARMONIZATION OF US AND CANADIAN REGULATIONS AND STANDARDS, AS REQUIRED UNDER THE PROVISIONS OF THE US - CANADA FREE TRADE AGREEMENT. I'M NOT FREE TO REVEAL THE DETAILS OF THOSE DISCUSSIONS OTHER THAN TO SAY THAT ONE OF THE AGENDA ITEMS TABLED AT THE LAST MEETING HELD ON SEPTEMBER 12 BY THE WORKING GROUP RESPONSIBLE FOR FOOD, BEVERAGES AND COLOUR ADDITIVES AND UNAVOIDABLE CONTAMINANTS, WAS THE CONCEPT OF THRESHOLD OF REGULATION FOR FOOD PACKAGING MIGRANTS. AS YOU ARE NO DOUBT AWARE, UNDER

SCHEDULE 8 OF CHAPTER 7, ARTICLE 708 OF THE FTA, BOTH PARTIES ARE COMMITTED TO DEVELOPING A UNIFORM THRESHOLD OF REGULATION POLICY FOR SUBSTANCES THAT MIGRATE TO FOODS.

CURRENT ISSUES

BEFORE CLOSING I'D JUST BRIEFLY LIKE TO MENTION A COUPLE OF ISSUES THAT MAY BE OF INTEREST TO YOU.

THE FIRST OF THESE IS THE QUESTION OF THE USE OF RECYCLED PLASTICS FOR FOOD PACKAGING.

OVER THE PAST 2 YEARS OR SO THERE HAS BEEN A GROWING INTEREST IN CANADA ON THE USE OF RECYLCED MATERIALS FOR FOOD PACKAGING APPLICATIONS AND PERHAPS NOT SURPRISINGLY, HPB HAS BEEN CONTACTED ON SEVERAL OCCASIONS BY RECYCLERS REGARDING THE REGULATORY STATUS OF RECYCLED FOOD AND NON-FOOD MATERIALS, PRINCIPALLY PLASTICS SUCH AS PET FOR SUCH END USES.

OUR POSITION ON THIS ISSUE IS BRIEFLY THIS: THERE IS NO SPECIFIC PROHIBITION AGAINST THE USE OF RECYCLED MATERIALS FOR FOOD PACKAGING PURPOSES UNDER THE CANADIAN FOOD AND DRUG REGULATIONS. THEREFORE, A FOOD MANUFACTURER COULD QUITE LEGALLY USE RECYCLED MATERIALS, PROVIDED OF COURSE THAT THEY COMPLIED WITH DIVISION 23 REQUIREMENTS. HOWEVER, AS WE HAVE BEEN ADVISING RECYCLERS - THE TASK OF PROVIDING SUFFICIENT SUPPORTING DATA THAT WOULD SATISFY OUR CONCERNS ABOUT THE SAFETY OF CONTAMINANTS THAT

MAY BE PRESENT IN A GIVEN RECYCLED PRODUCT, TO THE POINT THAT WE WOULD BE COMFORTABLE IN ISSUING A NO OBJECTION LETTER FOR ITS USE FOR FOOD PACKAGING, WOULD LIKELY BE A COSTLY, TIME-CONSUMING UNDERTAKING, NECESSARILY INVOLVING TIGHT CONTROL OVER THE MATERIAL SOURCE, CONTINUOUS MONITORING OF SOURCE MATERIAL TO EXCLUDE OVERTLY CONTAMINATED MATERIALS, APPROPRIATE DECONTAMINATION PROCESSES AND CONTINUOUS ANALYTICAL MONITORING OF THE FINAL PRODUCT TO ENSURE THAT IT IS FREE OF CONTAMINANTS. THEREFORE, WE BELIEVE THAT WHILE RECYCLING CERTAINLY IS A SENSIBLE ENVIRONMENTAL STRATEGY, AS A GENERAL PRINCIPLE, WITH SOME POSSIBLE EXCEPTIONS, FROM A PRACTICAL AND HEALTH RELATED PERSPECTIVE, PLASTICS RECYCLERS SHOULD PERHAPS BE DIRECTING THEIR RECYCLED PRODUCTS INTO NON-FOOD PACKAGING END USES - A PREFERENCE THAT HAS ALSO BEEN EXPRESSED BY THE ICH COMMITTEE OF THE SPI OF CANADA. - AND NOW, A FEW WORDS ABOUT

<u>DIARYLIDE PIGMENTS</u>

IN APRIL 1990 HOECHST CANADA INC. NOTIFIED HPB THAT STUDIES BY ITS PARENT COMPANY HOECHST AG HAD SHOWN THAT CERTAIN DIARYLIDE PIGMENTS UNDERWENT THERMAL DECOMPOSITION IN POLYMERS PROCESSED ABOVE 200°C, PRODUCING DECOMPOSITION PRODUCTS INCLUDING 3,3'-DICHLOROBENZIDINE A KNOWN CARCINOGEN. AS A RESULT OF THESE FINDINGS, HOECHST ADVISED ITS CUSTOMERS NOT TO USE THESE PIGMENTS

IN POLYMER APPLICATIONS INVOLVING PROCESSING TEMPERATURES ABOVE 200°C.

IN VIEW OF THE POTENTIAL HEALTH HAZARD POSED BY THE POSSIBLE MIGRATION OF 3,3'-DICHLOROBENZIDINE AND THE LACK OF TOXICOLOGICAL DATA ON THE OTHER THERMAL DECOMPOSITION SPECIES, WE ADVISED SPI OF CANADA AND COLOUR CONCENTRATE MANUFACTURERS IN MAY THAT HPB NO LONGER CONSIDERED CERTAIN OF THE DIARYLIDE PIGMENTS IN QUESTION TO BE ACCEPTABLE FOR USE IN FOOD CONTACT POLYMERS PROCESSED ABOVE 200°C. FURTHERMORE, AS A PRECAUTIONARY MEASURE AGAINST MIX-UPS, WE SUGGESTED THAT THIS RECOMMENDATION SHOULD BE FOLLOWED FOR ANY FOOD CONTACT POLYMERS, REGARDLESS OF TEMPERATURE OF PROCESSING.

IN A RECENT INFORMATION NOTICE RELEASED BY ETAD, THE EUROPEAN ECOLOGICAL AND TOXICOLOGICAL ASSOCIATION OF THE DYESTUFFS MANUFACTURING INDUSTRY, THE ASSOCIATION ALSO RECOMMENDS NOT USING DIARYLIDE PIGMENTS IN FOOD CONTACT POLYMERS PROCESSED ABOVE 200°C, FOR EXAMPLE POLYETHYLENE FILM, CERTAIN TYPES OF PVC AND INTERNAL CAN COATINGS. THE ETAD RELEASE ALSO CAUTIONS AGAINST THE USE OF RECYCLED PRINTED POLYETHYLENE FILMS CONTAINING DIARYLIDE PIGMENTED INKS FOR FOOD CONTACT APPLICATIONS.

AS A FALL-OUT FROM THE FINDINGS ON DIARYLIDE PIGMENTS, WE ARE NOW REQUIRING ALL SUBMISSIONS INVOLVING NEW ORGANIC COLOURANTS

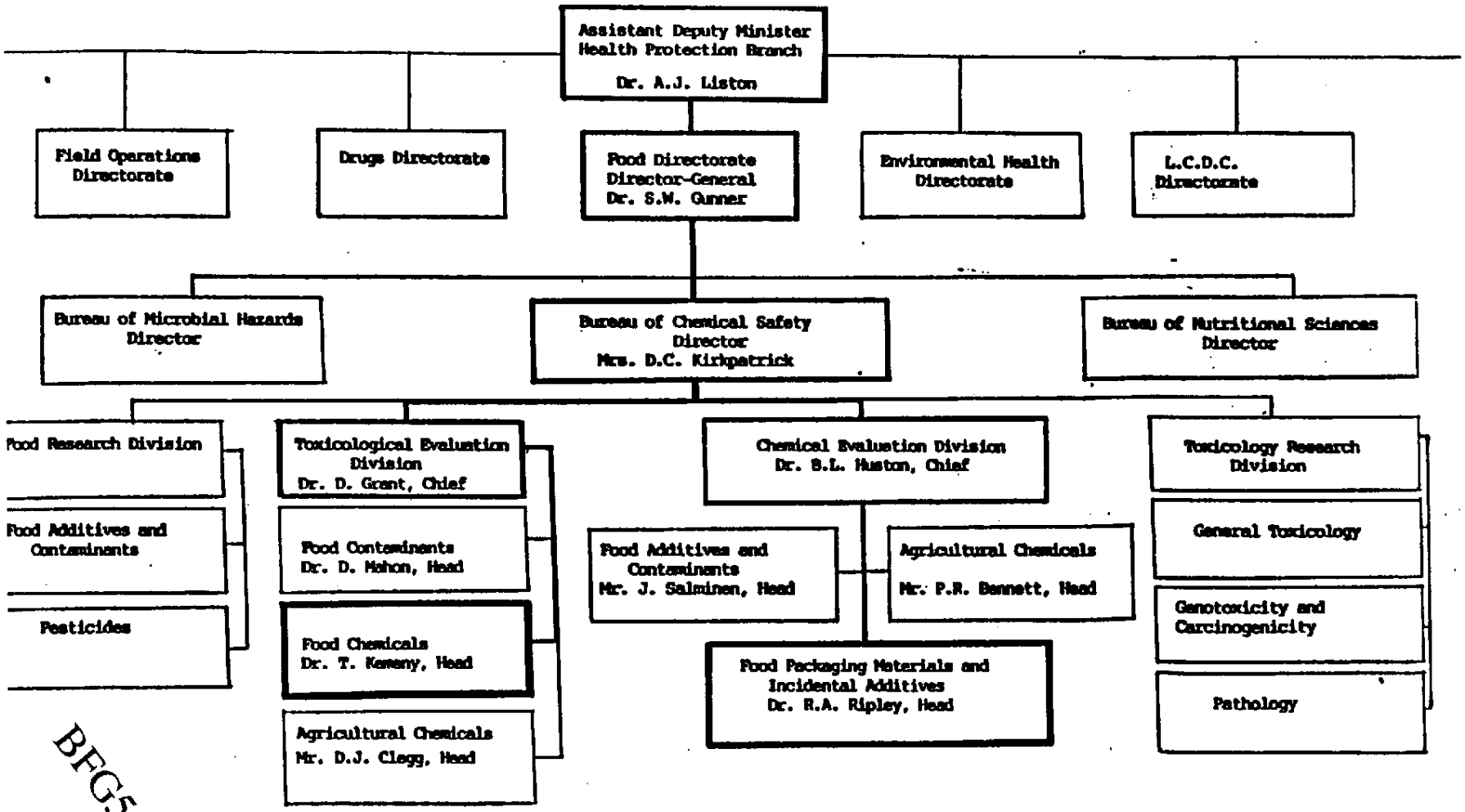
FOR FOOD CONTACT PLASTICS APPLICATIONS TO INCLUDE THERMAL STABILITY DATA IN SUPPORT OF THEIR SAFETY.

LADIES AND GENTLEMEN, I THANK YOU AGAIN FOR THIS OPPORTUNITY TO EXPLAIN THE CANADIAN APPROACH TO REGULATING FOOD PACKAGING MATERIALS. I TRUST THAT THE INFORMATION I HAVE CONVEYED HAS GIVEN YOU A BETTER INSIGHT INTO THE ACTIVITIES AND THINKING OF THE HEALTH PROTECTION BRANCH IN THAT REGARD, AND IN DOING SO HOPEFULLY ASSIST THOSE OF YOU WHO MAY BE INTERESTED IN EXPORTING YOUR PRODUCTS TO CANADA TO COMPLY WITH OUR REGULATORY REQUIREMENTS.

FINALLY, ON BEHALF OF THE HEALTH PROTECTION BRANCH, I WISH TO EXPRESS OUR APPRECIATION FOR THE COOPERATIVE SPIRIT IN WHICH SPI HAS SHARED WITH US CRITICAL TECHNICAL INFORMATION THAT HAS ASSISTED US SIGNIFICANTLY IN OUR DELIBERATIONS ON HEALTH RELATED ISSUES CONCERNING THE USE OF PLASTICS AS FOOD PACKAGING MATERIALS.

SLIDE I

HEALTH PROTECTION BRANCH



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SLIDE 2

CANADIAN FOOD AND DRUGS ACT (EXCERPTS)

EXCERPT FROM SECTION 4 OF THE FOOD AND DRUGS ACT

4. "NO PERSON SHALL SELL AN ARTICLE OF FOOD THAT:

(a) HAS IN OR UPON IT ANY POISONOUS OR HARMFUL SUBSTANCE".

EXCERPT FROM SECTION 30 OF THE FOOD AND DRUGS ACT.

"THE GOVERNOR IN COUNCIL MAY MAKE REGULATIONS FOR CARRYING THE PURPOSES AND PROVISIONS OF THIS ACT INTO EFFECT, AND, IN PARTICULAR, BUT NOT SO AS TO RESTRICT THE GENERALITY OF THE FOREGOING, MAY MAKE REGULATIONS.

(b) RESPECTING

(i) THE LABELLING AND PACKAGING AND THE OFFERING, EXPOSING AND ADVERTISING FOR SALE OF FOOD, DRUGS, COSMETICS AND DEVICES.

(ii) THE SIZE, DIMENSIONS, FILL AND OTHER SPECIFICATIONS OF PACKAGES OF FOOD, DRUGS, COSMETICS AND DEVICES, ... TO PREVENT THE CONSUMER OR PURCHASER THEREOF FROM BEING DECEIVED OR MISLED AS TO ITS DESIGN, CONSTRUCTION, PERFORMANCE, INTENDED USE, QUANTITY, CHARACTER, VALUE, COMPOSITION MERIT OR SAFETY, OR TO PREVENT INJURY TO THE HEALTH OF THE CONSUMER OF PURCHASER.

(e) RESPECTING THE METHOD OF PREPARATION, MANUFACTURE, PRESERVING, PACKING, STORING AND TESTING OF ANY FOOD, DRUG, COSMETIC OR DIVICE IN THE INTEREST OF,K OR FOR THE PREVENTION OF INJURY TO, THE HEALTH OF THE CONSUMER OR PURCHASER."

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SLIDE 3

DIVISION 23

Food Packaging Materials

B.23.001. No person shall sell any food in a package that may yield to its contents any substance that may b injurious to the health of a consumer of the food.

B.23.002. Subject to section B.23.003 no person shall sell any food in a package that has been manufactured from polyvinyl chloride formulation containing an octyltin chemical.

B.23.003. A person may sell food, other than milk, skim milk, partly skimmed milk, sterilized milk, malt beverage and carbonated non-alcoholic beverage products, in a package that has been manufactured from a polyviny
4-12-86 chloride formulation containing any or all of the octyltin chemicals, namely, di (n-octyl)tin S,S'-bis(isooctylmercaptoacetate), di (n-octyl)tin maleate polymer and (n-octyl)tin S,S',S"-tris (isooctyl mercaptoacetate) if the proportion of such chemicals, either singly or in combination, does not exceed a tota of 3 per cent of the resin, and the food in contact with the package contains not more than 1 part per millio total octyltin.

B.23.004. (1) Di (n-octyl)tin S,S'-bis (isooctylmercaptoacetate) shall be the octyltin chemical made from di (n-octyl)tin dichloride and shall contain 15.1 to 16.4 per cent of tin and 8.1 to 8.9 per cent of mercapto sulfur.

(2) For the purposes of this Division, di (n-octyl)tin dichloride shall be the chemical having an organotin composition of not less than 95 per cent di (n-octyl)tin dichloride and shall contain not more than
4-12-86

(a) 5 per cent total of n-octyltin trichloride or tri (n-octyl)tin chloride or both;
(b) 0.2 per cent total of other eight (8) carbon isomeric alkyltin derivatives; and
(c) 0.1 per cent total of the higher and lower homologous alkyltin derivatives.

B.23.005. Di (n-octyl)tin maleate polymer shall be the octyltin chemical made from di (n-octyl)tin dichloride and shall have the formula $((C_8H_{17})_2SnC_4H_2O_4)n$ (where n is between 2 and 4 inclusive), and a saponification number of 225 and 255, and shall contain 25.2 to 26.6 per cent of tin.

B.23.006. (1) (n-octyl)tin S,S',S"-tris (isooctylmercaptoacetate), being an octyltin chemical having the formula $n\text{-}C_8H_{17}Sn(SCH_2CO_2C_8H_{17})_3$, shall be made from (n-octyl)tin trichloride and shall contain 13.4 to 14.8 per cent of tin and 10.9 to 11.9 per cent of mercapto sulfur.

(2) For the purposes of this Division, (n-octyl)tin trichloride shall be the chemical having an organotin composition of not less than 95 per cent (n-octyl)tin trichloride and shall contain not more than
4-12-86

(a) 5 per cent total of di (n-octyl)tin dichloride, tri (n-octyl)tin chloride or the higher (more than eight (8) carbons) alkyltin chlorides or any combination of the foregoing.
(b) 0.2 per cent total of alkyl tin derivatives; and
(c) 0.1 per cent of the lower (less than eight carbons) homologous alkyltin derivatives.

5-8-82 B.23.007. No person shall sell a food in a package that may yield to its contents any amount of vinyl chloride, as determined by official method FO-40, Determination of Vinyl Chloride in Food, October 15, 1981, in respect of that food.

27-5-82 B.23.008. No person shall sell a food in a package that may yield to its contents any amount of acrylonitrile as determined by official method, FO-41, Determination of Acrylonitrile in Food, February 16, 1982, in respect of that food.

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SLIDE 4

PACKAGE - DEFINITION

EXCERPT FROM DIFINITIONS SECTION OF THE FOOD AND DRUGS ACT.

"PACKAGE" INCLUDES ANYTHING IN WHICH ANY FOOD, DRUG, COSMETIC OR DEVICE IS WHOLLY OR PARTLY CONTAINED, PLACED OR PACKED.

SLIDE 5

SECTION B23.001

"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"

SLIDE 6

EXCLUSION OF FOOD PACKAGING MATERIALS FROM FOOD ADDITIVE STATUS

EXCERPT FROM SECTION B.01.001 OF THE FOOD AND DRUG REGULATIONS.

"FOOD ADDITIVE MEANS ANY SUBSTANCE, INCLUDING ANY SOURCE OF RADIATION, THE USE OF WHICH RESULTS, OR MAY REASONABLY BE EXPECTED TO RESULT, IN IT OR ITS BY-PRODUCTS BECOMING A PART OF, OR AFFECTING THE CHARACTERISTICS OF, A FOOD, BUT DOES NOT INCLUDE ....

(e) FOOD PACKAGING MATERIALS AND COMPONENTS THEREOF".

SLIDE 7

FOOD ADDITIVE SUBMISSION REQUIREMENTS

B.16.002. A REQUEST THAT A FOOD ADDITIVE BE ADDED TO OR A CHANGE MADE IN THE TABLES FOLLOWING SECTION B.16.100 SHALL BE ACCOMPANIED BY A SUBMISSION TO THE MINISTER IN A FORM, MANNER AND CONTENT SATISFACTORY TO HIM AND SHALL INCLUDE

(a) A DESCRIPTION OF THE FOOD ADDITIVE, INCLUDING ITS CHEMICAL NAME UNDER WHICH IT IS PROPOSED TO BE SOLD, ITS METHOD OF MANUFACTURE, ITS CHEMICAL AND PHYSICAL PROPERTIES, ITS COMPOSITION AND ITS SPECIFICATIONS AND, WHERE THAT INFORMATION IS NOT AVAILABLE, A DETAILED EXPLANTAION;

(b) A STATEMENT OF THE AMOUNT OF THE FOOD ADDITIVE PROPOSED FOR USE, AND THE PURPOSE FOR WHICH IT IS PROPOSED, TOGETHER WITH ALL DIRECTIONS, RECOMMENDATIONS AND SUGGESTIONS FOR USE;

(c) WHERE NECESSARY, IN THE OPINION OF THE DIRECTOR, AN ACCEPTABLE METHOD OF ANALYSIS SUITABLE FOR REGULATORY PURPOSES THAT WILL DETERMINE THE AMOUNT OF THE FOOD ADDITIVE AND OF ANY SUBSTANCE RESULTING FROM THE USE OF THE FOOD ADDITIVE IN THE FINISHED FOOD;

(d) DATA ESTABLISHING THAT THE FOOD ADDITIVE WILL HAVE THE INTENDED PHYSICAL OR OTHER TECHNICAL EFFECT;

(e) DETAILED REPORTS OF TESTS MADE TO ESTABLISH THE SAFETY OF THE FOOD ADDITIVE UNDER THE CONDITIONS OF USE RECOMMENDED;

(f) DATA TO INDICATE THE RESIDUES THAT MAY REMAIN IN OR UPON THE FINISHED FOOD WHEN THE FOOD ADDITIVE IS USED IN ACCORDANCE WITH GOOD MANUFACTURING PRACTICE.

(g) A PROPOSED MAXIMUM LIMIT FOR RESIDUES OF THE FOOD ADDITIVE IN OR UPON THE FINISHED FOOD;

(h) SPECIMENS OF THE LABELLING PROPOSED FOR THE FOOD ADDITIVE; AND

(i) A SAMPLE OF THE FOOD ADDITIVE IN THE FORM IN WHICH IT IS PROPOSED TO BE USED IN FOODS, A SAMPLE OF THE ACTIVE INGREDIENT, AND, ON REQUEST A SAMPLE OF FOOD CONTAINING THE FOOD ADDITIVE.