Introduction to Packaging Safety and Compliance Initiative

Packaging Safety & Compliance Assessment Training

Gabriela Leszczyk – NQAC
Passion for Consumer Trust

Consumer trust is the level of confidence consumers have...

...about the performance of the product...

...versus the communicated promises
Materials in contact with food and non-food items...

<table>
<thead>
<tr>
<th>Materials in contact (processing)</th>
<th>Packaging materials of finished products</th>
<th>Promotional items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conveyor belts</td>
<td>Polymers</td>
<td>Toys</td>
</tr>
<tr>
<td>Plastic moulds</td>
<td>Paper &amp; board</td>
<td>Premiums</td>
</tr>
<tr>
<td>Ultrafiltration membranes</td>
<td>Metals</td>
<td>Pacifiers</td>
</tr>
<tr>
<td>Ion exchange resins</td>
<td>Glass</td>
<td>Accessories</td>
</tr>
<tr>
<td>Plastic pipes</td>
<td>Coatings</td>
<td></td>
</tr>
<tr>
<td>Rubber gaskets</td>
<td>Packaging inks</td>
<td></td>
</tr>
<tr>
<td>Coated tanks</td>
<td>Adhesives</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Jute and sisal</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Auxiliary items</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Measuring spoons, Ice cream sticks, Straws</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Fluid systems in beverage dispensing machines  |                                        |                            |

| Packaging materials of raw materials and intermediate products |}

Nestlé
...make for a complex supply chain

It is in the interest of all partners of the packaging value chain to have a full knowledge of the products they sell, including the raw materials they purchase.
Set-off phenomena caused a crisis at Nestlé
Perceived Safety Issues

Baby milk scare widens in Europe

Swiss-based food giant Nestle has ordered the recall of baby milk from France, Spain, Portugal and Italy after tests suggested chemical contamination.

Police in Italy, the largest market of the four, have begun seizing 30m litres of the baby milk from shops and depots.

The alarm was raised after traces of a chemical involved in the printing process were found in samples in Italy.

Nestle denies the chemical poses a risk to health but has recalled the cartons, with an expiry date of September 2006.
ITX: an issue damaging for our brand in Italy and Europe, but also world-wide
It takes years to build trust and fidelity in brands and products.

It only takes seconds to destroy that trust.
Packaging Issues in the past have had big Business Impact

- Mineral oils in jute sacs (1991)
- BADGE from metal coating (1996)
- Mineral oils from printing paperboard (1997)
- SEM, ESBO from metal closures (2003)
- ITX from UV-printing (2005)
- BPA from PC and epoxy lacquers (2008-...)
- Benzophenone from printing inks (2009-...)
- Mineral oils from printed/recycled paper (2010…)

Are you ready for the next one?
What is the **Goal** of the Nestlé Packaging Safety and Compliance Initiative?

*To prevent a packaging safety and compliance **incident** (including a **recall** of product) due to safety and compliance failures.*
What were the root causes?

Could we have prevented these issues?
Root Causes: a Summary

1 - Lack of knowledge

2 - Lack of monitoring

3 - Insufficient partnership
How to react?

1. Launched a Nestlé project on Packaging Safety & Compliance
2. Increased bilateral discussions with our main suppliers
3. Initiated multilateral discussions in joint industry groups / lobbying activity
Nestlé Packaging Safety and Compliance Initiative- Established Process

1 - New Supplier Audit focusing on safety aspects

2 - Updated Nestlé Specifications including a food contact SAP “phrasing”

3 - Certificate of Compliance disclosing the qualitative composition of materials in contact with food

4 - Surveillance Plan identifying & mastering the potential risks

5 - New technical Supplier Partnership aiming to change the mindset of the whole value chain
...Sustained by a set of Instructions...
...Sustained by a set of Instructions...

NESTLE STANDARDS ON MATERIALS IN CONTACT WITH

ABSTRACT

This document is an abstract of a Nestlé General Instruction (GI 80.008-2) that includes 29 STANDARDS. The abstract must be shared with material suppliers and the one-page STANDARDS are intended for internal use. Reproduction, distribution, or disclosure of any party not involved with proper authorization is not allowed.

The STANDARDS are mandatory. The following rules apply:
- When no local legal requirements exist in the domains covered by the STANDARDS, the STANDARDS must be enforced.
- Where local legal requirements exist in the domains covered by the STANDARDS, the local requirements must be enforced. These local requirements must be supplemented.

Some of these requirements are specific to Nestlé (e.g., styrene monomer) and correspond to regulations enforced in one or more countries (e.g., azodicarbonamide regulation applied to all countries).

The changes compared with the previous version (Version 2.0 of 2 Feb 2013) are highlighted in grey.

<table>
<thead>
<tr>
<th>#</th>
<th>STANDARD</th>
<th>Individual Substance Name (acronym and CAS number)</th>
<th>Restriction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Active packaging</td>
<td>Phthalates</td>
<td>Must not be used (exception for DIBP and DIOBP when used as catalysts of PP)</td>
</tr>
<tr>
<td>2</td>
<td>Auxiliary items</td>
<td>Polystyrene (PS)</td>
<td>- Styrene (100-42-5)</td>
</tr>
<tr>
<td>3</td>
<td>Easy food packaging</td>
<td>Residual solvents</td>
<td>- Total amount</td>
</tr>
</tbody>
</table>

(Continued on next page...)
Nestlé Guidance Note on Packaging Inks

Purpose
This document refers to t’ Compliance and specifically a materials. This document coatings and varishes.

As a rule, only ink ingredic Materials and Articles can the components, listed in t from ink formulations.

This document must be sh packaging value chain (manufacturers).

Contents
This Note contains the followi

Table: Exclusion list for acrylates

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>Swiss ordinance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butanediol Diacrylate (BDDA)</td>
<td>1076-70-3</td>
<td>B</td>
</tr>
<tr>
<td>Diethylene glycol diacrylate (DEGDA)</td>
<td>4674-68-3</td>
<td>B</td>
</tr>
<tr>
<td>2-Ethyl hexyl acrylate (2EHA)</td>
<td>103-11-7</td>
<td>A</td>
</tr>
<tr>
<td>Isodecyl acrylate (IDA)</td>
<td>1330-61-5</td>
<td>B</td>
</tr>
<tr>
<td>Octyl acrylate (ODA)</td>
<td>2499-59-4</td>
<td>A</td>
</tr>
<tr>
<td>Phenoxyl ethyl acrylate</td>
<td>48145-04-5</td>
<td>B</td>
</tr>
<tr>
<td>1,6-Hexanediol diacrylate (HDDA)</td>
<td>13048-33-4</td>
<td>B</td>
</tr>
<tr>
<td>Mixtures of pentaerythritol tri- and tetra-acrylates (FETA)</td>
<td>3524-68-3</td>
<td>B</td>
</tr>
<tr>
<td>Tetraethylene glycol diacrylate (TEGDA)</td>
<td>17631-71-9</td>
<td>B</td>
</tr>
</tbody>
</table>

Table: Exclusion list for solvents

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>Swiss ordinance</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Methoxyethanol (methyl glycol)</td>
<td>109-88-4</td>
<td>A</td>
</tr>
<tr>
<td>2-Ethoxyethanol (Ethyl glycol)</td>
<td>110-85-5</td>
<td>A</td>
</tr>
<tr>
<td>Monochlorobenzene</td>
<td>108-30-7</td>
<td>A</td>
</tr>
<tr>
<td>Toluene</td>
<td>108-88-3</td>
<td>A</td>
</tr>
<tr>
<td>1-methyl-2-pyridone</td>
<td>972-50-4</td>
<td>A</td>
</tr>
</tbody>
</table>
The Partnership: Group of Pilot Suppliers and extended group

- **Direct suppliers (converters)**
  - Tetra Pak
  - Mondi
  - Constantia Packaging
  - Mayr-Melnhof Karton
  - Ackelund & Rausing
  - Fieldgroup
  - AMCOR-Flexibles (ex ALCAN)
  - Crown Cork & Seal
  - Silgan

- **Ink makers**
  - Siegwerk
  - Flint
  - SunChemical
  - Huber
  - Gmelin & Zeller

- **Inks**
  - Agfa Graphics
  - HP
  - Toyo Ink

- **Flexible Packaging**
  - Ahlstrom
  - ExxonMobil
  - Sealed Air/Cryovac
  - Huhtamaki
  - Nordenia
  - Printpack (USA)
  - Uflex (India)
  - Treofan
  - Wipf
  - SIG Combibloc
  - BigDrum
  - Seda
  - Payne

- **Adhesives**
  - Henkel
  - Dow (Rohm & Haas)

- **Coatings**
  - Weilburger-graphics
  - Valspar
  - Akzo Nobel
  - PPG

- **Masterbatch**
  - Clariant

- **Resins**
  - DuPont
  - Ineos
  - Mitsubishi
  - Total
  - Borealis
  - Grace
  - BASF

- **Paper & Board**
  - SCA
  - M-real
  - StoraEnso
  - Rock Tenn (USA)
  - Van Genechten
  - Cascades (RdM)
  - Smurfit-Kappa
  - MeadWestvaco

- **Metal**
  - Impress

- **Rigid Plastic**
  - MPC
  - Piebergroup
Nestlé Packaging Safety and Compliance Initiative

1 - New Supplier Audit focusing on safety aspects

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# Packaging Supplier Assessment

## GMP audit versus Safety audit

<table>
<thead>
<tr>
<th>GMP</th>
<th>Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>The GMP Audit is concerned with the production process and the handling of the packaging materials</td>
<td>The Safety &amp; Compliance Audit is concerned with the design (composition) of the packaging materials</td>
</tr>
<tr>
<td><strong>GMP Scope</strong></td>
<td><strong>SAFETY Scope</strong></td>
</tr>
<tr>
<td>○ Pest Control</td>
<td>○ How is supplier applying Nestlé Specification to design a packaging with takes into consideration:</td>
</tr>
<tr>
<td>○ Cleaning</td>
<td>- Nestlé Processes</td>
</tr>
<tr>
<td>○ HACCP</td>
<td>- Selling Market</td>
</tr>
<tr>
<td>○ Product Inspection</td>
<td>- End user</td>
</tr>
<tr>
<td>○ Product Release</td>
<td>○ Compliance of Raw Materials for Nestlé packaging</td>
</tr>
<tr>
<td>○ Traceability</td>
<td>○ Regulatory Controls.</td>
</tr>
<tr>
<td></td>
<td>○ Supplier’s processes mastership: (risks, contaminations, etc)</td>
</tr>
<tr>
<td></td>
<td>- Printing &amp; Converting</td>
</tr>
<tr>
<td></td>
<td>- Recovered Materials: Rework, Recycled</td>
</tr>
</tbody>
</table>

1. **Outsource OR**
2. **Request supplier to be accredited against BRC-IoP or EN 15593**

To be carried by Nestlé Staff (or equivalent if available)
Packaging Vendors Assessment

Safety audit - supplier needs to demonstrate:

1. Audit frequency and priority?
2. Knowledge of all components of materials that may contact our product
3. Awareness of current legislation and process to capture updates
4. Processes for evaluating potential migration
5. Willingness to share this information with Nestlé

Priority and Frequency of Audits

<table>
<thead>
<tr>
<th>Risk level</th>
<th>Contact status</th>
<th>Assessment frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Materials in direct or indirect contact</td>
<td>Within 3 years after the last audit</td>
</tr>
<tr>
<td>Low</td>
<td>Any other packaging materials</td>
<td>Within 5 years after the last audit</td>
</tr>
</tbody>
</table>
Packaging Vendors Assessment

Packaging Material Supplier Safety & Compliance Assessment Questionnaire

Foreword
This Questionnaire is intended for the preparation of the Packaging Safety and Compliance (PS&C) assessment. The completed Questionnaire must be sent back to Nestlé before the assessment. Its purpose is to guide the assessment team and supplier to topics that require in-depth discussion with the vendors’ team. The Packaging Safety and Compliance assessment is carried out in one central place (e.g., Head Office, Central Laboratory) and covers all the producing facilities of the packaging supplier. If the plants are not certified for GMP (BRC-foP or equivalent – see Annex 2), a GMP audit per plant supplying Nestlé is required. The GMP audits can be carried out by Nestlé auditors or approved 3rd party auditors.

Content
1. Company identification
2. Vendor/Production Site
3. Quality organisation
4. Crisis management related to Public/Safety concern
5. Nestlé Specification
6. Compliance for food contact
7. Legal compliance
8. Hazard evaluation
8.1 Printing and converting
8.2 Adhesives
8.3 Coatings/Varnishes
8.4 Additives
8.5 Non-intended Added Substances (NAS)
8.6 Pallet Treatment
9. Recovered materials
10. Recycled materials
11. Traceability/Validation
12. Review of PS&C Deviations

Annex 1: List of vendor sites
Annex 2: List of Nestlé approved Audit Standards
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### Guideline for the Creation of Packaging Material Purchasing Specifications

**Identification**
- GI-80.002
- October 2008

**Classification**
- Document type: Internal Standard
- Hierarchical level: Procedure
- Confidentiality: Yellow class

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Information to be Exchanged

User
**Sends a specification**
Provides information on the packed product
Defines requirements

Supplier
**Gives his agreement on the specification**
Takes into account the packed product
Provides a declaration of compliance for food contact application of the packaging material
Example of Specification

Film mOPP/PE 18-35um - 470W x600D mm
Status: Approved

Pack classification
- Material group: 30 - Flexible / laminate / monofilm
- Pack type: 03 - reel fed

STYLE
- Description: Metallized OPP adhesive laminated to PE - peelable
- Type of delivery: Reel fed
- Core material: Board
- Closure / Sealing for Flexibles: Heat sealed

Additional information
Max of one colour joint on top side flagged at the reel edges

FOOD CONTACT

<table>
<thead>
<tr>
<th>Food contact</th>
<th>Direct Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Material must comply with the legislation for materials and articles intended to come into contact with food of the country where the packed product is sold. Supplier shall provide to Nestlé the Certificate of Compliance and - without further notice - a revised version of the said Certificate in case of changes in the legal situation or material used.</td>
<td></td>
</tr>
<tr>
<td>(2) Supplier shall comply with the latest version of the Nestlé requirements published in the &quot;Nestlé Standards on Materials in Contact with Food&quot; (including &quot;Guidance Note on Packaging Inks&quot;).</td>
<td></td>
</tr>
</tbody>
</table>

Product Interaction
- Protection of product against: Water vapor
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The Certificate of Compliance is a document prepared and signed by the supplier of materials intended to be brought in contact with food.

In Europe it is a mandatory requirement of Framework Regulation 1935/2004 (Article 16).

Nestlé CoC (GI-80.103-1) as per the EU regulation, plus list of substances without restriction in the positive list.

In this document, the supplier states that the material complies with the relevant legislation (ideally with the regulations of the countries where the finished product is commercialised).

Must fulfil the specification and serve as a source of information for the HACCP (risk assessment) study and the monitoring plan.
Structure of the CoC

- References of the supplier and the packaging material
- Packaging description
- Intended use
- Ratio area/volume
- Legal aspect
- Global migration
- List of substances with or without restriction in the relevant law
- Dual use additives
- Validity
- Signature
Annex 1: CoC Template

Name of the Company, Address

SAP Specification Number (10 digits)

Certificate of Compliance for Food Contact Materials

1st packaging material description
Name of the packaging material and description, from the outer to the inner layer (according to the specifications).

2nd intended food contact
a) Type of food (e.g. infant product, culinary product, confectionery), fresman shelf life and storage conditions.
b) Description of the suitability for food contact, i.e., suitable for all types of food or only one/some of the following categories (Remark: delete when not relevant):
   - Dry food
   - Dry and non-latty food
   - Wet and aqueous food
   - Fatty food (correction factor if applicable)
   - Specific food (e.g. acid, alcoholic)
   - Frozen food (frozen and defrosted in packaging or freeze and defrosted outside packaging)
   - Food to be sealed in packaging (time and max. temperatures in °C)
c) Ratio of food-contact surface area to volume used to establish the compliance of the material or article, if different from 6dm²/kg.

3rd legal compliance
a) Europe
   When relevant, compliance with (Remark: delete when not relevant):
   - Plastic materials: EC Regulation 10/2011 (as amended by date).
   - Reconstituted collagen: EC Directive 2007/42 (as amended by date).
   - Ceramic: EC Directive 84/500 (as amended by date).
   - Rubber and elastomers: EC Directive 90/119 (membrane)
   - Specific EC Directives or Regulations, e.g. 1885/2005 BADGENOISE, 321/2011 Epithallol, A, 142/1978 Vinyl Chlorides

   If not regulated at European Union level, compliance with one of the Member State regulations, e.g. German BVR, Recommission, Dutch Waterweg, French Document 1227, etc. is required (Remark: Reference texts to be explicitly mentioned).

b) FDA
   Compliance with the US Food, Drug and Cosmetic regulations of the United States of America as set out in the Code of Federal Regulations of the US Food and Drug Administration (FDA), under 21 CFR.

c) Other national/northern regulation

[Date, Signature]
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In the framework of ISO 22000 the **hazards of packaging materials** have to be taken into consideration by food producers.

The current hazard analysis applied by food industry, **historically focused on food**, does not take into consideration packaging.

The hazard analysis performed by our packaging suppliers does not really take **food-packaging interaction into consideration**.

**Nestlé Initiative:**

Packaging Safety and Compliance project set-up of a « training set » for hazard analysis of packaging materials.
Hazard identification (5 hazards classes M, P, C, A, N)

- Microbiological
- Physical (including choking hazards)
- Chemical
- Allergen
- Nutritional
Physical and Chemical Factors to be considered

Physical damage and allergen:
- Low hygiene conditions (rodents, insects, dust, dirt, people manipulation…)
- Wrong conditions of transportation and storage and transportation (compression, puncture, …)
- Change of temperature and humidity during storage and distribution

Consequence:
- Presence of foreign bodies
- Insufficient protection of food product (contamination)
- Oxygen and humidity content modification (microbial growth)

Labelling and allergen from packaging:
- Incorrect allergen labelling declaration

Consequence:
- Allergy

Chemicals from packaging:
- Migration of compounds from packaging to food

Regulation existing, Food contamination
- Off-flavour, chemical residue in food (low occurrence of health effect)

No regulation available > food safety concern

Food poisoning/ sickness /injury
Inputs

- Specification, supplier audit, GMPs, CoCs
- GI’s, NRC guidance, support documents, analysis results Y-1

Hazard Analysis

- GI 31.202-3 HACCP
- NQAC Database
- NQAC Template

Outputs:

- Revised QMS
- Packaging Surveillance Plans

Packaging Monitoring Plan 2012-NPPE
Nestlé Packaging Safety and Compliance Initiative - Summary

- Management support (Central and local level)
- Support from 4 major involved functions
  - Packaging
  - Quality
  - Purchasing
  - Regulatory Affairs
- Adequate resources (in teams and supports e.g. NQAC)
- Process well described locally: who does what GI 80.100
- Training plan
- The most important the Suppliers Partnership
Any Questions?
Thank you!