

Issues and tasks of the Regulatory Affairs

Dr. Christine Spitzlei

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Outline

- Introduction of the Regulatory Affairs Team
- Responsibilities – What we are doing
- Legal basics
- Communication within the supply chain
- Current topics

Team „Regulatory Affairs“



Dr. Christine Spitzlei
Head of Regulatory Affairs



Christina Grau
Regulatory Affairs



Carmen Held
Regulatory Affairs





Tobias Körmer
Regulatory Affairs/
GC-MS-Analytics

Our responsibilities

Safety Data Sheets (SDS)/ Data administration

- Incorporation of new raw materials
- Maintenance / administration of the raw materials SDS
- Creation / maintenance of the product SDS (ERP software)
 - o GHS-Labeling for mixtures since May 2015



Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No 453/2010		 WEILBURGER
Article No.:	350152	SENOLTH WB GLOSS COATING FP DC
Print date:	20.10.2016	Revision date: 16.09.2016
Version:	5.2	Issue date: 18.09.2016
		40200 EN Page 1 / 7
SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.1. Product identifiers:	Article No. (manufacturer/supplier): 350152 Identification of the substance or mixture: SENOLTH WB GLOSS COATING FP DC 27-1423	
1.2. Relevant identified uses of the substance or mixture and uses advised against	Relevant identified uses: Coating for graphic application Uses advised against: No data available	
1.3. Details of the supplier of the safety data sheet	manufacturer: WEILBURGER Graphics GmbH Am Rosenbühl 5 D-91466 Gerolzhofen Dept. responsible for information: Regulatory Affairs E-mail (competent person): +49 9183 9992510 c.spitzlei@weilburger-graphics.de Dr. Christine Spitzlei	
1.4. Emergency telephone number	Emergency telephone number: Only available during office hours +49 9183 99920	
SECTION 2: Hazard identification		
2.1. Classification of the substance or mixture	Classification according to Regulation (EC) No. 1272/2008 (CLP) This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 (CLP). Eye Dam. 1 (H318) Serious eye damage/eye irritation Causes serious eye damage.	
2.2. Label elements	The product is classified and labelled according to EC directives or corresponding national laws. Labelling according to Regulation (EC) No. 1272/2008 (CLP) Hazard pictograms  Danger Hazard statements H318 Causes serious eye damage. Precautionary statements P308 + P313 + P338 Wear protective gloves and eye/face protection. P308 + P313 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER or doctor/poisonician. contains: docosate sodium Supplemental Hazard Information (EU) not applicable	
2.3. Other hazards	Not applicable	
SECTION 3: Composition / information on ingredients		
3.2. Mixtures	Product description / chemical characterization Description: Mixture of substances listed below with nonhazardous additions	

Our responsibilities

Generally compliance work

- Reply to customer requests regarding critical substances e. g. Bisphenol A, MOSH/MOAH, Benzophenone, Animal-based materials, Per- and polyfluorinated chemicals (PFC), Polycyclic aromatic hydrocarbons (PAH)
- Intensive exchange with suppliers
- Confirmation of compliance with different regulations, guidelines and norms, e. g. Cosmetics Regulation, Biocides Regulation, Toys Regulation etc.



Our responsibilities

Generally compliance work

- Clarification of raw materials listing in inventory lists, e. g. TSCA (USA), DSL/NDSL (Canada), Export/Import questions
- Ecolabels (UZ 24, „Blauer Engel“, EU-Ecolabel, Nordic Ecolabel - „Swan Label“)
- Compliance with different special end user forms, e. g. IKEA, Schleich, Mattel, Procter & Gamble



Our responsibilities

Food Packaging



- Clarification of the suitability of raw materials for food packaging (FP NDC, FP DC)
- Compliance with Swiss Ordinance, „Nestlé Guidance Note on Packaging Inks“, FDA regulations or BfR recommendations etc.
- Risk assessment relating to migration (Worst-Case calculation)
↳ based on concentrations of SML substances (raw materials)
- Creation of SoC´s (SoC = Statement of Composition)



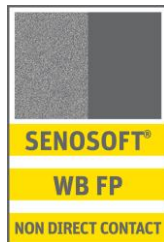
Our responsibilities

Food Packaging

- Organisation of externally performed migration tests (ISEGA, SQTS, etc.)
- Administration of Certificates of Compliance



MigraCell
makes migration testing easy



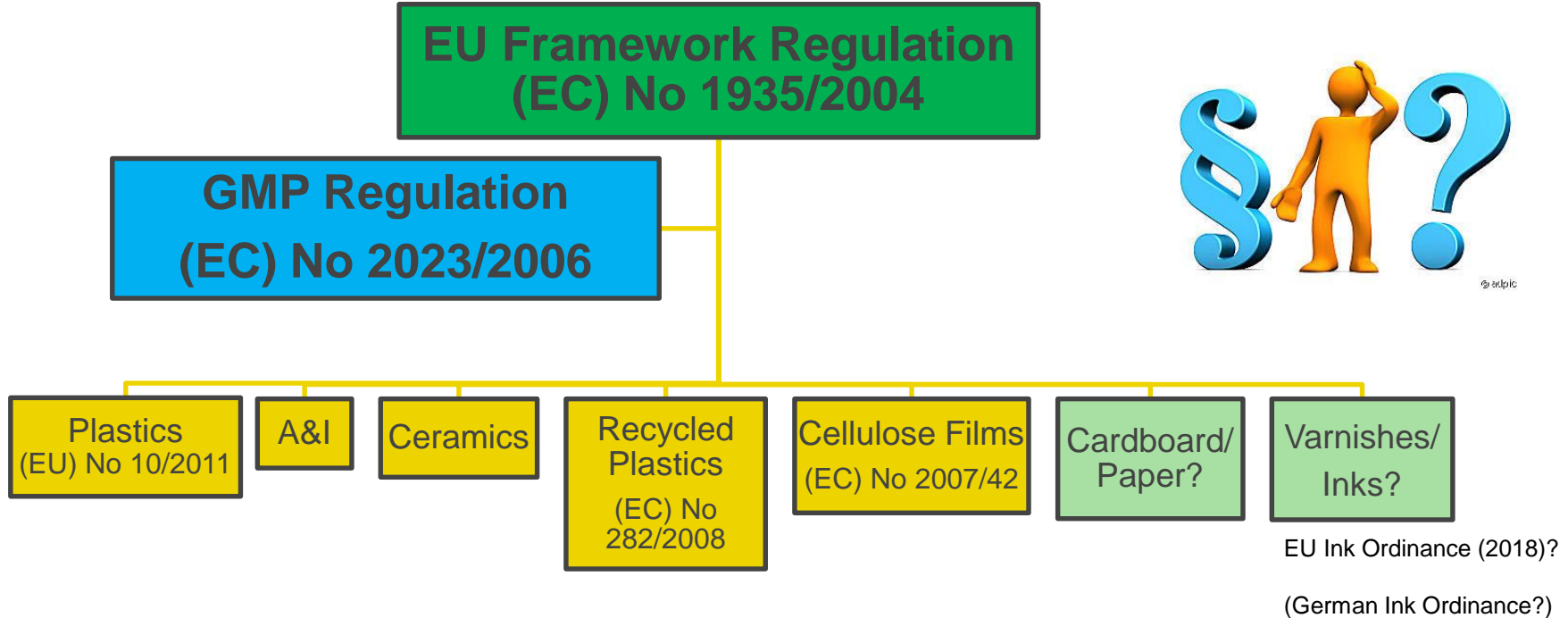
New task – GC/MS analytics

Establishment of an in-house GC/MS analytic – why?

- **Own testing of compliance** with food legislation for **new developed varnishes** before submission to testing instituts
- ➔ **Acceleration of food contact approvals of new products** through avoidance of repeated tests
- Search for NIAS in **new FP raw materials**
- **Quality control** of already established FP raw materials (randomized, incoming goods inspection)



Legal EU Framework for Food Contact Materials (FCM)



Legal EU framework for Food Contact Materials (FCM)

EU Framework Regulation (EC) No 1935/2004

Article 3: General requirements

Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with *good manufacturing practice* so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- a) endanger human health or
- b) bring about an unacceptable change in the composition of the food or
- c) bring about a deterioration in the organoleptic characteristics thereof.

Legal EU framework for Food Contact Materials (FCM)

EU-Framework Regulation (EC) No 1935/2004

Article 17: Traceability

(1) The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.



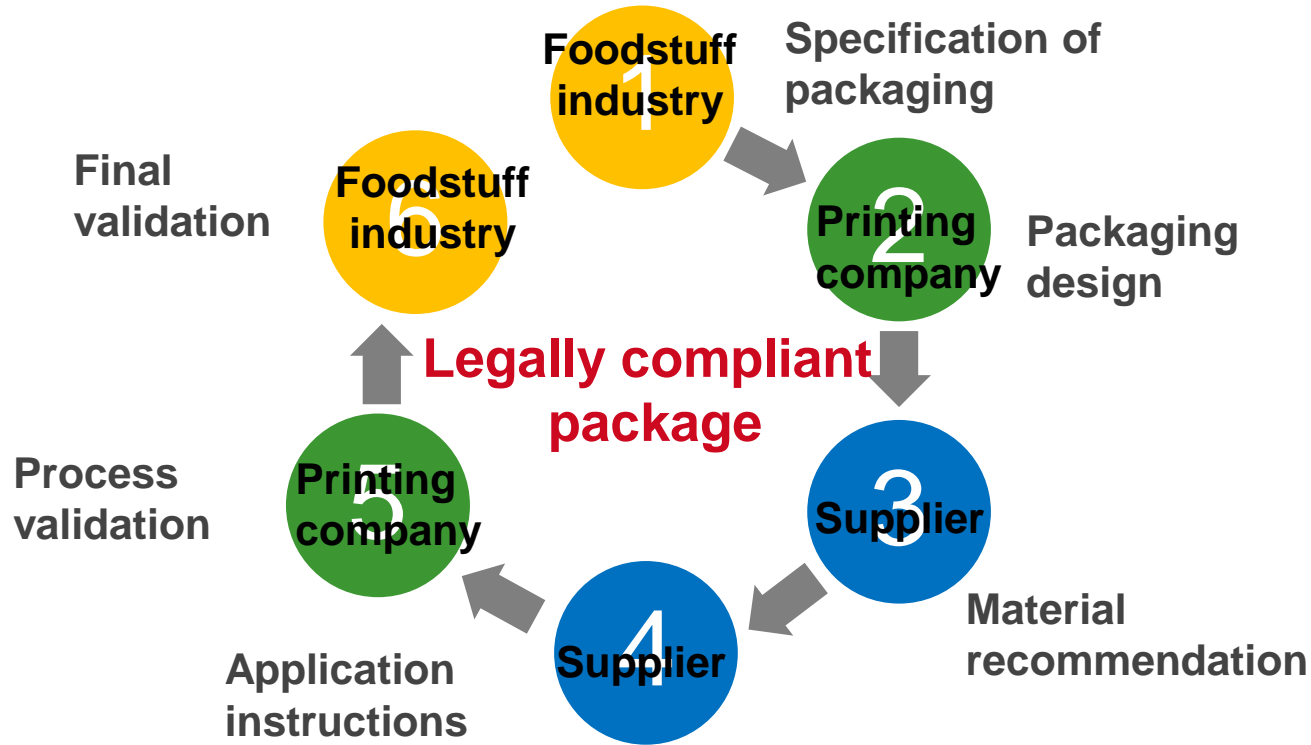
Legal EU framework for Food Contact Materials (FCM)

GMP – Regulation (EC) No 2023/2006 (in force since 01.08.2008)

- Refined the definition GMP (Good Manufacturing Practice)
- Regulates a uniform procedure concerning GMP for materials and items, determined for food contact
- Applies for all parts and stages of manufacture, processing and distribution of materials and articles through to raw materials



Exchange of information within the supply chain



Current topics

„European Printing Ink Regulation“

- German Federal Ministry of Food and Agriculture has suspended its draft for a „German Ink Ordinance“ (notified on 5th July 2016 to the European Commission)
- After the notification expressed the concern by some EU member states about the competitiveness of Germany ⇨ European Regulation is preferred
- Draft of the European Commission is expected for summer 2018, latest at the end of 2018

Current topics

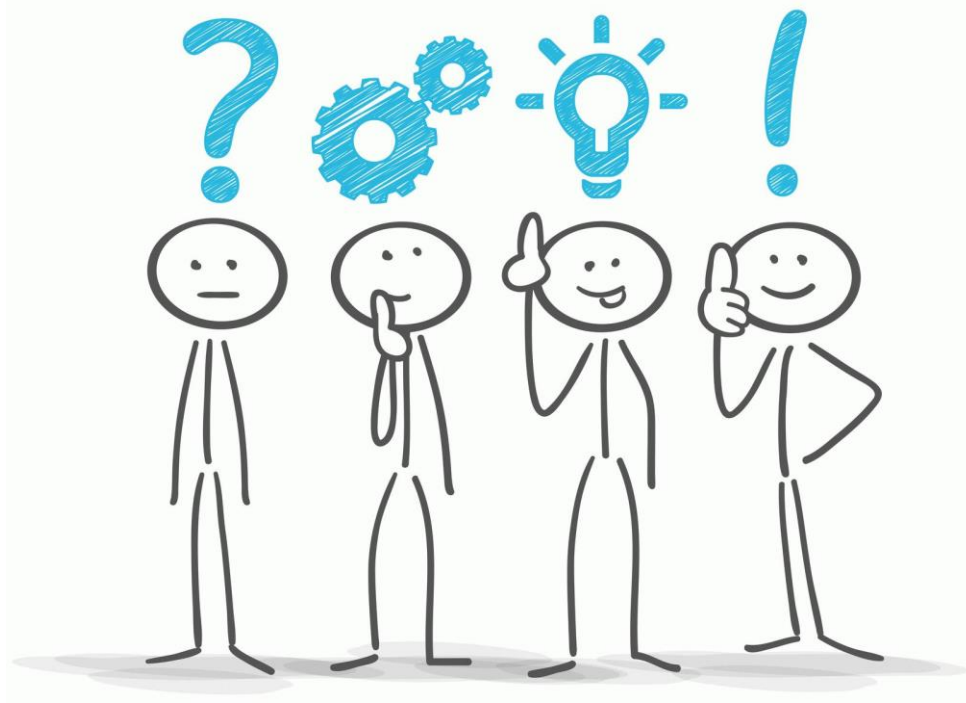
Revision of Annex 6 of the Swiss Ordinance (SR 817.023.21)

- Revision of authorised substances in Part B (CMR-substances)
- Published in May 2017

Draft of „Mineral oil Regulation“

(22nd Regulation on the modification of the German Consumer Goods Ordinance)

- not relevant for our FP products, because they do not contain MOSH/MOAH, but many customer requests
- up to now appropriate analytical standards for the quantification of MOSH/MOAH do not exist



Any questions?