Assessment of IAS and NIAS in Packaging

A global brand owner approach

The 5th Food Contact Material Symposium
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AGENDA

1. Introduction

2. Nestlé approach for Packaging Safety & Compliance

3. Requirements going beyond legislation

4. Surveillance of packaging materials

5. Summary
Nestlé Quality Assurance Centers
Global Organization

- 11'500 analytical results per day
- 26 NQACs Analytical Facilities
- > 40 Experts
- Delivering analytical services and technical assistance to markets and businesses

Nestlé laboratories generate more than **130 million analytical results** / year
**260,000 analytical results/day** at factory level for product release and raw material acceptance

Xi'an Symposium FCM/November 2-3 2017/ LSpack
Managing safety: the value chain is a challenge

Knowledge on chemicals

- Monomers, pigments, antiox., UV-stabil., solvents, …
- Adhesives, inks, plastics, glass, cans, papers, boards, …
- Additional contributions of the different parts
- Interaction between food and packaging

Complexity

- Chemicals
- Base Materials
- Finished Packaging
- Food products

- Co packers
- Co packers
- Co packers
- Co packers
- Co packers
- Co packers
Challenge for a worldwide Brand Owner

1) Food Contact Legislation by Areas/Countries
2) Requirements not aligned
3) Limit in FCM or by migration not aligned
4) Culture of secret different
5) Level of knowledge of suppliers extremely heterogeneous

This needs to align with legislations of main area/countries: China, US, EU, Mercosur, Japan, etc…
Intended Added Substances (IAS) are in principle listed substances and the majority should have been evaluated for their use. The information on IAS should be available for the next step of the supply chain.

The final user shall control the migration according to predefined limits:

- Compliance check
- Worst case calculation
- If ok stop

- Mathematical Model
- If ok stop

- Migration tests in simulant
- If ok stop, if not ok FCM cannot be used

- Migration in food
- If ok stop
Compliance Check and Risk Assessment for NIAS

Non-Intentionally Added Substances (NIAS) are in principle substances that have not been evaluated and in many cases the information on NIAS is not available for the next step of the supply chain.

The final user shall control the migration and in case of migration higher than 10 ug/kg, a risk assessment has to be conducted:

Risk Assessment

Knowledge Survey → Exposure Evaluation → Hazard Estimation → Risk Characterisation
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5 Summary
A - **Supplier Audit** focusing on safety aspects

**C – Certificate of Compliance** with adequate information on substances

**F – Technical Supplier Partnership:** Aiming to change the mindset of the supply chain

**B – Nestlé Specifications** including food contact description

**D – Risk Management** of packaging materials

**E – Surveillance Plan** identifying & assessing the potential risks
Main platforms of exchange of information about chemicals

- Raw materials
- Transformation
- Release tests

- Supplier audit

- Specification of Packaging Materials
- Clear requirements
- Substances to be avoided
- Substances to be controlled

- Surveillance Plan
- Chemical screening
- Feedback to supplier
- Self assessment

- Declaration of Compliance
- Main platform of exchange
- List of substances
- Evidence of testing

- Raw materials
- Transformation
- Release tests

- Supplier audit

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- Declaration of Compliance
- Main platform of exchange
- List of substances
- Evidence of testing
...The Technical Partnership with Suppliers

- Direct suppliers (converters)
- Ink makers
- Adhesives makers
- Coatings makers
- Resins suppliers
- ....

- Benefit for consumers
  - Technical assessment
  - Safety consideration

- Interaction with food
  - Sensorial requirement
  - Safety evaluation

- Interaction with food
  - Sensorial requirement
  - Safety evaluation

- Corrective actions
  - Agreement on limits in packaging materials
  - Ban on substances

- Issue prevention
  - Set of standard

- Early Warning
- New technologies
- Material Development
- Issues

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..Nestlé requirements beyond legislation...

- 26 Standards on:
  - Banned compounds: no ortho-phthalates, no BPA
  - Restrictions:
    - Limit of residues: styrene max 500 mg/kg pack
    - Minimum quality: max 600 mg/kg mineral oil in recycled board
- Restriction on perfluoro-compounds
- Guidance Note on Printing Inks
- Recommendation for adhesives (in preparation)
- Full standard not shared by default
- Abstract of standards available for suppliers
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New chemical screening methods developed by Nestlé

Packaging Material

- Analysis of composition
  - Extraction with organic solvents
    - Recommended for R&D purpose

- Analysis of simulant after migration
  - Use of simulants recommended in Regulation 10/2011
    - Recommended for Surveillance
Chemical screening: main findings

1) Flexibles and Rigid Plastics

I. The IAS are not observed above their SML, but the NIAS are sometimes observed > 10 ug/kg (simulants)

II. Degradation compounds from antioxidants, slip agent, adhesives

III. Oligomers from polyolefins: PE or PP, also called POH,

IV. Residues from inks

V. On-going work with R&D and suppliers to evaluate «self-derived» SML for the most observed NIAS.
Chemical screening main findings

1) Cardboards
   I. Unprinted: residues of resins, sometimes paraffinic oil used to dilute additives, transformation products of sizing agents
   II. Printed: residues of inks, most likely migrating via set-off -> in case of high residues it is recommended to review the design of drying/curing with the suppliers
   III. Glued: series of NIAS originating from hotmelts and dispersions
   IV. Except in case of high set-off, IAS under control, mainly NIAS could observed >10 ug/kg (simulant)
Example of NIAS distribution

Cyclic ester from adhesive

Is it possible to determine a safety based limit?

Is it possible to determine a quality based limit?

Samples of laminates

mg/dm²

0.120
0.100
0.080
0.060
0.040
0.020
0.000
Risk Assessment of NIAS or non-listed substances: basic principles

The document from PlasticEurope or more comprehensive the Guidance published by ILSI Europe, summarize the steps:

1) Literature survey on existing legislation; documentation about the material

2) Exposure assessment
   I. Migration data
   II. Food consumption and packaging use data
   III. Derivation of Estimated Daily Intake (EDI) number

3) Toxicological Assessment
   I. Determination of Tolerable Daily Intake (TDI) based on specific toxicological studies
   II. Determination of Threshold of Toxicological Concern (TTC)

4) Risk Characterisation
   Is EDI < TDI or specific migration < self derived migration limit?
Summary

1) Information throughout the supply chain is difficult to manage
2) The two main work to conduct: compliance check for IAS, eventually risk assessment for NIAS
3) Food companies need to set-up platforms of information exchange
4) Nestlé developed a Packaging Safety & Compliance Program
5) Nestlé Standards go beyond legislation
6) The chemical screening allow highlighting the relevant chemicals: IAS under control, some NIAS need risk assessment
Outlook & Wish list

I. Positive lists protect consumers, but should be «easy» to update if substances are already approved in other regulations

II. Our wish is one UNIQUE positive list, covering all food contact materials (and not individual positive list per FCM category)

III. To simplify the circulation of goods, a worldwide acknowledged positive list would be the main goal and achievement of the FCM community
Thank you