

SAFETY OF FOOD CONTACT MATERIALS (FCMs)

Prof. Alejandro Ariosti
NATIONAL INSTITUTE OF INDUSTRIAL TECHNOLOGY
(INTI) – PLASTICS CENTRE
FACULTY OF PHARMACY AND BIOCHEMISTRY –
UNIVERSITY OF BUENOS AIRES
ARGENTINA

Leiden, 28th. March 2019.



AGENDA:

- **WHAT ARE FOOD CONTACT MATERIALS (FCMs)?**
- **MIGRATION OF SUBSTANCES FROM FCMs TO FOOD**
- **RISK ASSESSMENT (RA) OF FCMs**
- **FCMs REGULATIONS**
- **CASE STUDY: HARMONIZATION OF MEMBER STATES FCMs REGULATIONS IN MERCOSUR (THE COMMON MARKET OF THE SOUTH)**
- **ANNOUNCEMENT: EVALUATION OF EU FCMs REGULATION (2018-2020)**

Food contact materials (FCMs) comprise mainly the following categories:

- **food packaging** and its accessories (e.g. caps, stoppers);
- **promotional articles** (e.g. toys, cards, labels) included into the primary package;
- **equipment, devices, utensils and containers** for the production/industrial manufacture, storage and packaging of food;
- **equipment for the distribution and storage** of drinking water;
- **kitchenware, utensils and containers** for the institutional/domestic preparation and consumption of food.



Composition:

- **conventional plastic**
- **biodegradable plastic (sustainability)**
- **post-consumer recycled (PCR) plastic (circularity)**
- **active and intelligent materials (AIMs)**
- **nanomaterials (nanotechnology)**



PET packaging for organic honey

Safety-by-design:

- **Intentionally added substances (IAS)** (monomers, additives, catalysts, etc.)
- **Non-intentionally added substances (NIAS)** (impurities, oligomers, reaction products, etc.)
- **PCR materials** (plastics, paper and board, etc.) (residual food, chemicals by misuse, printing inks, adhesives, etc.)

MIGRATION

(all must be risk - assessed)

Regulations worldwide (e.g. Article 3 Regulation (EC) 1935/2004; MERCOSUR Resolution (3/1992); US-FDA 21 CFR 174.5), establish general requirements for FCMs; while acknowledging that migration of components occurs, set limits to it.

Migrants from FCMs must not:

- (a) change the nutritional composition of food;**
- (b) pose a risk to human health;**
- (c) cause taints problems in food, with undesirable changes to their sensory characteristics.**

DETERMINATION OF MIGRATION:

➤ STANDARDIZED TESTS WITH FOOD SIMULANTS

➤ PREDICTION BY MATHEMATICAL MODELS

➤ CALCULATION OF POTENTIAL MIGRATION (ASSUMING 100% MIGRATION TO FOOD OF THE SUBSTANCE PRESENT IN THE FCM)

**RISK ASSESSMENT (RA) OF SUBSTANCES (FCMs
REGULATIONS ADDRESS ALMOST ONLY CHEMICAL
RISKS)**

RISK = HAZARD x EXPOSURE

HAZARD IDENTIFICATION AND CHARACTERIZATION

IN VIVO TESTS (e.g. chronic toxicity, 2nd. generation chronic)

IN VITRO BIOASSAYS

- cytotoxicity (e.g. Microtox®, cell proliferation)
- genotoxicity (e.g. Ames, Comet)
- endocrine activity (e.g. AR Calux, ER α Calux)

IN SILICO METHODS (e.g. (Q)SAR, structural alerts, read-across)

- **In vitro and in silico tests need to be validated; difficulties in interpretation; used in combination. Trend: in vitro + HepG2.**
- **In vivo test required by EU and US-FDA (according to migration or estimated daily intake (EDI), respectively).**

EXPOSURE ASSESSMENT

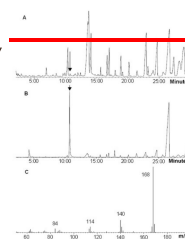
Traditional approach: different schemes. E.g.:

- **EU:** migration from a 6 dm² cubic packaging where the substance under evaluation is present, to 1 kg of food consumed daily;
- **US-FDA:** databases of consumption factors per type of food and material are used to calculate cumulative estimated daily intakes (CEDI).

(case by case evaluation of known substances for clearance and inclusion in positive lists or repositories)

Prioritization strategies (screening methods, multiple migrants, NIAS):

- the Matrix European Exposure Project (2005-2011) approach applied to plastic food packaging;
- the exposure modeling tool developed by the FACET (Flavors, Additives and Food Contact Materials Exposure Task) EU FP7 Project (2008-2012) (kept actually by the EU JRC)
- the Threshold of Toxicological Concern (TTC) for substances for which there is a lack of toxicological data (EFSA/WHO, 2016);
- the Complex Mixture Safety Assessment Strategy (CoMSAS) (TNO-NL) applying the TTC + bioassays for chemical mixtures.



- Validated applications in specific cases; TTC for NIAS recommended by EFSA, questioned by Nordic Council of Ministers.


RISK MANAGEMENT

- Regulations in several countries (e.g. China, Japan, Switzerland, USA) and blocks (e.g. EU, MERCOSUR): different schemes in some jurisdictions (no Codex recommendations on FCMs).

For instance:

- Positive lists (China, EU, MERCOSUR, US-FDA; not in Japan)
- Functional barrier layer concept (China, EU, US-FDA) (for non CMR substances, non nanofirms, ensures migration $\leq 10 \mu\text{g}/\text{kg}$) (CMR: non carcinogenic, mutagenic, toxic to reproduction)
- Threshold of regulation (TOR) (US-FDA; not accepted by the EU) (migration $\leq 0.5 \mu\text{g}/\text{kg}$ food (dietary base) no concern)

- EU and US-FDA schemes are attracting the attention of countries/blocks that are developing or reviewing their legislations (e.g. ASEAN in SE Asia, Australia-New Zealand, Canada, China, Japan, MERCOSUR in South America).



The Common Market of the South (1991):

- MERCOSUR (Spanish)
- MERCOSUL (Portuguese)

Member States:


- Argentina
- Brazil
- Paraguay
- Uruguay
- Venezuela (suspended)

Member State in integration process:


- Bolivia

Associated States:


- Chile
- Colombia
- Ecuador
- Guyana
- Peru
- Surinam




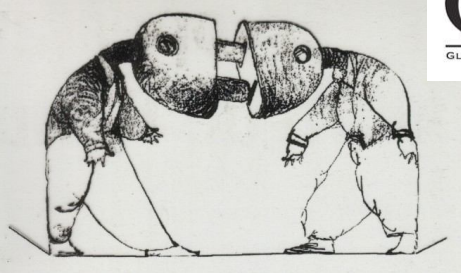
THE HARMONIZATION OF NATIONAL REGULATIONS



Divergent efforts




Convergent efforts




Standardization – Consumers safety + Technical Barriers to Trade (TBT) removal

Recommendations





COUNCIL OF EUROPE CONSEIL DE L'EUROPE





Bundesinstitut für Risikobewertung


GERMANY (BfR)

European Union

USA




REFERENCE REGULATIONS AND RECOMMENDATIONS FOR THE HARMONIZATION PROCESS IN MERCOSUR.

Christine Boisrobert, Sangsuk Oh, Aleksandra Stjepanovic and Huub Lelieveld, Editors.

Academic Press – Elsevier – UK, 2009.

Chapter 14: “Food Packaging Legislation: Sanitary Aspects”.


Authors: Gisela Kopper (US-FDA Regional Office, San José de Costa Rica; University of Costa Rica) and Alejandro Ariosti (INTI-Plastics Center; University of Buenos Aires).




GLOBAL HARMONIZATION INITIATIVE

UPDATED 2nd. Edition in process

ENSURING GLOBAL FOOD SAFETY
EXPLORING GLOBAL HARMONIZATION



EDITED BY
CHRISTINE BOISROBERT • SANGSUK OH
ALEKSANDRA STJEPANOVIC • HUUB LELIEVELD

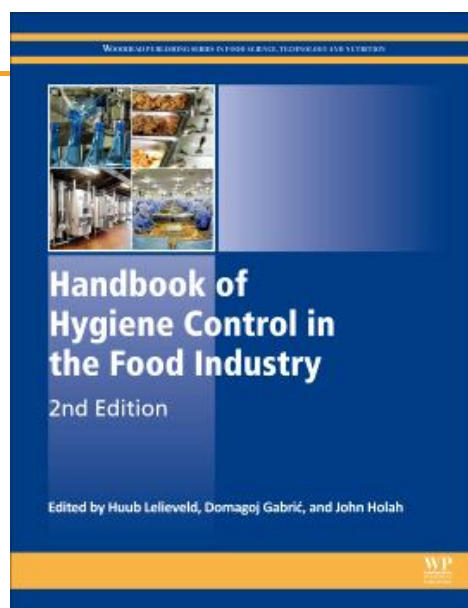


**H. Lelieveld, D. Gabric
and J. Holah, editors.**

**Chapter 11: “Managing
contamination risks from
packaging materials”.**

**Author: Alejandro Ariosti
(INTI-Plastics Centre;
University of Buenos
Aires)**

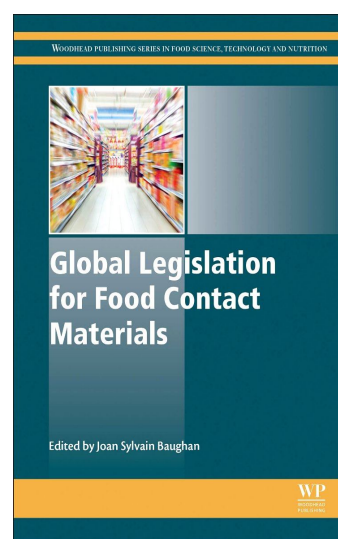
Published June 2016.









**Joan Sylvain Baughan (Keller and Heckman
LLP, Washington DC., USA) , editor.
Woodhead Publishing - Elsevier, Cambridge,
UK. Published April 2015.**

**Chapters of interest that describe the
MERCOSUR regulations for different
materials:**

- Ch. 4: Plastics, by R. T. LeNoir (USA)
- Ch. 5: Regenerated cellulose, by A. Ariosti (Argentina)
- Ch. 6: Rubber, by J. Sidwell (UK)
- Ch. 9: Paper and board, by J. S. Baughan (USA)



Subject	US-FDA 	EU 	MERCOSUR 
Legal status of FCMs	<p>Drinking water supply equipment is excluded from the Regulation.</p> <p>➤FCMs are considered as indirect food additives.</p> <p>Houseware and utensils are excluded.</p>	<p>Drinking water supply equipment is excluded from the Regulation.</p> <p>Houseware and utensils <u>are not</u> excluded.</p>	<p>Drinking water supply equipment is excluded from the Regulation.</p> <p>Houseware and utensils <u>are not</u> excluded.</p>

Subject	US-FDA 	EU 	MERCOSUR 
Overall migration limits (plastics)	<p>0.5 mg/in² (=7.75mg/dm²)</p> <p>50 mg/kg (supposing 10 g food / in² FCM surface area contact)</p>	<p>10 mg/dm²</p> <p>60 mg/kg (for infants and children FCMs)</p>	<p>8 mg/dm²</p> <p>50 mg/kg</p>
Threshold of regulation (TOR)	<p>0.5 µg/kg (dietary base) (21 CFR 170.39)</p>	<p>Not established</p>	<p>0.5 µg/kg (dietary base), only in the case of PCR-PET (Resolution GMC 30/07)</p>



“Stakeholder Workshop on the Evaluation of Food Contact Materials Legislation in the European Union”, held on 24 September 2018, in Brussels.

The Workshop was organized by the EC DG SANTE and the material is available at:

https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/evaluation_en

[\(the GHI/EHEDG had a delegate there\)](#)

ADDRESSED KEY POINTS (1):

EC:

- Different approaches towards risk assessment (RA) in EU Member States (MS)
- Information flow along supply chain (e.g. Declaration of Compliance (DoC))
- Enforcement of FCMs Regulation across MS
- Possible overlap of FCMs Regulation with other EU legislation (e.g. REACH, biocides) and EU policies (e.g. circular economy)
- Lack of standardized methods
- Non-harmonized MS regulations
- Issues with mutual recognition
- [Final report by Contractor \(ECORYS\) by early 2020, after evaluation process.](#)

NGOs:

- Specific harmonized measures for all FCMs (4 vs. 13) and periodical review
- Integration of REACH information on chemicals
- Assessing of mixture of chemicals
- Endocrine disrupting chemicals (EDCs) (e.g. bisphenol A (BPA))
- Assessment of non-intentionally added substances (NIAS)
- Innovation in terms of safer materials/services, not only in substances
- Balanced representation of stakeholders in the EU expert group on FCMs

ADDRESSED KEY POINTS (2):**Industrial Associations:**

- Analytical methods and tests (not always available, validation, standardisation, guidelines)
- Very limited access to *in silico* tools for RA
- Lack of pre-submission discussions with EFSA panel
- High barrier for new products development
- Lengthy RA and authorisation process
- Lack of official rules on compliance with Article 3 Regulation (EC) 1935/2004

Official Food Control Authority of the Canton of Zürich (KLZH) - Switzerland:

- Lack of European-level working group on enforcement
- High number of substances as potential migrants (estimated 100.000, 10.000 intentionally added, 1000 specifically regulated, less than 100 effectively controlled)
- Lack of resources for FCMs controls
- Lack of knowledge on risk associated with migration from FCM (unknown toxicity and migration behaviour)

CONCLUSIONS:

➤ **NON-HARMONIZED METHODOLOGIES, STANDARDS AND REGULATIONS WORLDWIDE MAY ESTABLISH DIFFERENT LEVELS OF PROTECTION OF CONSUMER'S HEALTH AND TECHNICAL BARRIERS TO TRADE.**

➤ **ARE HARMONIZATION AND MUTUAL RECOGNITION POSSIBLE AT PRESENT? EXPLORE THE CLIMATE IN GLOBAL FOOD CONTACT 2019 (LISBON, PORTUGAL, MAY 14-16) AND US PLASTICS INDUSTRY 14th. SYMPOSIUM REGULATION OF FOOD PACKAGING WORLDWIDE (BALTIMORE, MD, JUNE 11-14).**

➤ **TWO MAJOR FCMs REGULATORY SCHEMES SEEM TO BE GRAVITATING AS INTERNATIONAL REFERENCES: EU AND US-FDA.**

➤ **DIVERSE ENFORCEMENT OF REGULATIONS WORLDWIDE.**

➤ **FOLLOW-UP OF THE ECORYS REPORT ON EU REGULATION EVALUATION (EARLY 2020).**

**THANK YOU VERY MUCH FOR YOUR
KIND ATTENTION!!**

Prof. Alejandro Ariosti
ariostia@inti.gob.ar
proslear@hotmail.com

