FOOD CONTACT PLASTICS SEMINAR 2018
Ensuring safety of products:
Focus on retailers and consumers
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Strategy for a Common Approach to Risk Assessment

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forewords

- The Food Contact Materials legislation is historically incomplete
- The Positive Lists approach has largely been demonstrated unsuitable to address the complex composition of FCM
- For many years Industry advocated for the use of Risk Assessment methods to address safety of FCM
- Risk Assessment was instrumental to cover plastics' non-listed substances, NIAS, as well as non-plastic FCM
- Significant progress was made in Hazard Identification (analytical), and Risk Evaluation (exposure, thresholds of concerns and other scientifically recognized tools)

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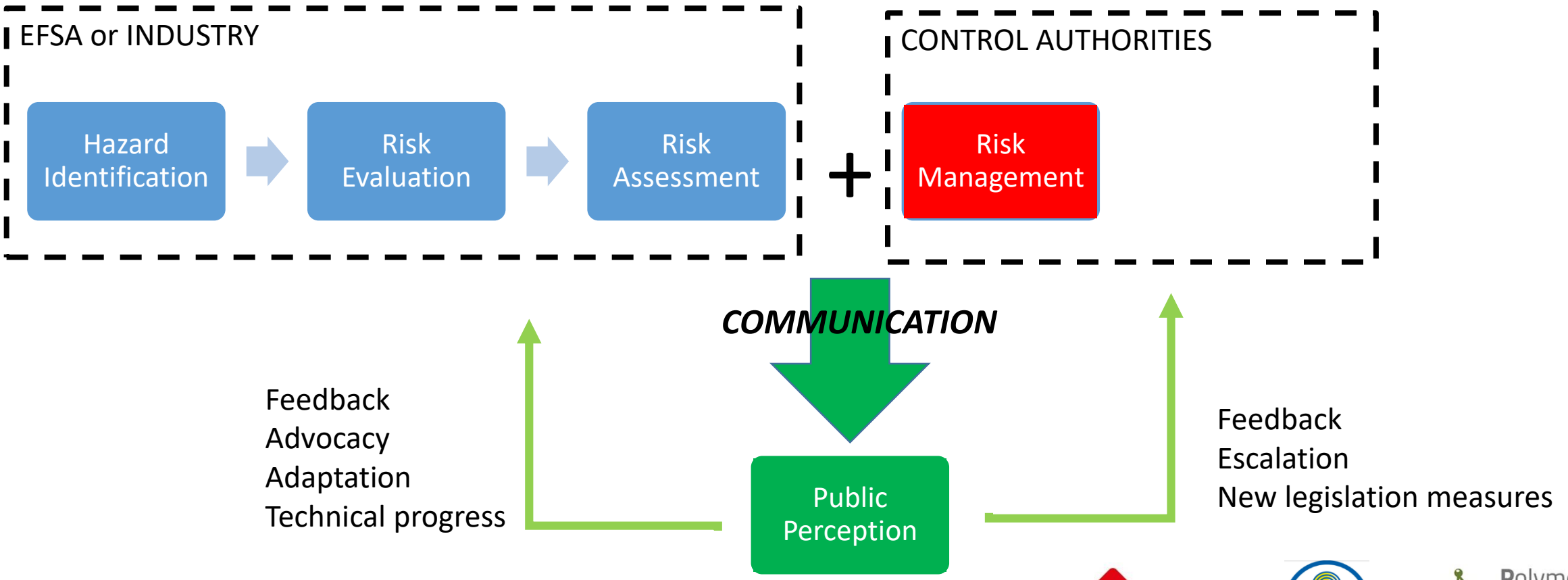
The Risk Communication Cycle



Compliance

- Very elaborated set of administrative rules, much more effort into demonstrating compliance rather than demonstrating safety
- Press, NGO's, 3rd party testing laboratories, enforcement authorities claim that the current rules are not sufficient to show the safety of the consumer.
- Trend towards *more* regulation without giving much thought to what would be *better* regulation, or better enforcement of existing legislation.

Safety

- Science advancement, market data, food consumption data➔ gap between the scientific options to demonstrate safety and administrative requirements to demonstrate that a food contact plastic is compliant
- Uncertainty whether or not safe products put on the market today will remain compliant and acceptable in the future

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Why the systems fails

- Risk Management is scanty
  - Lack of skilled resources in National Control Authorities
  - Not considered a priority at National level
  - The current legislation fails to address key issues (lack of harmonization, inconsistent plastics vs. non-plastics approach, focus on specific, e.g. printed FCM, instead of addressing the general case, etc.)
  - The current legislation is outdated: not up-to-speed with the expectations of downstream stakeholders (e.g. NIAS)
- Communication is undermined ➔ creates lack of trust and negative Public Perception
  - A lot of room for scaremongers
  - Industry constantly under pressure

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Consequences

- The liability issue is overlooked by the Regulators:
  - “demonstrate the absence” is a logic paradox
  - Technical requirements that are beyond the analytical capabilities (e.g. SML on oligomers with MW<1000D)
- Proliferation of self-made policies by food industries and retailers (often very questionable)
- Serious threat for innovation, for ex. Regulation 282/2006 not yet enforced, Reg. 450/2009 missing Community List, etc.

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Is there a way out?

Maybe…

Time for a new Policy on FCM legislation

- Continue to maintain a high level of protection of human health and increase public confidence in the safety of packed food and FCM.
- Foster the role of and the value of Food Contact Materials, in the modern food distribution economy
- Cope with media food scares linked to FCM while improving the supply chain's response on them.
- Lead to a level playing field for all kinds of food contact materials and articles.
- Satisfy the needs of transparency of all stakeholders, and be flexible to facilitate the functioning of the internal market
- Enable an efficient introduction into the market of innovative materials, and Improve the regulatory management of the existing ones
- Ensure that imported materials (and packed foods) are subject to the same regulations and standards as those produced within the EU.

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Elements for an EuPC-PCE Proposal for Risk Management of FCM: how it should be

- Designed for HARMONIZATION and TRANSPARENCY
- Designed to improve trust by downstream stakeholders, EU Authorities, Member States, NGO's and opinion leaders
- Implies continuous improvement
- Open to industry and other stakeholders' contribution, don't take it as a carve in the stone
- Determined to challenge and change the status-quo
- Built on existing concepts, not re-inventing the wheel
- Please stop talking and start doing

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1. The Risk Assessment methods should be AGREED among all interested stakeholders

- Key stakeholders should develop Guidelines for Industry on “How To Make Risk Assessment For FCM”
- These might consists on general principles and general approach, and include specific Sections depending on the type of FCM
- Key stakeholders are:
  - DGSANTE’
  - EFSA
  - JRC
  - Member States reps
  - Industry reps
  - Academy

2. Industry should use the Guidelines to carry out self-assessment of all substances not assessed by EFSA, including NIAS

- Self-assessment can be done at every level of the stakeholders' chain, it may be transferred to the next in the chain upon business-to-business agreements
- May use internal analytical and toxicology resources and skill sets
- May also use external institutes, consultants, laboratories, law firms etc., provided that liability rests in full to the business operator which sells the product under its company name

3. Build external trust through 3 rd party review

- Allow the development of recognized (public and/or private) Third Parties (R3P) with the capability of reviewing the protocols, processes and procedures adopted by Industry
- Key stakeholders (as above) to develop methodology to ensure same level playing field for all companies, no matter the Country or the type of FCM or FCA
- To avoid conflicts of interests the R3P should NOT be same institutes, consultants, laboratories, law firms etc., that may be contracted by Industry to carry out the self-assessment

some key points:

- Adhere to agreed protocols
- Focus on processes and procedures leading to thorough risk assessment
- Avoid focusing on transactional activities and on products
- Shall be manageable and compatible with time-to-market logic

Additional key features

- Substances assessed by Industry based on a standard protocol may originate a “Registry” of Risk Assessment data
  - Avoid duplication of efforts, incentive data sharing
  - Selective access by stakeholders
  - Improve transparency and acceptance
  - Governance issues to be addressed
- Review by R3P may leverage food industries’ experience on suppliers auditing
  - Extended standardized checklists approach
  - Collaborative improvement
  - Build on existing processes

SWOT

Strengths

Simple, builds on existing concepts

Very high transparency

Gain of trust

Achieves harmonization

May be easily done through an amendment of the GMP Regulation

Weaknesses

At least five years away (if we start now)

Key stakeholders may not have highly skilled professionals

Shall demonstrate that the Guidelines stems from objective and scientifically sound procedures

Requires continuous external communication to ensure buy-in

Opportunities

No need for further legislation

Stop scaremongering

Creates a highly specialized scientific community

Can be used for innovative FCM

Threats

Requires consensus and commitment among stakeholders to start

Requires strong drive by the Commission (unless delegated)

Can be backfired by industry stakeholders

Don’t expect scaremongers to support!

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Open questions

- How to ensure that IMPORTED FCM are equally treated? As the importers carry the product liability, will they be subjected to the same criteria of FCM manufacturers?
- Will DGSANTE' politically support that change?

Next step: reach agreement within Industry

PLASTIC COORDINATION GROUP – PCG. The European think-tank envisioning future policy and governance in the plastic FCM field

CROSS-SECTOR INDUSTRY GROUP. Established 2016 to partner the EU effort in pursuing the FCM Evaluation Roadmap

PRINTING INKS JOINT INDUSTRY TASK FORCE-PIJITF. Relevant in the context of the printed-FCM discussion

FURTHER STEPS

Gain buy-in by Members States

Broadcast and get support from all other key stakeholders

Map out NGO's positions

Address legal issues

- How Commission's Roadmap on FCM's reform will evolve?
- Consider EP-Schaldemose's report and consequent actions
- EU Parliament elections in 2019, potential change in political environment, slow-down of Parliamentary activity

conclusions

- Concrete: not a time-buying exercise
- First serious attempt of collaborative effort towards better regulations
- Win-win between consumers protection and promotion of innovation
- Highest transparency ever, lack-of-trust killer
- Wise use of resources
- Stop scaremongering
- Call for the EU Commission to act promptly
- …
- Enough?

Thanks for Your Attention

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