



GLOBAL FOOD REGULATORY SCIENCE SOCIETY

GFORSS is a Disciplinary Organization of IUFOST, devoted to Food Regulatory Science



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GFORSS Capacity Building Program Food Contact Materials: International Regulatory Framework

Overview of Regulatory Management Approaches for Food Contact Materials CANADA

February 22, 2022
Virtual Event

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General Description

Data Requirements

Chemical Identity

Uses

Migration

Exposure

Toxicology



Regulatory Oversight of FPM in Canada

- Food industry (domestic and imported) is responsible for ensuring that their products comply with Canada's food standards and regulatory requirements
- Canadian Food and Drugs Act: core food safety statute that applies to all food sold in Canada; defines health and safety provisions of food products
- Act is supported by corresponding regulations as described in the Food and Drug Regulations; prescribe the standards of composition, strength, potency, purity, quality or other properties of the article of food or drug to which they refer
- Violation of the F&DA is considered a criminal offense



Overview

F&DA¹: Prohibited sales of food

4 (1) No person shall sell an article of food that:
(a) has in or on it any poisonous or harmful substance;

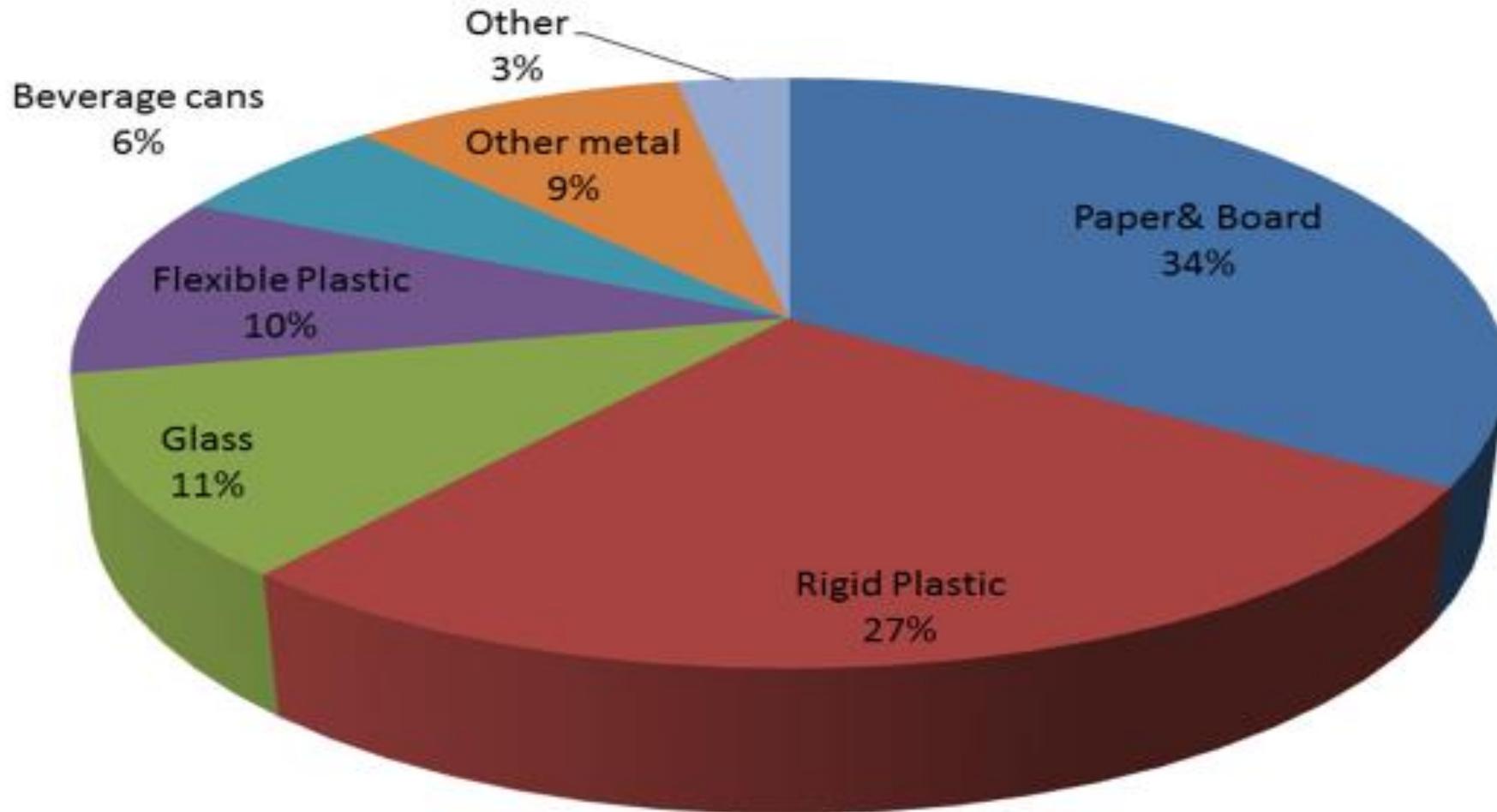
F&DR²: Division 23 - Food Packaging Materials

Section 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”



1. <https://laws-lois.justice.gc.ca/eng/acts/F-27/>
2. https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/

Market Share of Food Packaging Materials



Food Packaging Forum, 2012

Data Requirements

- Requests for “opinions” on food packaging materials can be submitted to Health Canada for a pre-market assessment of their chemical safety in relation to Section B.23.001 of the *F&DR*
- Guidance “*Information Requirements For Food Packaging Submissions*¹” is available on HC website
- Formulated/finished products and specific additives – product identity, conditions of use, technical effect and efficacy data, types of foods involved, migration data/extraction data, toxicological data, regulatory status in other jurisdictions



1. <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/information-requirements-food-packaging-submissions.html>

Data Requirements (2)

Most common food–package interactions:

Migration of Low Molecular Weight



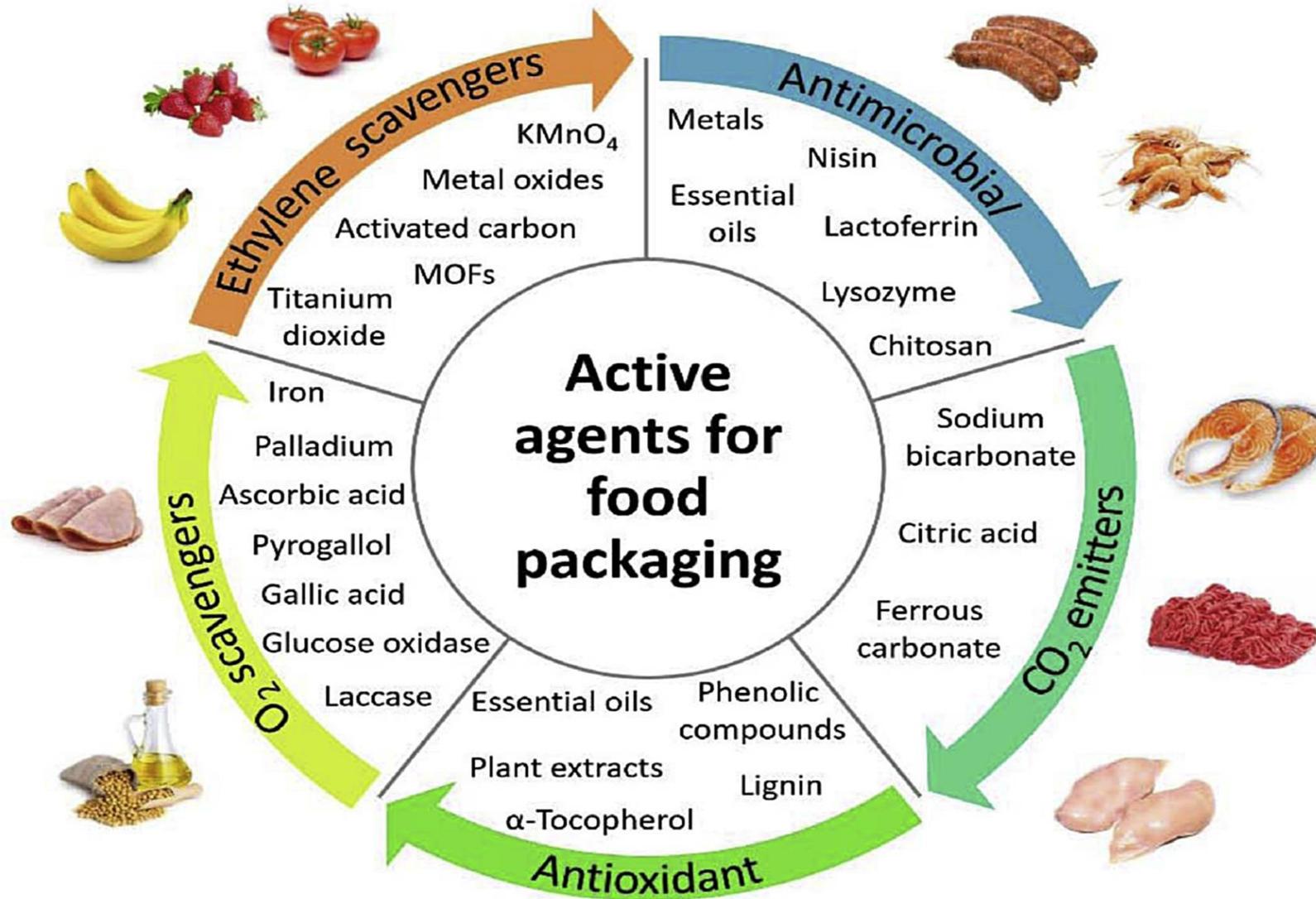
FOOD

Substances:

- Stabilizers
- Plasticizers
- Antioxidants
- Monomers
- Oligomers



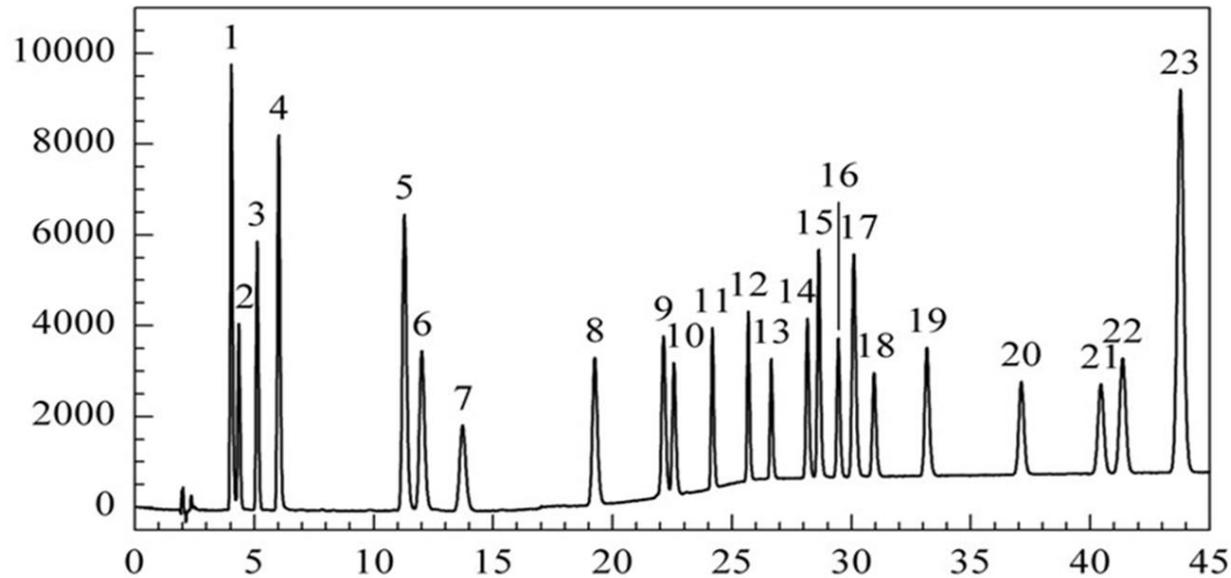
Data Requirements (3)



Data Requirements (4)



**Simulants
Migration**



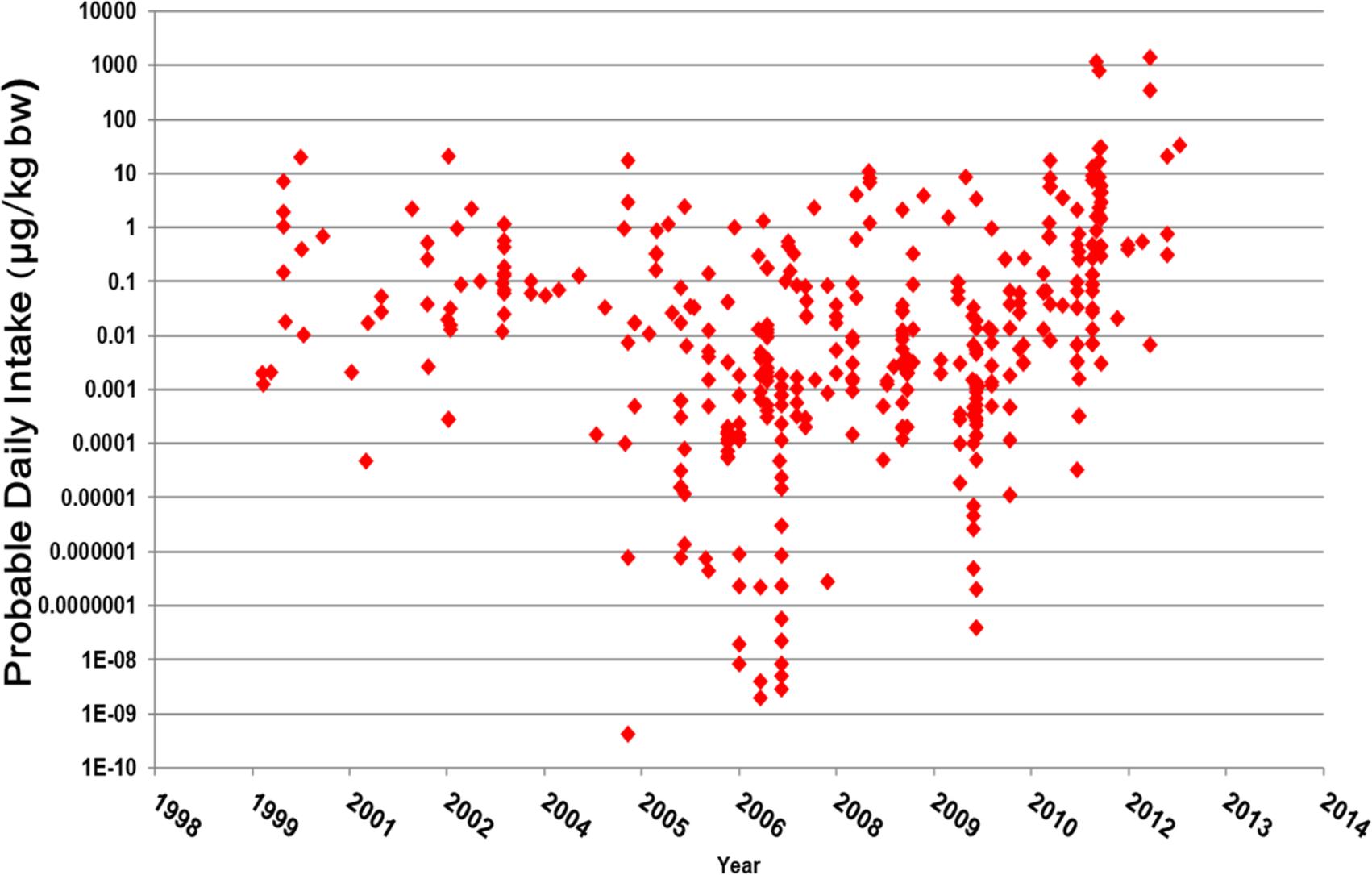
Analysis

Probably Daily Intake Estimation

$$\text{PDI } \mu\text{g/kg bw)} = [(\text{C}_{\text{aq}} \times \text{F}_{\text{aq}}) + (\text{C}_{\text{acid}} \times \text{F}_{\text{acid}}) + (\text{C}_{\text{fat}} \times \text{F}_{\text{fat}}) + (\text{C}_{\text{alc}} \times \text{F}_{\text{alc}})] \text{D}_p \times \text{M}_p \times \text{K}_p / \text{Bw}$$

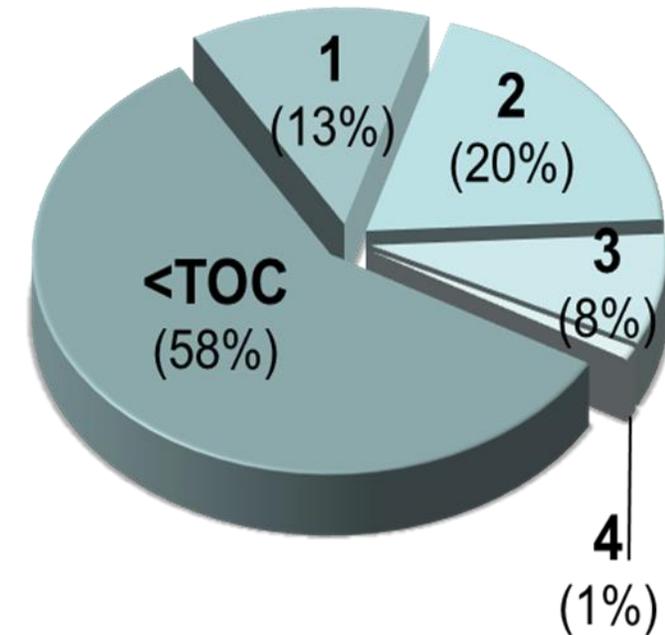
PDI	Probable daily intake
C	Concentration ($\mu\text{g/kg}$) of extracted constituent in aqueous, acidic, alcoholic and fatty food simulants, normalized to an exposure ratio of 5g/in^2
F	Intake of aqueous, acidic, alcoholic and fatty foods in the daily diet (g/day) (total of 2 kg/day)
D_p	Fraction of the total diet likely to be packaged in a particular material P in which the substance may be present
M_p	Fraction of P type packaging material, which realistically is likely to contain the constituent
K_p	Market penetration fraction for additives only
Bw	The average adult body weight in kg (use 70 kg)

Potential for Exposure: Daily intake estimates



Toxicology Data Requirements

Concern Level	Probable Daily Intake ($\mu\text{g}/\text{kg bw}$)	Toxicity Testing Guidelines
Threshold of Regulation	<0.025	none
1. Very Low	0.025 – 0.1	Structure activity data (QSAR)
2. Low	0.1 – 2.5	As above + <i>in vitro</i> mutagenicity, <i>in vitro</i> clastogenicity, 28-day oral study (rodent)
3. Medium	2.5 – 25	As above + 90-day oral, multigeneration and teratology rodent studies
4. High	> 25	As above + chronic feeding studies in rodent and non-rodent species



Approval Process

- If sufficient toxicology data has been submitted for estimated PDIs, HC will issue a letter of no objection (LONO) for the use of the FPM as described in the submission
- Petitioner can then use the LONO from HC to legally market the FPM
- Up until 2014, details of the LONO were added to a searchable data base (Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products Database¹)
- Currently, industry using FPM can provide a Letter Of Guarantee (LOG) from their suppliers stating that their packaging materials meet the requirements as set out in the F&DR



1. <https://food-nutrition.canada.ca/food-safety/referencelist/index-en.php>



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GFORSS Capacity Building Program

Food Contact Materials: International Regulatory Framework

A Review of the Australia/New Zealand Standards for Food Packaging Chemicals

Dr Scott Crerar

February 22, 2022

OFFICIAL
Virtual Event

Outline

- About FSANZ and Australia/New Zealand Food Standards Code
- Review of requirements around food packaging chemicals
- Surveys and risk assessment
- Risk management approach

About Food Standards Australia New Zealand

- FSANZ is an Australian statutory agency within the Australian Government Health portfolio
- Our main function is to develop and administer the Australia New Zealand Food Standards Code (the Code)
- The Code is a legislative instrument, that is given effect by state and territory or New Zealand laws
- Not responsible for enforcement

Australia New Zealand Food Standards Code

Chapter 1

Chapter 2

Chapter 3

Chapter 4

Schedules

General food standards:

- Definitions
- Labelling requirements
- Use of substances added to food
- Use of new foods
- MRLs (Aus)
- Food processing requirements (Aus)

Food product standards:

- Cereals
- Fruits
- Vegetables
- Dairy products
- Beverages
- Special purpose foods

Food safety standards Australia only

- Food safety programs
- Food premises and equipment

Primary production standards Australia only

- Production and processing of seafood
- Poultry meat
- Meat, and
- Other commodities

Permissions for use of:

- substances added to food
- use of new foods
- Permitted MRLs

Chemicals migrating from food packaging

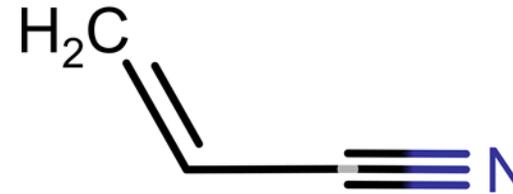
Risk management

- Contaminants – establish maximum levels in foods
- ML is established only when it serves an effective risk management function and only for those foods which provide a significant contribution to the total dietary exposure
 - Only a few MLs in Food Standards Code
 - Other general food safety requirements apply
- Alternative? - Establish ML for packaging material not the food (but FSANZ can only regulate food)
- Non-regulatory measures – information, codes of practice
- Self-regulation such as industry standards

Standards around food packaging chemicals

Vinyl chloride (PVC) and acrylonitrile (range of plastics) – carcinogenic in animal studies, VC human carcinogen (occupational exposure).

MLs set at limit of detection (ppb).



Tin (Sn, Sn²⁺, Sn⁴⁺) from canned foods – gastrointestinal disturbances at relatively high oral exposures (acute).

ML = 250 mg/kg.

Review risk from food packaging chemicals

A risk assessment challenge

- Several thousand chemicals are used in the manufacture of food packaging and other materials that come into contact with food during its production and processing.
 - Food packaging - glass, paper, cardboard, plastics, aluminium
 - Chemicals used for production, bulk packaging material + adhesives, protective coatings and printing inks, etc.
- How to assess risk that may arise from such chemicals?
- Are current risk management measures managing risk?
 - Issues raised by industry around imports, recycled materials, low level of knowledge of chemicals migrating from packaging

Review undertaken by FSANZ

- Potential public health and safety risk ?
- Risk management measures in place?
- Adequacy of regulation?
- Activities undertaken:
 - ❖ Industry Advisory Group
 - ❖ Consultation
 - ❖ Surveys – analytical; qualitative
 - ❖ Review of overseas requirements



Chemicals migrating from food packaging

Chemical risk assessment (**Risk** = **Hazard** x **Exposure**)

1. Hazard Assessment

- Hazard Identification
- Hazard Characterisation (dose-response assessment)
- Derivation of a “Health-Based Guidance Value” (HBGV)
e.g. a Tolerable Daily Intake (in mg/kg bodyweight/day)

2. Dietary Exposure Assessment

- Chemical concentration data
- Food consumption data
- Estimated Dietary Exposure to the chemical (in mg/kg bodyweight/day)

3. Risk Characterisation

- Comparison of HBGV with Estimated Dietary Exposure

Chemicals migrating from food packaging

Dietary exposure assessment

- Data on consumption of specific foods and levels of chemicals in those foods
- Migration levels are typically very low e.g. < 0.1 mg/kg
- Screening approaches based on worst-case exposure scenarios often sufficient for risk assessment purposes
 - E.g. Maximum detected concentration assumed for foods not analysed
- If simple DEA not adequate then test more foods and refine DEA

Threshold of Toxicological Concern Approach

- Threshold of Toxicological Concern (TTC) approach
 - “pragmatic risk assessment tool that is based on the principle of establishing a human exposure threshold value for all chemicals, below which there is a very low probability of a risk to human health”
- Based on chemical structure and the known toxicity of chemicals which share similar structural characteristics.
- Chemicals allocated to one of several thresholds depending on structure/functional groups.
- Estimated dietary exposure is compared to the applicable threshold.

Chemicals migrating from food packaging

Analytical surveys of Aus/NZ food supply

- 2010: BPA. Detections in some foods but no safety concerns.
- 2010: Phthalates, perfluorinated compounds, ESBO, semicarbazide, acrylonitrile and vinyl chloride. 65 foods and beverages packaged in glass, paper, plastic or cans. No safety concerns.
- 2015: 24th ATDS. No safety concerns for 28 of the 30 chemicals tested (BPA, ESBO, phthalates, printing ink chemicals). **For the phthalates DEHP and DINP, additional concentration data required.**
- 2017: NZ. Phthalates, photoinitiators/printing inks. No safety concerns.
- 2018: Survey of plasticisers (DEHP, DINP, BBP, DBP, DEHA, ATBC). No safety concerns.
- 2018: Mineral oil hydrocarbons. No safety concerns.

Chemicals migrating from food packaging

Conclusions – Aus/NZ work on Food Contact Materials

- Exposures to most chemicals from food packaging are low and unlikely to pose a public health and safety concern
- Overall, sufficient control measures are in place to control chemical migration into food
- Analytical surveys of targeted chemicals did not show a risk
- However, some food businesses showed poor knowledge of the issue. More evident for small-to-medium enterprises
- FSANZ to develop a food packaging information guide for industry, provide general information on safety issues for consumers, and describe the obligations on food businesses (particularly SMEs) to use safe packaging materials

