Manufacturing for Quality, Performance and Printability

Zeller+Gmelin GmbH & Co. KG

Michael Handl

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Outline

- Introduction Zeller+Gmelin
- Understanding the Manufacturing Process
- Needs for High Quality Manufacturing
- Challenge Food Contact Materials (FCM)

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The Zeller+Gmelin Group

- Founded in 1866
- Company headquarter in Eislingen/Fils
- Since 1900 development and production of printing inks
- More then 30 years of experience in UV printing technology
- Own Analytical Service Center since 2006
- Experienced in low migration flexo and offset inks/varnishes for different substrates

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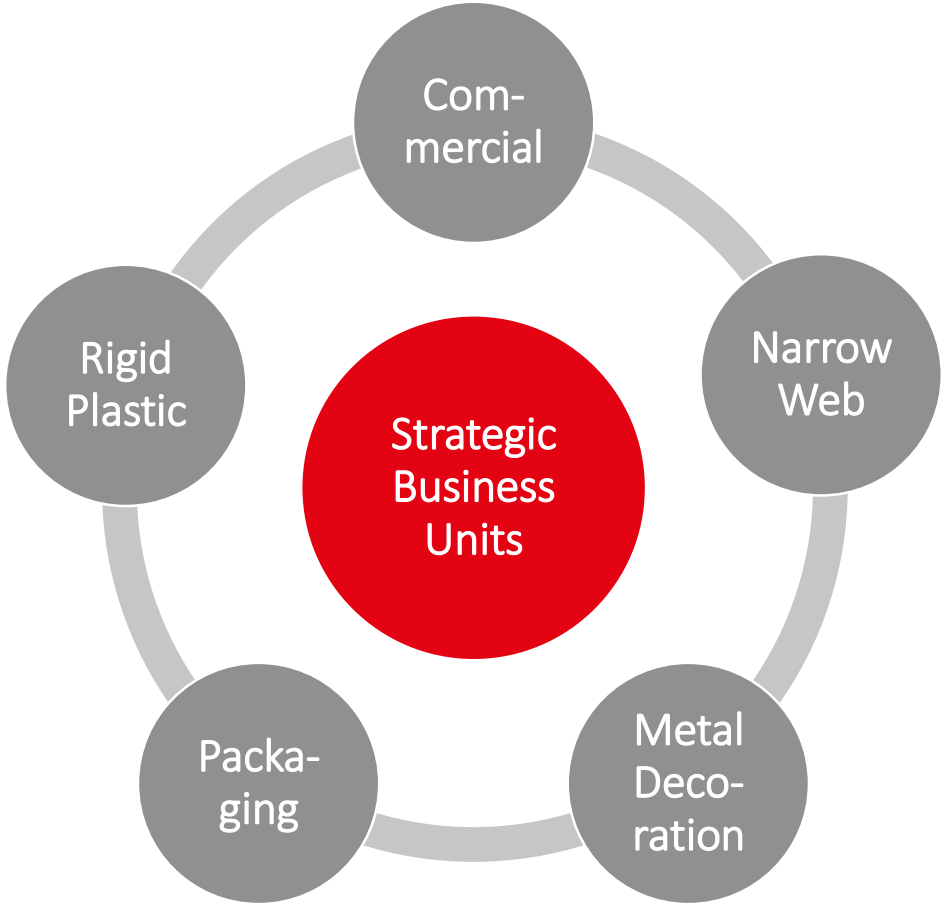
Printing Inks - Strategic Business Units

Plastic containers

Plastic closing cups

Flexible packaging

Folding cartons



Self-adhesive labels

Aluminium bottles

Crown corks

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Manufacturing process

Printing Inks – Holistic View

Ink

Overprint Varnish (OPV)

Resins

~~Pigments~~

Additives

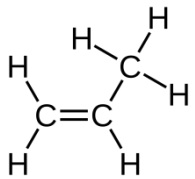
Solvents

Resource processing → Production chemical precursors → Production chemical intermediates → Ink Manufacturing → Application → Use → Disposal/ Recycling

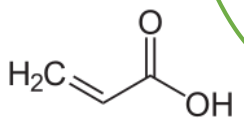
Offset

Flexographic

Screen printing



Propene



Acrylic acid

www.wikipedia.de

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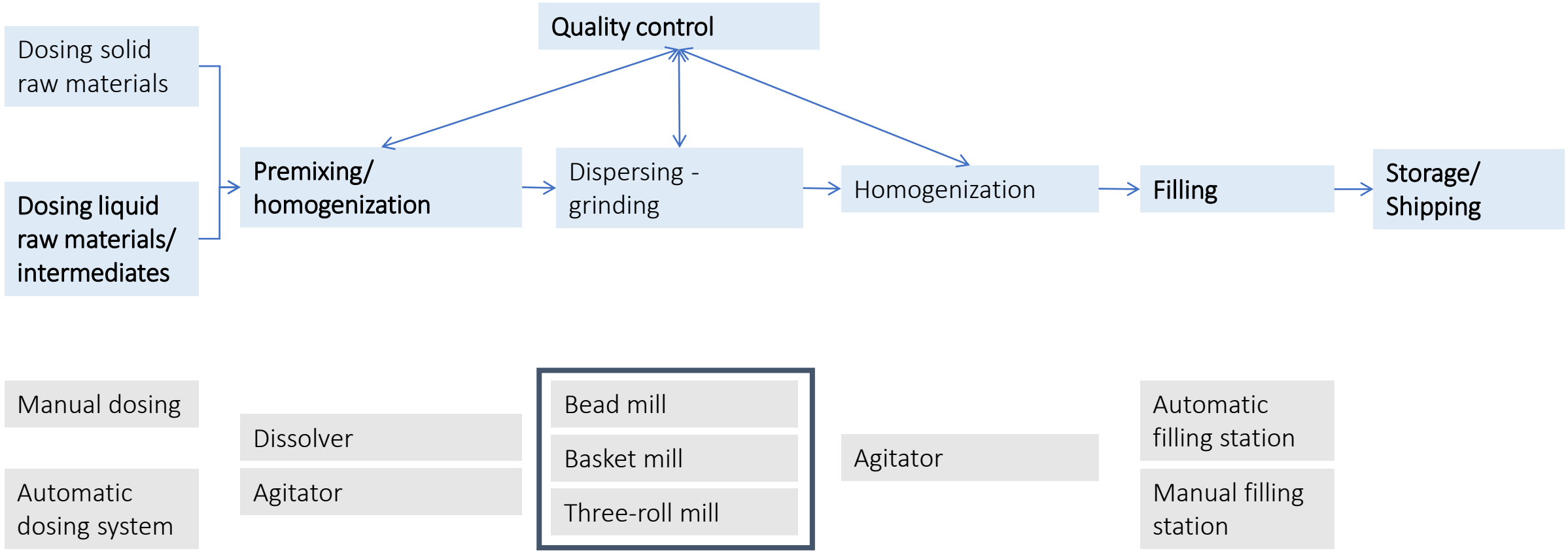
Manufacturing process

The Ink Manufacturing Process in General



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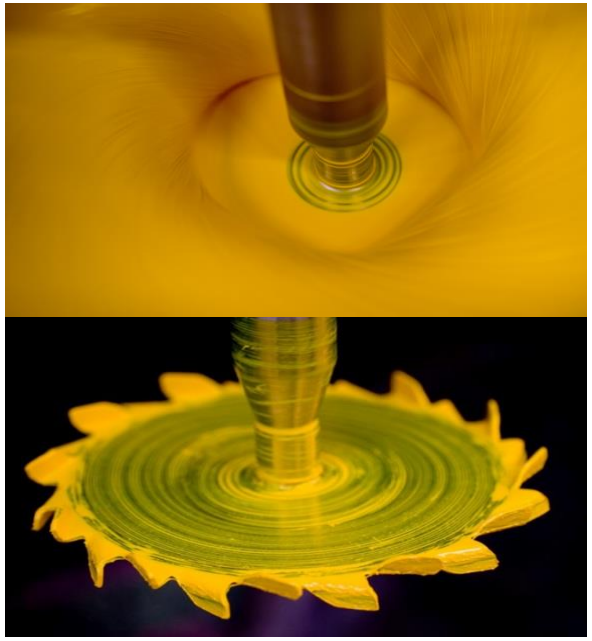
Manufacturing process

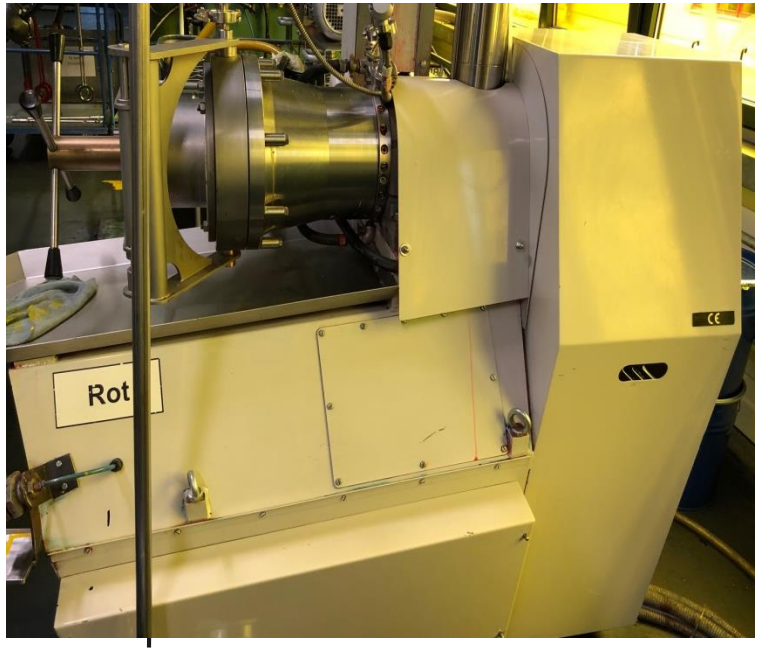
Why Different Grinding Technologies

Dissolver



- Low to high viscosity
- Shear forces at disc teeth
- Mainly for pre-dispersing and homogenization

Bead mill



- Low viscosity
- Impact between beads
- Effective grinding/dispersing

Three-roll mill

- High viscosity
- Shear gradient between rolls
- Effective grinding/dispersing

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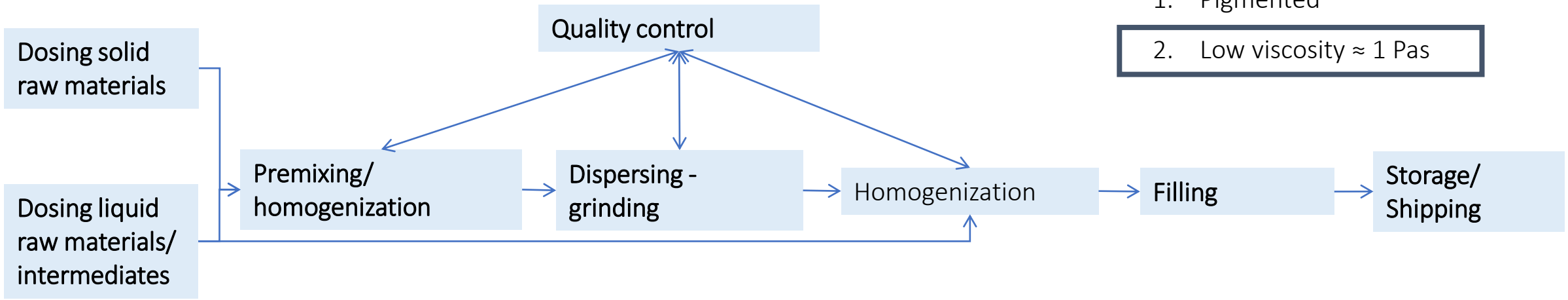
Manufacturing process

The Ink Manufacturing Process – Flexo Ink

Properties:

1. Pigmented
2. Low viscosity ≈ 1 Pas



Manual dosing	Dissolver	Bead mill	Agitator	Automatic filling station
Automatic dosing system	Agitator	Basket mill		Manual filling station
		~~Three-Roll Mill~~		

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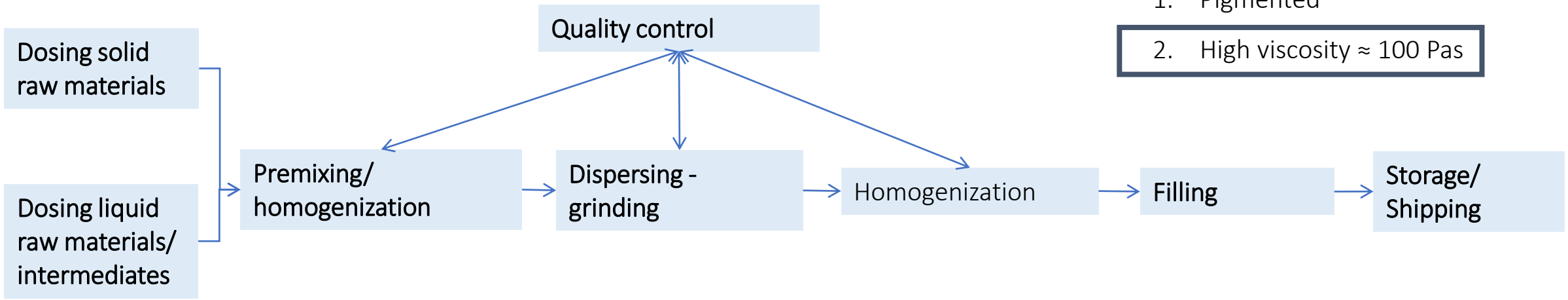
Manufacturing process

The Ink Manufacturing Process – Offset Ink

Properties:

1. Pigmented
2. High viscosity ≈ 100 Pas



Manual dosing	Dissolver	~~Bead Mill~~	Agitator	Automatic filling station
Automatic dosing system	Agitator	~~Basket Mill~~		Manual filling station
		Three-roll mill		

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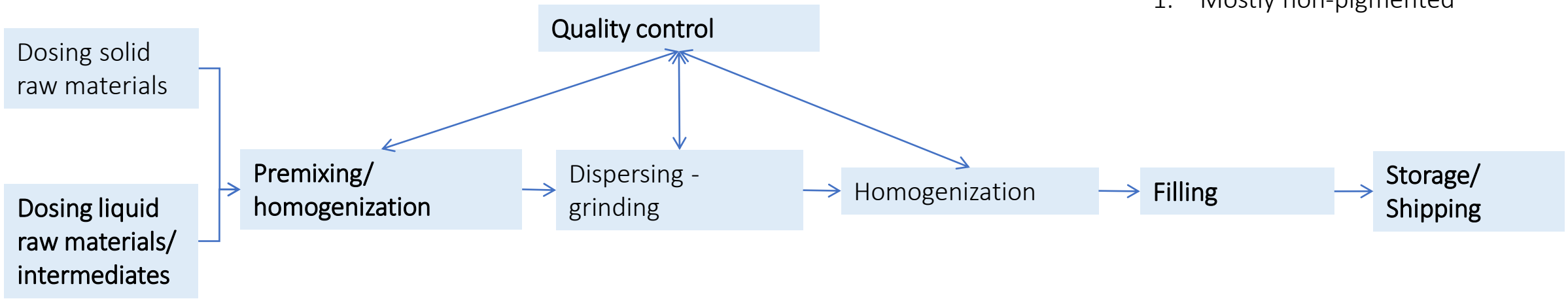
Manufacturing process

The Ink Manufacturing Process – OVP

Properties:

1. Mostly non-pigmented



Manual dosing	Dissolver	~~Bead mill~~	Agitator	Automatic filling station
Automatic dosing system	**Agitator**	~~Basket mill~~		Manual filling station
		~~Three-Roll mill~~		

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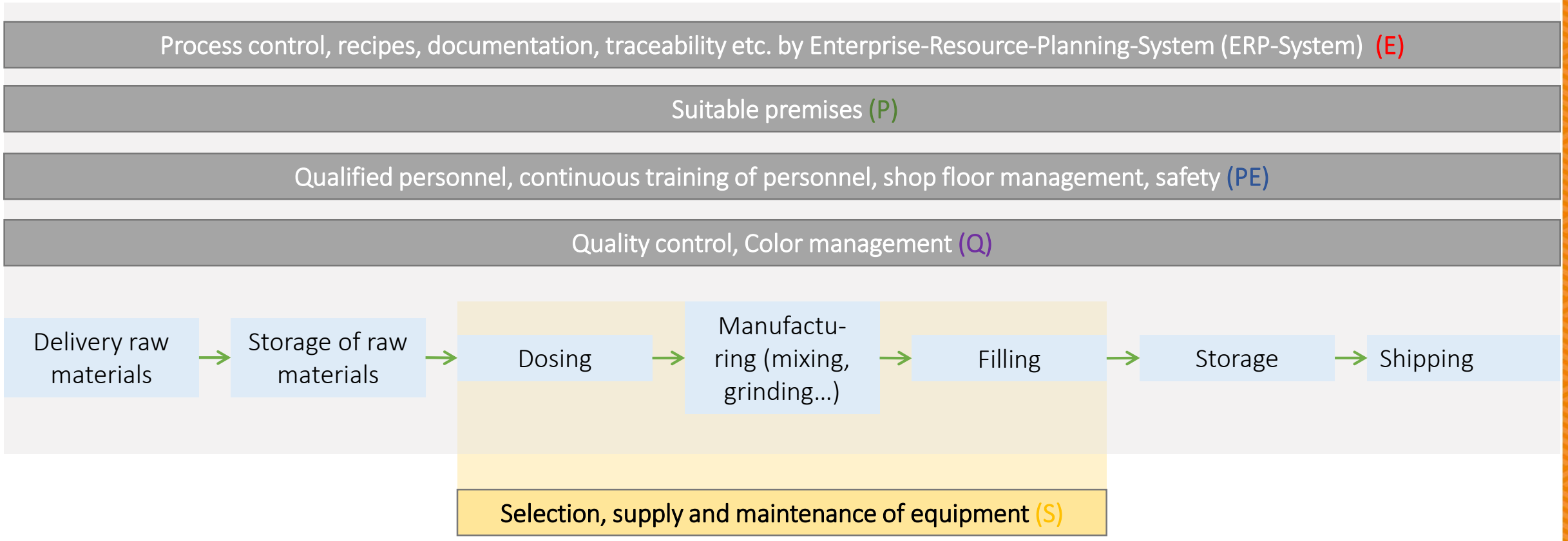
Needs for High Quality Manufacturing



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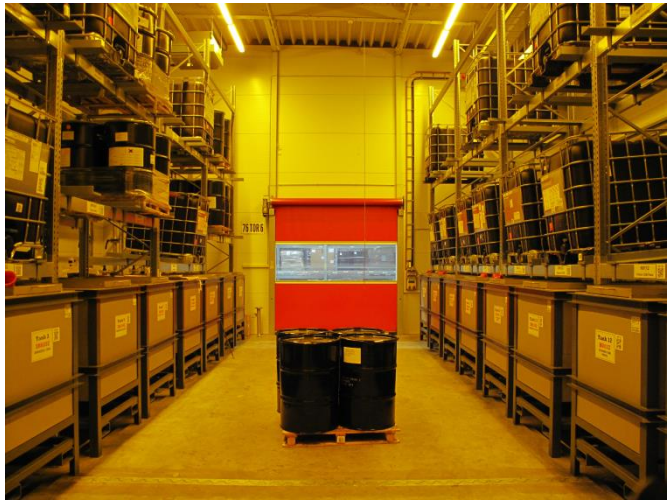
Needs for High Quality Manufacturing

Delivery and Storage of Raw Materials



- Documentation (batch number, quantity, date of delivery…) (E)
- Reception control (Q)
  - Package integrity
  - Comparison to specifications/certificates of analysis
- Storage
  - Constant and defined ambient conditions (P)
  - Exclusion from mixing up by clear description /and documentation in ERP-System (E)
  - First in first out principle (E)

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Needs for High Quality Manufacturing

Dosing, homogenization, grinding

- Automatic dosing system preferred (S)
  - highest precision
  - Minimizing cross-contamination by tools
  - Elimination of mixing-up raw materials
  - Less time consuming
  - Reduced personnel costs
  - Automated depreciation from stock
- Documentation of each production step and parameter by bar-/QR-code system + balance value (E)

- Selection of proper equipment (Three-roll mill, bead mill, dissolver, agitator…) (S)
- Minimization / elimination of color changes
  - Reduced cleaning effort
  - Reduced cross-contamination
- Manufacturing in campaigns

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Needs for High Quality Manufacturing

Filling, Storage, Shipping

- Automatic filling station (S)
  - Depending on viscosity either with pressure or by gravity
  - Precise and clean
- Identification of containers by unique batch number and labels. (E)

- Storage at well defined and controlled ambient conditions (P)
- First in first out
- Clean and tidy environment (P)
- Documentation of storage location (E)

- Optical detection of batch number (S)
- Fusion of batch number with customer label (S) (E)
- Last quality check of container integrity (S) (PE)

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Needs for High Quality Manufacturing

Supply and Maintenance of Equipment, Premises

- Automatic, highly concentrated alkaline wash-up system for containers, tools and equipment (S)
  - Cascade system
  - Very low residuals on equipment
- Maintenance on regular basis (S)
  - Do not wait until there is a malfunction
- Repairs and service by qualified personnel only (PE)
- Premises (i.E. for UV-curable inks) (P):
  - UV-absorbing windows
  - Low UV light bulbs
  - Ventilation

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Needs for High Quality Manufacturing

Enterprise-Resource-Planning-System

- Traceability and documentation of
  - Raw materials (Batch number, expiration date, stock yard…)
  - Process documentation (process parameters, weighted quantities, quality control…)
- Production management
  - Recipe and detailed process description
  - Manufacturing order
- Supply Chain Management
  - Purchasing
  - Inventory
  - Warehousing

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Needs for High Quality Manufacturing

Quality Management and Control, Personnel

- Control of specifications (Q)
  - Raw material
  - Intermediates
  - Finished product
- Control of inspection, measuring and test equipment according standard(Q) (S)
- Process control (Q) (PE)
- Training and qualification of personnel (PE)
- Shop floor management (PE)
- No compromises on safety (PE)

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Challenge Food Contact Materials (FCM)

Good Manufacturing Practice

Packaging

Quality Control

Change Management

Quality Management

Recall of defective FCM Printing Inks

EuPIA GMP

Outsourcing

Identification and Traceability

Risk Assessment

Establishment

Equipment

Hygiene Management

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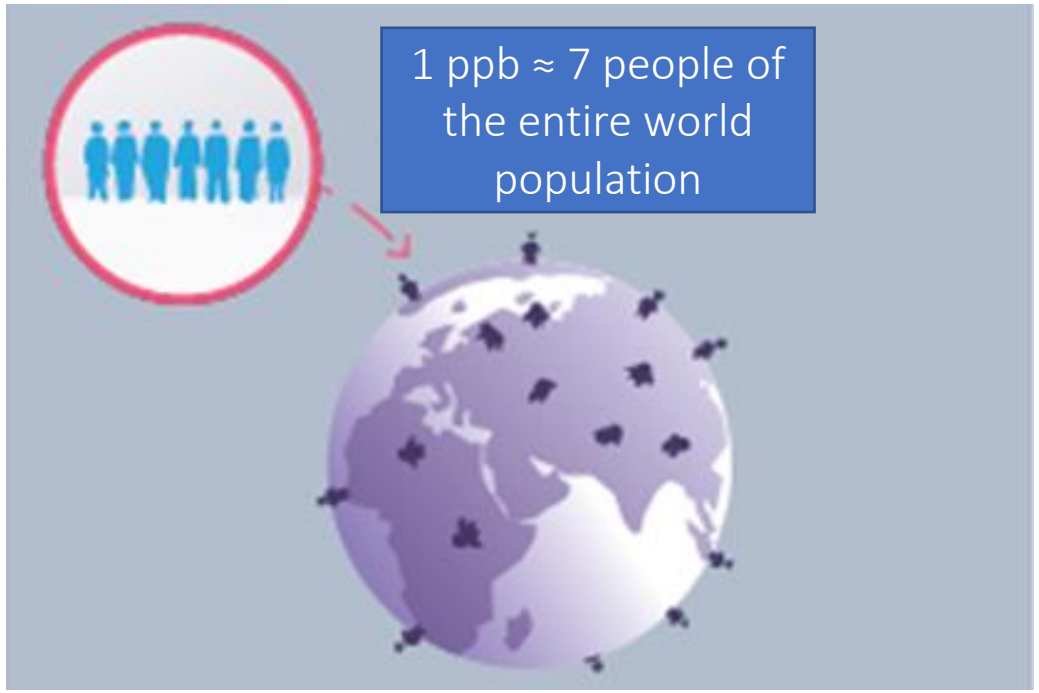
Challenge Food Contact Materials (FCM)

Challenges towards Non-FCM Inks



- Selection of raw materials
  - Low migration through substrate
  - Low toxicity of raw materials
  - Tolerance of chemicals migrating through substrate mostly 10 parts per billion (ppb)
  - Exclusion of BPA containing materials
- Exclusion of non-FCM compliant chemicals
- Good Manufacturing Practice (GMP)

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Challenge Food Contact Materials (FCM)

Possible sources and exclusion of errors

1. **Carryover of chemicals**
2. **Contamination**
    - Tools
    - Container
    - Pipes
3. **Mix-up**
    - Raw materials
    - Manufactured articles
4. **Storage**
    - Environmental conditions
    - Container
    - (Control) Closure
5. **Risk assessment**
    - Worst case scenarios
    - Contaminations
    - Glass management
    - Hygiene management

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Challenge Food Contact Materials (FCM)

Minimizing of Errors in Production – Carryover + Contaminations

Cleaning/choice of equipment

- Container
  - Automatic cleaning machine
  - Alkaline washing solution
  - Highly efficient
- Dissolver/agitator
- Three-roll mill
  - Cleaning paste
- Bead mill
  - Preferably no mixed production
- Filling Station
  - Separate and clean pipes and valves

Choice of milling equipment

- Three-roll mill
  - Simple apparatus
  - Easy to clean
  - Low risk of carryover
  - Mixed production possible
- Bead mill
  - Difficult apparatus (pipes, beads…)
  - Difficult and extensive to clean
  - High risk of carryover
  - Mixed production mostly not practicable

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Challenge Food Contact Materials (FCM)

Minimizing of Errors in Production – Mix-up

- Process control by Enterprise-Resource-Planning-System (ERP-System)
  - Monitoring and tracing of all production steps and ingredients quantities by bar-/QR-code systems
  - Raw materials (starting with acceptance tests, weighting protocol)
  - Pre-labeling with QR-codes; final, customized labeling in picking area
- Automatic dosing Unit
  - Elimination mix-up of ingredients
  - No contamination by tools (spatulas, scoops…)
  - Precise and quick dosing

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Challenge Food Contact Materials (FCM)

Minimizing of Errors in Production – Storage

- Storage in food contact compliant containers
  - Monitoring of containers for defects
  - Air-tight sealing
  - Control closure (tap closure, seal…)
- Controlled and clean ambient conditions
- Documentation of storage location
  - Preventing of mix-up by bar-/QR-coded batch labels
  - Automated labeling and commissioning

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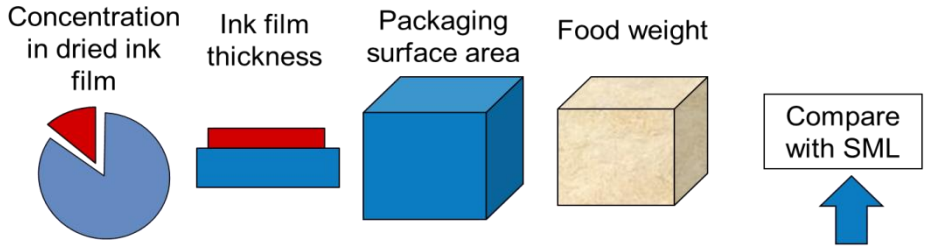
Challenge Food Contact Materials (FCM)

Risk assessment – Worst case calculation according to GMP



CI	= Concentration in dried ink layer (mg/Kg or ppm)
F	= Dried ink layer weight (g/m²)
P	= Pack surface area (m²)
W	= Weight of food (kg)
CF	= Concentration in food (mg/kg or ppm)

$$(1)\ CI\ x\ \frac{F}{1000}\ x\ P\ x\ \frac{1}{W} = CF$$

$$(2)\ \frac{CF}{P}\ x\ \frac{1000}{F}\ x\ W = CI$$

Example:

- 5 % non-FCM compliant photoinitiator (PI) in ink
  - 1 kg carryover in process
  - 50 g(PI) = 50×10^3 mg
- Batch size: 1000 kg = 10^3 kg
- Film thickness: 2 g/m²
- Packaging area: 0.06 m²
- Food weight: 1 kg

$$CF = \frac{50 \cdot \cancel{10^3}\ mg}{\cancel{10^3}\ kg} \cdot \frac{2\ \cancel{kg}}{1000\ \cancel{m^2}} \cdot 0.06\ \cancel{m^2} \cdot \frac{1}{1\ \cancel{kg}}$$

$$= 0.006\ \frac{mg}{kg}$$

$$= \mathbf{6\ ppb}$$

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