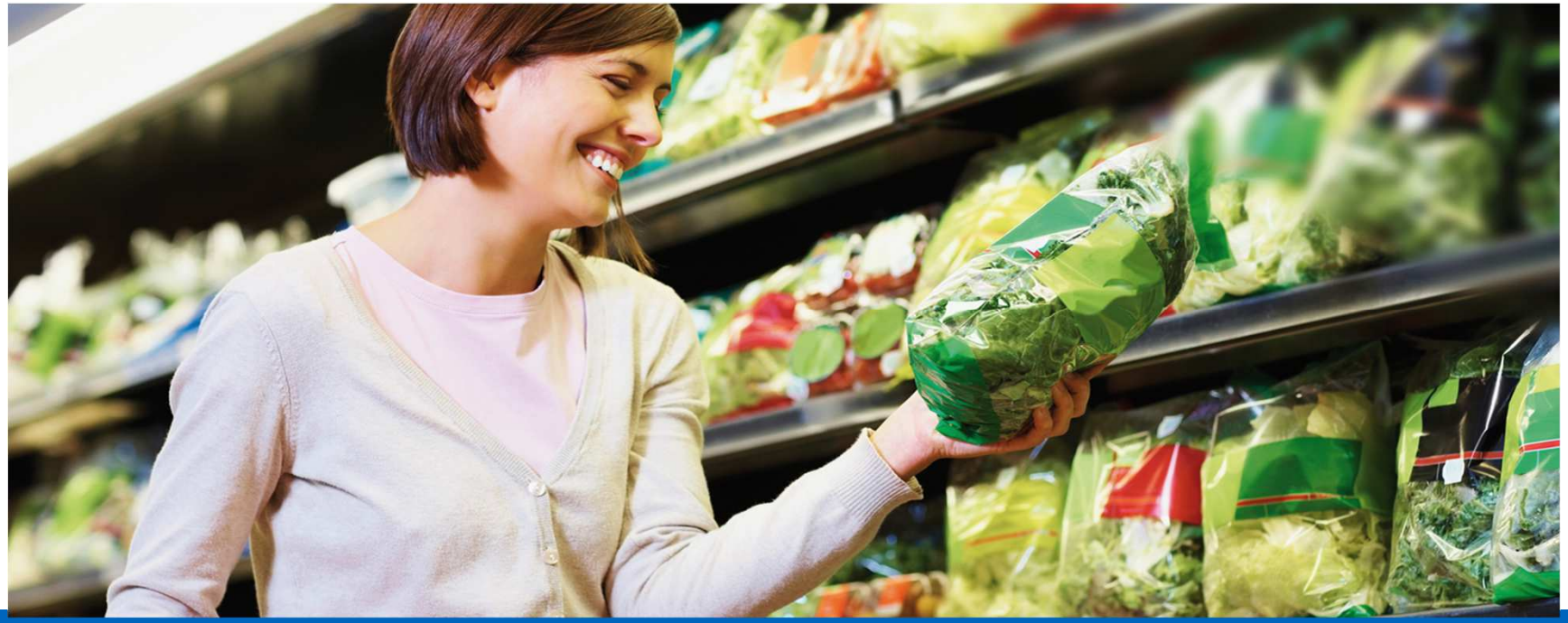

A repository to support risk assessments of NLS and NIAS

Michel Cassart/Marcel Bosma

PlasticsEurope
Association of Plastics Manufacturers

Food Packaging Forum 2019 Workshop (October 2019)

European plastics demand by segments and polymer types

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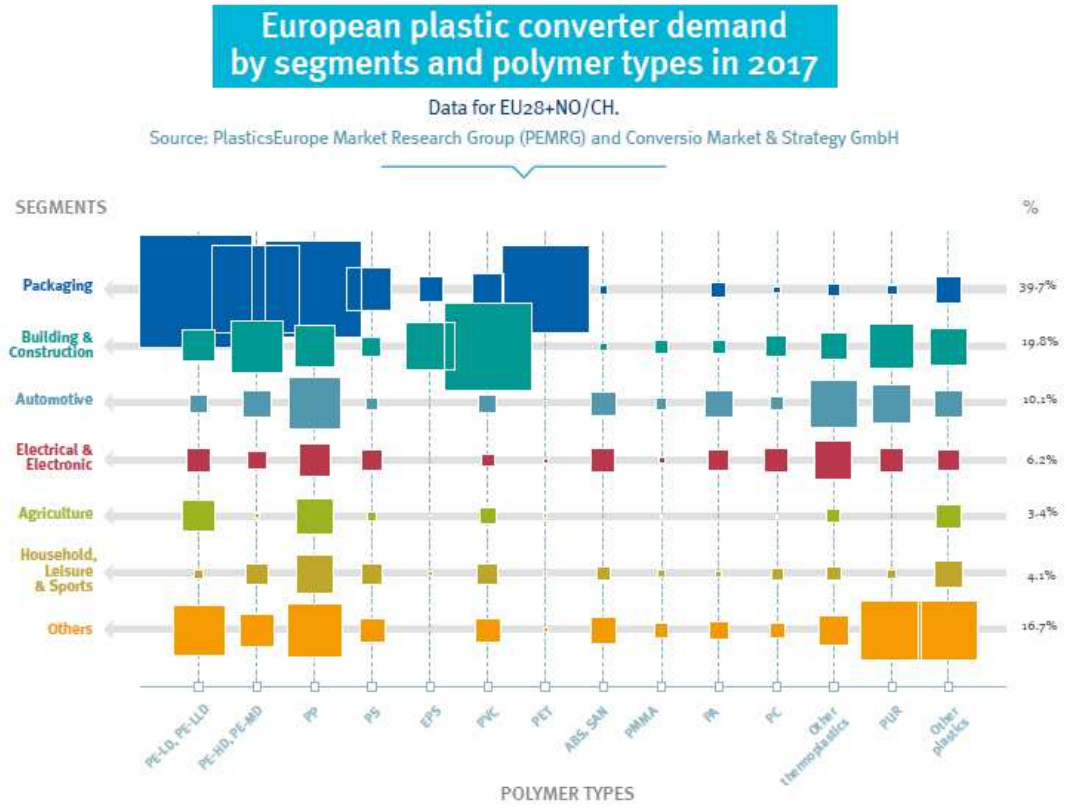
Association of Plastics Manufacturers



2017 EUROPEAN Plastics converter demand: ~51 millions Tonnes/y
Food Contact Application: > 10-12 millions Tonnes/y (~50% packaging +…)

Data: 2017 : https://www.plasticseurope.org/en/resources/publications/619-plastics-facts-2018

The EU Food Contact Requirements for plastics (in short)

PlasticsEurope
Association of Plastics Manufacturers

Article 3 Regulation (EC) 1935/2004	o **must not** under normal or foreseeable conditions: • **Endanger human health** • Unacceptable change in composition of food • Deterioration of organoleptic characteristics
Article 5 Regulation (EC) 10/2011	o Monomers or other starting substances o Additives excluding colorants o Polymer production aids excluding solvents o Macromolecules obtained from microbial fermentation
Article 6.2/6.4 Regulation (EC) 10/2011	o Non-intentionally added substances (NIAS) o Aids to polymerization (AP) o Colorants and solvents } NLS
Article 19 Regulation (EC) 10/2011	o NLS (non-listed substances) and NIAS are subject to a risk assessment acc. to internationally recognized principles

Risk-Assessment according to Article 19

- Guidance for Risk Assessment according to Internationally Recognized Principles
  - https://www.plasticseurope.org/application/files/6215/1704/0232/20141010ra_for_non_listed_substances_and_nias_under_article.pdf; https://fca.cefic.org/images/FCA_Risk_Assessment_Guidelines_v2.0.pdf; https://ilsi.eu/publication/guidance-on-best-practices-on-the-risk-assessment-of-non-intentionally-added-substances-nias-in-food-contact-materials-and-articles/ ; https://www.who.int/foodsafety/publications/chemical-food/en/
  - Based on modern scientific approaches, address new concern
    - Progress ahead of regulation and follow modern sciences
  - Use a broad sources of validated data
    - Toxtree, TTC, Peer reviewed scientific literatures, Reach data,…
    - Evaluation from Authorities (EFSA, Member States,…)
    - Industry toxicological studies, Exposure assessments,...
- Challenges
  - Limited recognition at EU enforcement
  - Due to confidentiality and competition, detailed information cannot be easily shared and transferred all along the entire value chain

→ Suggestion to make the industry human exposure assessments more transparent: REPOSITORY

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REPOSITORY

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Association of Plastics Manufacturers

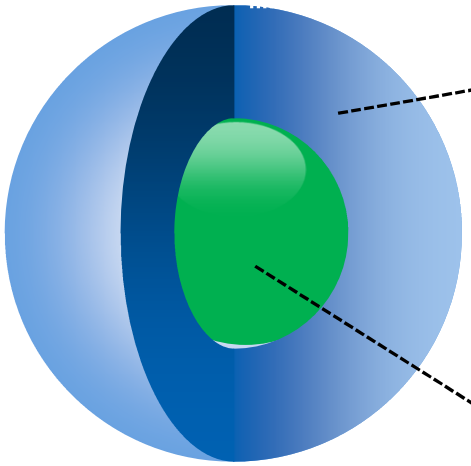
The aim of the repository:

- To make industry the human exposure assessments **more visible**
- To **avoid duplication/multiplication** of assessment work in the value chain
- To **allow data sharing** (and compensation of data) of a specific substance of interest for e.g. risk assessment purposes
- **Creating recognition** of hazard information at enforcement authorities

Without a repository such data would stay isolated and non-standardized in the value chain

Please note that the content of this presentation provides only a brief overview of the ideas developed during brainstorming sessions. The content needs to be further analyzed and developed

General Concept



The repository shall contain information assessed by Industry or Member States, incl. estimated human exposure limits and toxicological endpoints.

Access open to the general public and all stakeholders*

***Packaging and Food industry, Retailers, Importers, National & European authorities, NGO's, Consumers,…**

The Core shall contain the detailed assessment by data holder

Access is based on Authorization

Please note that the content of this presentation provides only a brief overview of the ideas developed during brainstorming sessions. The content needs to be further analyzed and developed

A repository to support communication

PlasticsEurope
Association of Plastics Manufacturers

Today	Future …
Listed Substances: EU “food” limits (e.g. SML’s) risk evaluation by EFSA and the Commission are generic data Open to all stakeholders via Annex I of Regulation (EU) No. 10/2011 Communication via Documentation of Compliance (DoC)	
Industry substance assessments (Art.19) documented in the supporting documentation (SD) SD can be accessed by enforcement authorities Risk Management Measures (RMM) (when applicable) communicated via the DoC	
	Substance evaluations stored in a repository - General information open to stakeholders including general public - Detailed human exposure assessment only accessible via Authorization - All repository information accessible to enforcement authorities - Ownership of data stays in the repository community

Please note that the content of this presentation provides only a brief overview of the ideas developed during brainstorming sessions. The content needs to be further analyzed and developed

Pilot phase development

- Dedicated to plastic at starting phase
  - Involvement of the all Plastics Food Contact Industry via Plastics Coordination Group (PCG)*
- Organization (work in progress)
  - Supervisory board: Defining the scene and overviewing the process
  - Project team: Making the repository idea a reality
- Many challenges to be overcome
  - Database model/ownership
  - Substance identity/retrieval
  - Data quality/consistency, ownership, data sharing
  - Liability, misuses, copyright, protection of confidential business information
  - Business model & Cost sharing
  - Authorities participation
- Timeline: Not yet defined

PCG is a think-tank for regulatory topics of the plastics Food Contact Material and Article Value chain composed of CEFIC-FCA, PlasticsEurope, EuPC, Flexible Packaging Europe (FPE), PRE (Plastics Recycling Europe), APPLIA

Please note that the content of this presentation provides only a brief overview of the ideas developed during brainstorming sessions. The content needs to be further analyzed and developed

Example of existing tools

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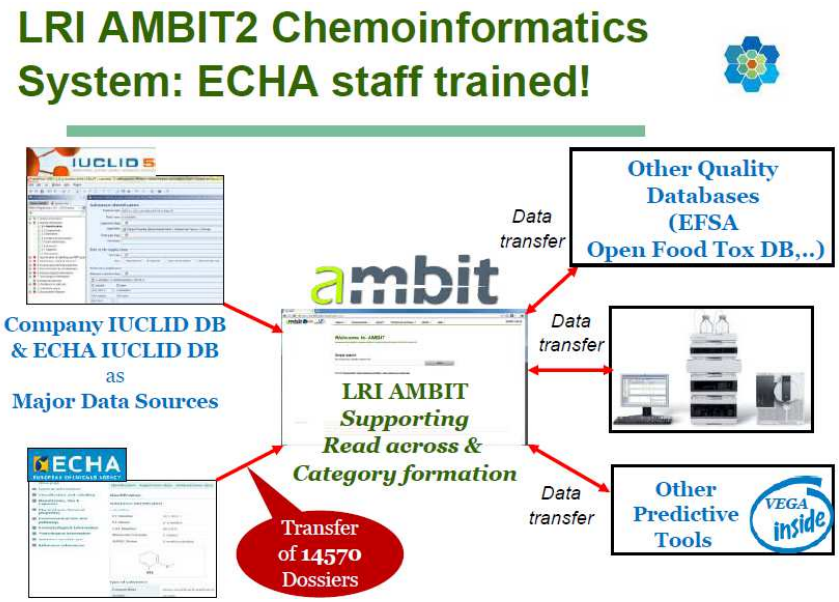

http://cefic-lri.org/toolbox/ambit2/

AMBIT2 main functions

- **Search structures & Data**
  - exact, similar, substructure
  - combined with data search
- **Retrieval and management of IUCLID6 substance data** (New)
  - substance identification and composition
  - Assigning structures to constituents, impurities
  - 43 data endpoints of 14.570 substances (New)
- **Read across/category formation**
  - Workflows facilitates search for target and source structures, generating data matrices, gap filling and generating assessment reports with predefined formats automatically
- **Prediction tools / databases** (New)
  - VEGA models, Toxtree, Cramer rules, Protein binding / OpenFoodToxDB (New)
- **Data management & exchange**
  - flexible import/export of dataset
  - manual upload of i6z files exported from IUCLID or semi-automatic import via IUCLID Web services.

AMBIT3 ?

- CompTox Dashboard database from US EPA (700k chemicals)
- TK integration (IndusChemFate?, others), ADME's
- FAME2 (Univ.Hamburg): predictive metabolism e-tool
- Open source, Application Programming Interface available
- Stand alone and web versions
- IUCLID n+1 New and better functionalities
- Platform/hub?
- 2019?
- And more...(REACH post 2018, METEOR, ToxRevDB-USEPA, PBT profiler, DIAMONDS, EPISUITE, ...)
- ? Belgian Food Contact Database

Risk Assessment: in Short

https://www.plasticseurope.org/application/files/2615/2933/0926/The_Role_of_Food_Packaging_2018.pdf

THANKS for your attention

Others in development

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