



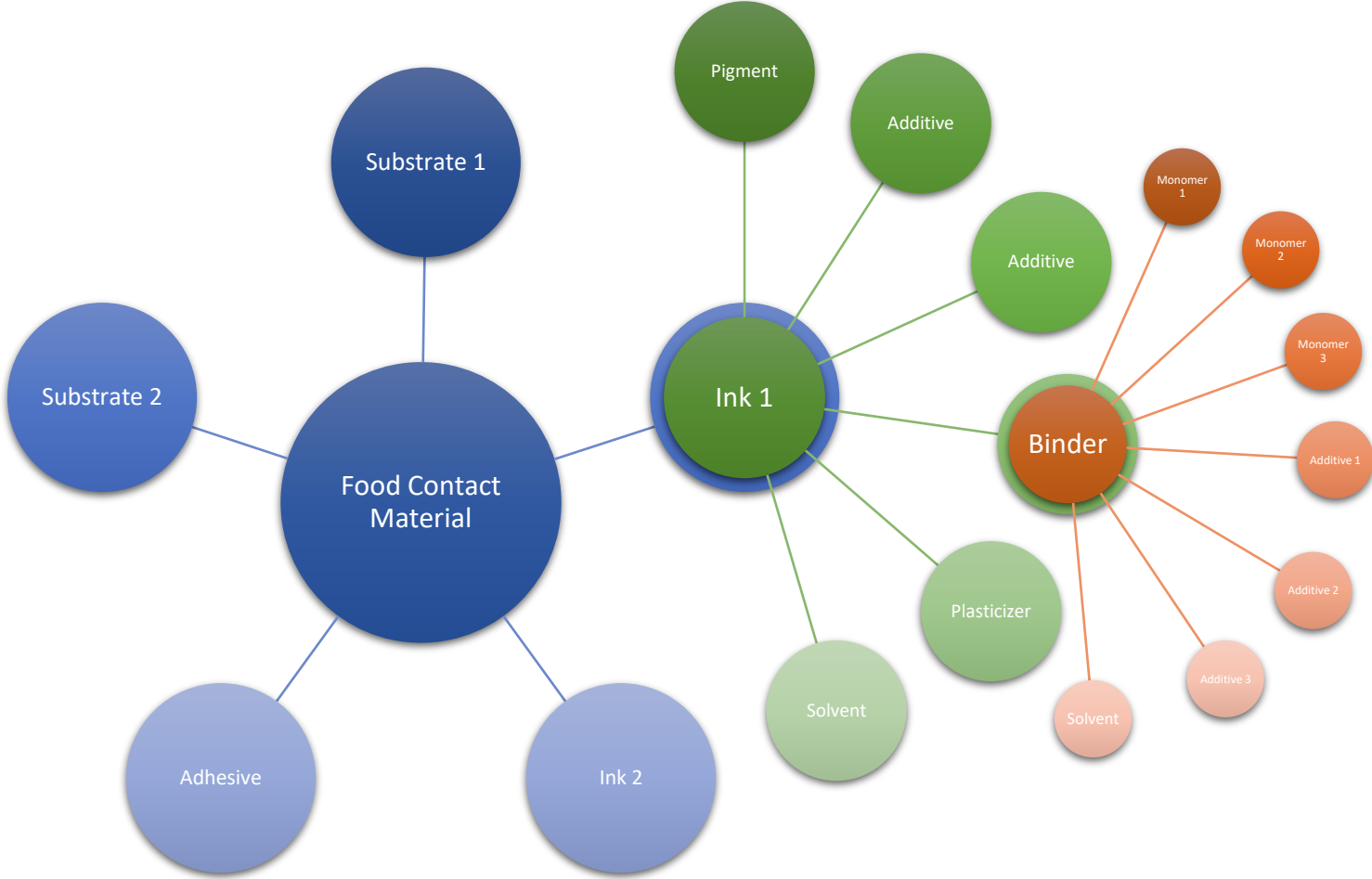
# Regulatory requirements for food contact material inks

Dr. Sarah-Lisa Theisen

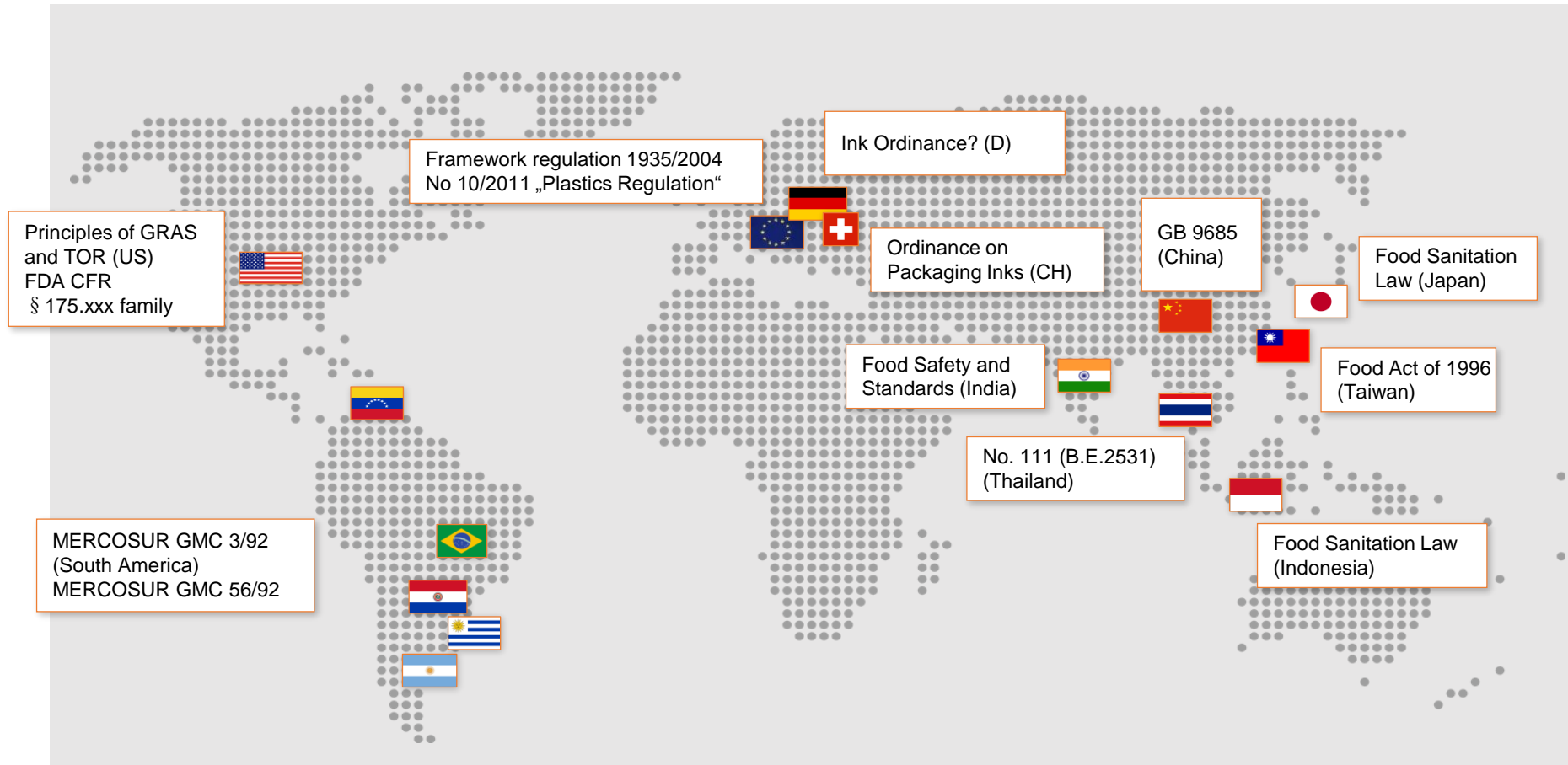
Department Manager for Product Safety & Regulations and Recipe Management EMEA

Siegwerk Druckfarben AG & Co. KGaA

# Just a small glimpse of the chain...



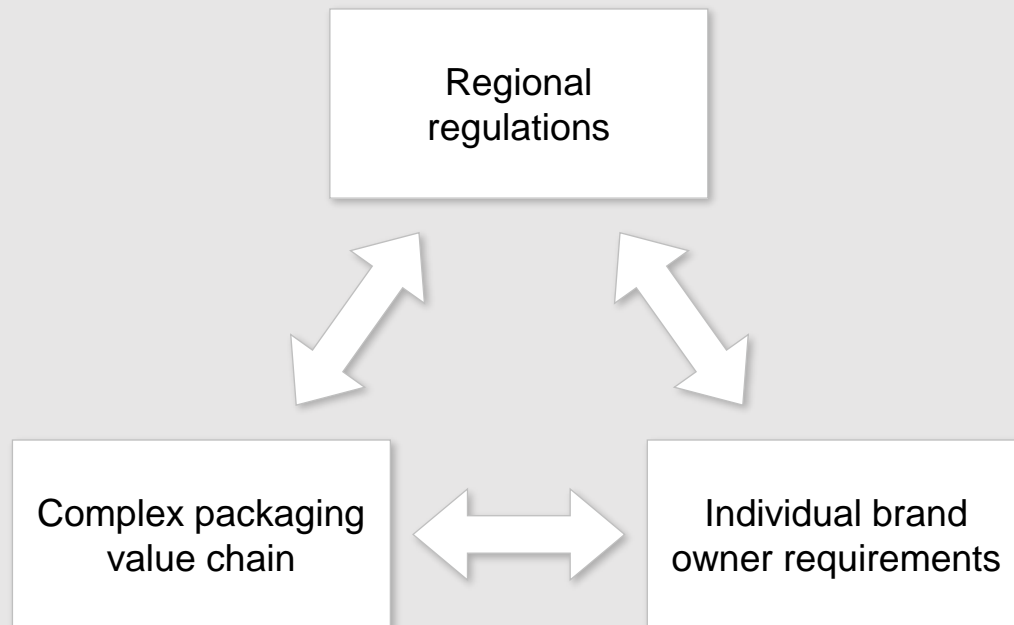
# Different countries implemented own FCM Regulations





# Converters work in a complex environment

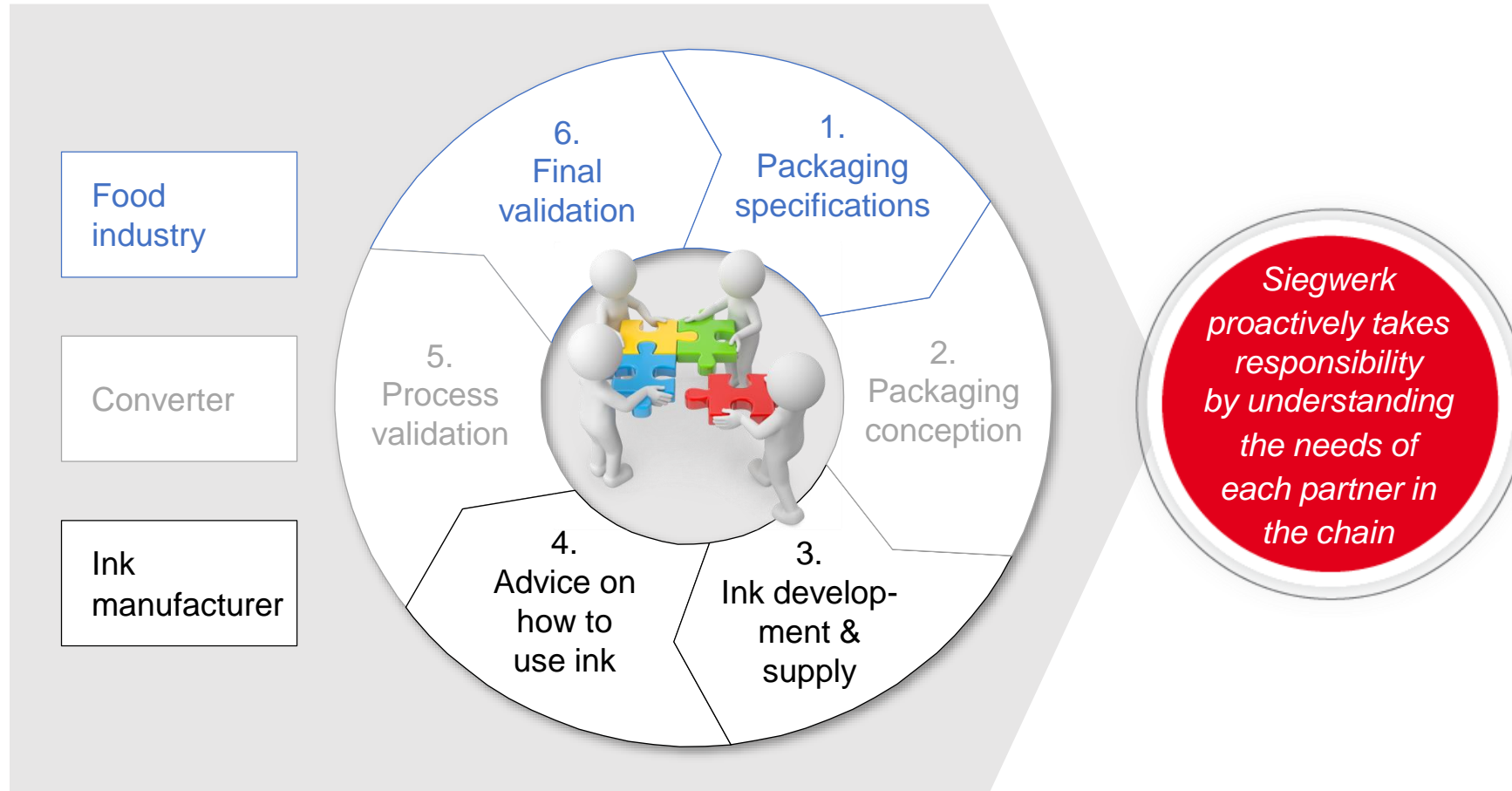
## 3 key pillars for suppliers in food industry to manage



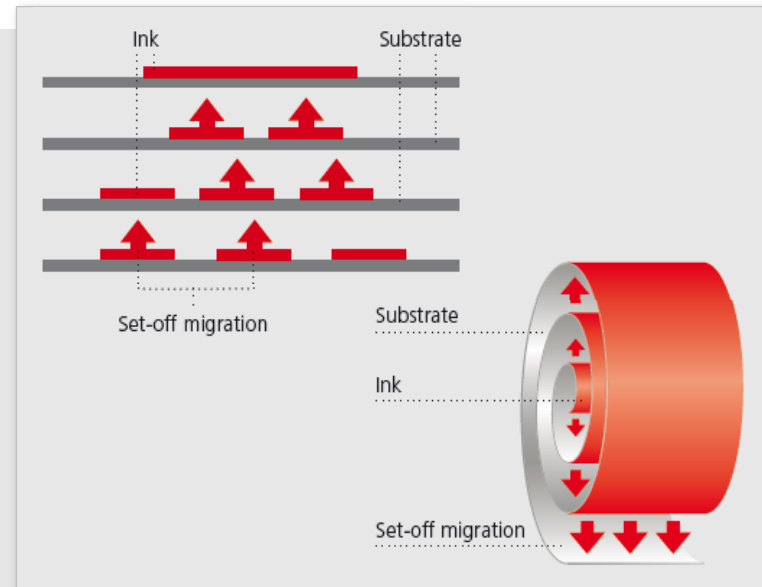
*Navigating the food packaging safety space is difficult to all producers*



# Sharing responsibilities in the chain is key to success!

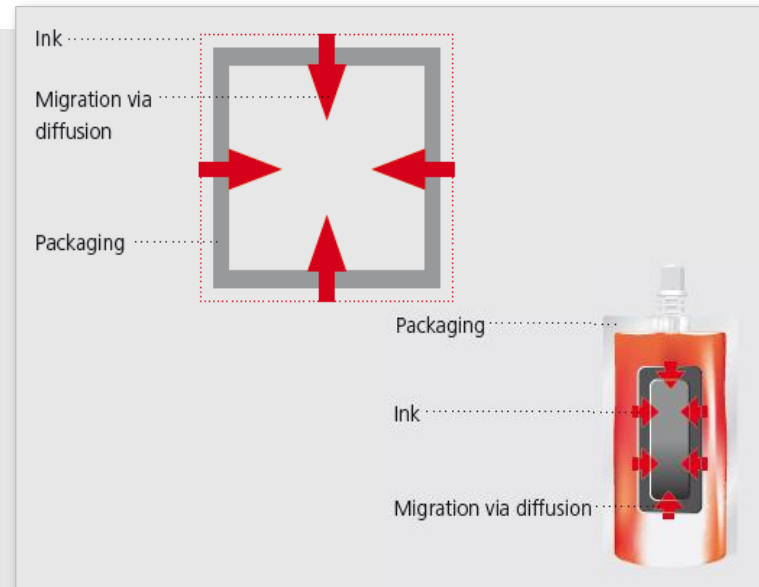


# Migration can come in different ways...



## Set-off principle

- Transfer from ink to reverse side of substrate (reels, stacks, piles, etc.)
- Reverse side later in direct food contact



## Diffusion principle

- Diffusion across packaging materials into food (or gas transfer)
- Even rigid materials (e.g. PE bottle) are not always a sufficient barrier

# Migration can come in different ways...

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## **Migration depends on**

- Packaging structure
- Migrant's properties: e.g. molecular weight, polarity
- Diffusion coefficient in different food (simulants)
- Time and temperature of production and storage

**Associated risks need to be evaluated in each case!**

## **Set-off principle**

- Transfer from ink to reverse side of substrate (reels, stacks, piles, etc.)
- Reverse side later in direct food contact

## **Diffusion principle**

- Diffusion across packaging materials into food (or gas transfer)
- Even rigid materials (e.g. PE bottle) are not always a sufficient barrier





# Food and packaging have influence on migration

## Packaging structure / design



- Packaging type
- Layer structure
- Components in packaging system
- Size & design of packaging (s/v ratio)
- Nature of print on article

## Food properties

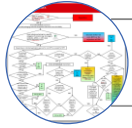


- Type of food
- Expected maximum shelf life
- Process requirements on post packaging  
(e.g. pasteurization, microwave, oven...)

*Brands/food  
companies are  
responsible to  
share information  
for safe  
packaging*



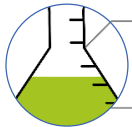
# Safe inks - from raw material to packaging



**Globally harmonized raw material introduction process including 100% disclosure of composition**



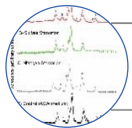
**All raw materials comply with regulatory and internal requirements**



**Raw materials are analyzed for quality assurance**



**Worst Case Calculation**



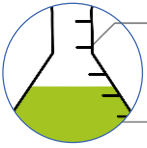
**Products are analyzed under worst case conditions**



**Extensive customer information, including Statement of Composition (SoC)**







Raw materials are analyzed for quality assurance



### Incoming goods controls

- Conformance with specifications
- Purity control



### Spot-check for pigments

- Regular spot-check analyses
- Heavy metals, PCB, HCB, paa, dioxines...

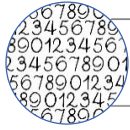


### Verification of composition

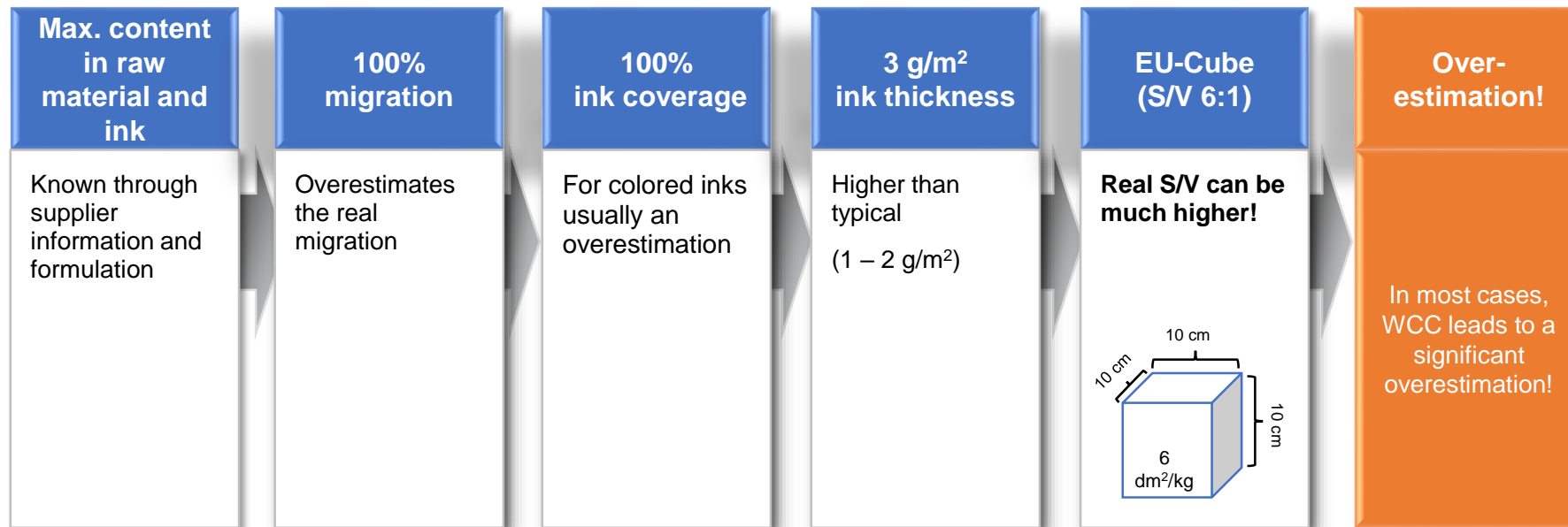
- Residual monomers, molecular weight distribution, ...
- Non Intentionally Added Substances (NIAS)







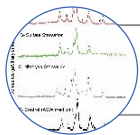
## Worst Case Calculation



Further information:

[https://www.siegwerk.com/fileadmin/DATEN/Documents/safe\\_food\\_packaging/Annex for SoC Internet Version 2019 V3.1 EN.pdf](https://www.siegwerk.com/fileadmin/DATEN/Documents/safe_food_packaging/Annex_for_SoC_Internet_Version_2019_V3.1_EN.pdf)



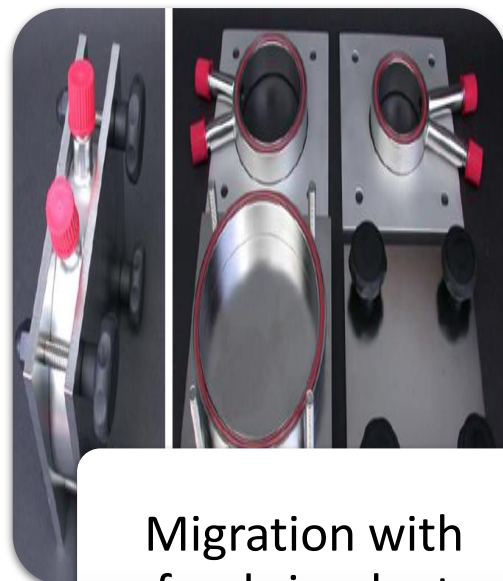


Products are analyzed under worst case conditions

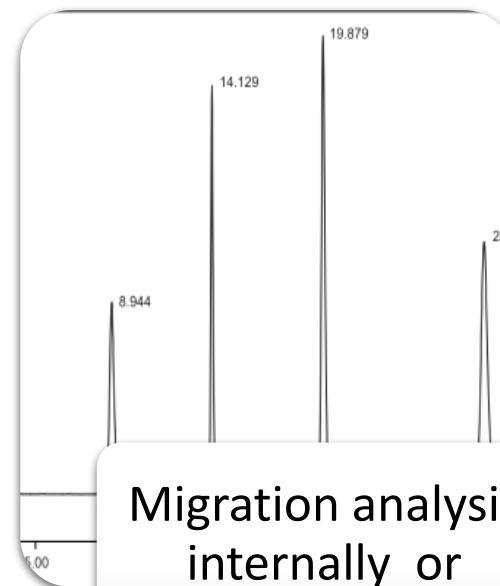
If worst case calculation is not sufficient, migration tests are performed



Worst-case print  
in the lab  
(or at customer)



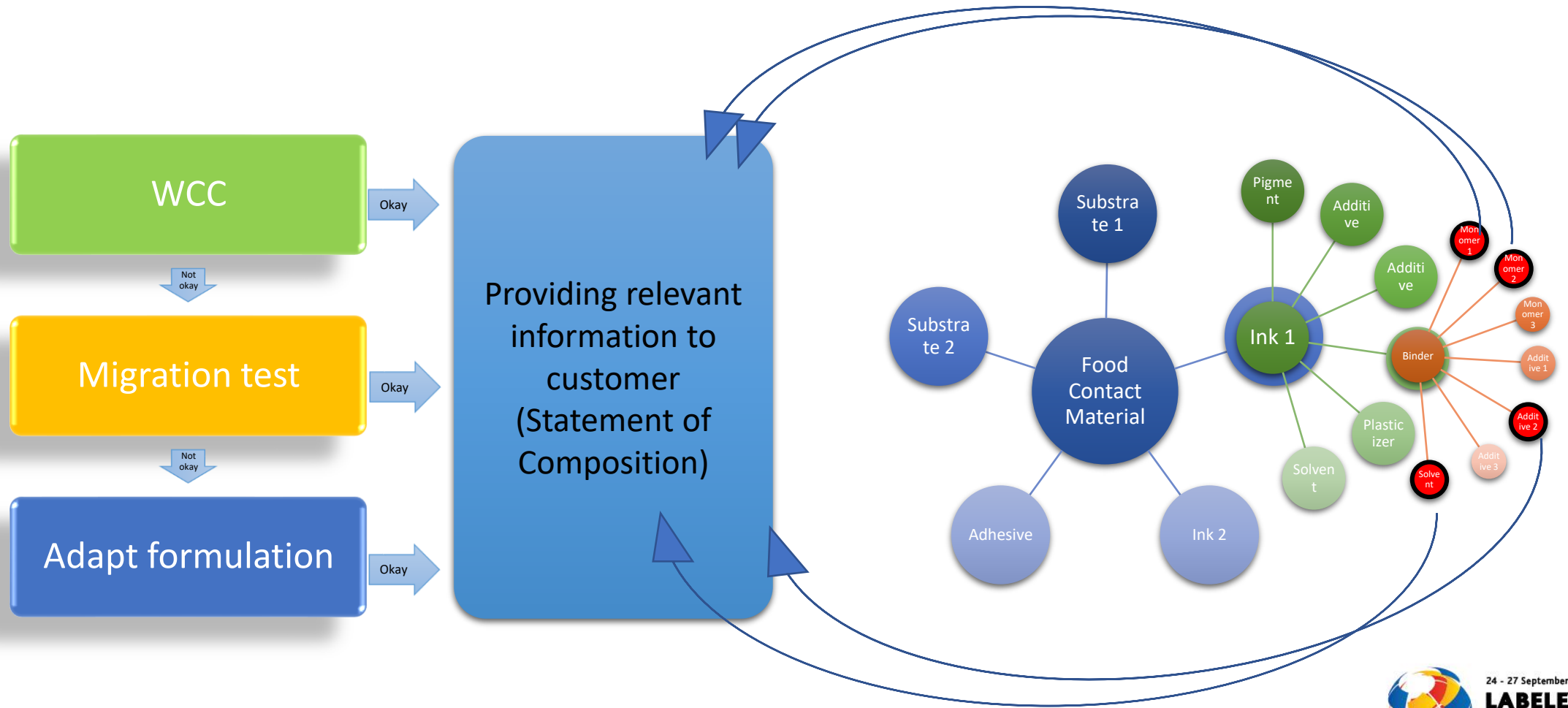
Migration with  
food simulant



Migration analysis  
internally or  
externally




# Simple process for assessment of migrants





# Regulatory information in Statement of Composition

**INK, HEART & SOUL**  **SIEGWERK**

**Angaben zur Zusammensetzung der folgenden Druckfarben-/Drucklacksysteme**

Farbe Nr. 12345

**die für die Herstellung von Lebensmittelverpackungen verwendet werden**

Die Verordnung (EG) Nr. 1935/2004 und die Schweizer Bedarfsgegenständeverordnung 817.023.21 schreiben vor, dass Bedarfsgegenstände, die als Fertigerzeugnisse dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen oder die bestimmungsgemäß mit Lebensmitteln in Berührung kommen, keine Bestandteile an das abgepackte Lebensmittel in Mengen abgeben dürfen, die geeignet sind, die menschliche Gesundheit zu gefährden oder eine unverträgliche Veränderung der Zusammensetzung oder eine Beeinträchtigung der organoleptischen Eigenschaften der Lebensmittel herbeizuführen.

Das bedeutet, dass der Hersteller des fertigen Endprodukts und der **Abpacker** die rechtliche Verantwortung dafür tragen sicherzustellen, dass die Lebensmittelverpackung für den bestimmungsgemäßen Zweck geeignet ist.

Unter der Voraussetzung der Verwendung unserer oben genannten Produkte gemäß den Angaben im technischen Datenblatt oder vergleichbarer technischer Informationen, ihrer fachgerechten Verarbeitung und einer Gestaltung der Lebensmittelverpackung derart, dass der Druck nicht mit dem Lebensmittel in Berührung kommt, können wir Ihnen hiermit bestätigen, dass es unsere Produkte grundsätzlich ermöglichen, dass das Endprodukt die Anforderungen der Verordnung (EG) Nr. 1935/2004 und der Schweizer Bedarfsgegenständeverordnung 817.023.21 erfüllt.

- Die Produkte von Siegwerk werden in Übereinstimmung mit der „EuPIA-Leitlinie für Druckfarben zur Verwendung auf der vom Lebensmittel abgewandten Oberfläche von Lebensmittelverpackungen und Gegenständen“ rezeptiert und hergestellt ([www.eupia.org](http://www.eupia.org)).
- Die oben genannten Produkte werden in Übereinstimmung mit der „Guten Herstellungspraxis für die Produktion von Verpackungsdruckfarben zur Verwendung auf der vom Lebensmittel abgewandten Oberfläche von Lebensmittelverpackungen und Gegenständen, welche bestimmungsgemäß mit Lebensmitteln in Kontakt kommen (GMP)“ der EuPIA hergestellt ([www.eupia.org](http://www.eupia.org)).
- Gemäß den von den Rohstofflieferanten zur Verfügung gestellten Angaben enthält eine mit den oben genannten Produkten hergestellte bedruckte Verpackung die in der Tabelle aufgeführten Stoffe.

Ausführlichere Informationen zum rechtlichen Hintergrund, zu Siegwerks Standardannahmen, zu Risikobewertung und Migrationstests finden Sie auf unserer Homepage unter [www.siegwerk.com/de/customer-segments/customer-service/food-packaging-safety](http://www.siegwerk.com/de/customer-segments/customer-service/food-packaging-safety).

Name and number of printing ink

Confirmation that requirements of Framework Regulation and Swiss ordinance can be met

EuPIA requirements fulfilled

GMP fulfilled



# Migrant information in Statement of Composition

CAS No.	PM/Ref No.	FCM No.	Name	Restrictions and specific migration limits (SML) [mg/kg]		Regulation (EC) No 1333/2008	For non-volatile/non-reactive substances: Maximum amount in dried ink film [%]	WCC, S/V ratio 6:1 [mg/kg]	Comment
				Regulation (EU) No 10/2011	Swiss Ordinance 817.023.21 [either "SML" or "part B"]				
112-84-5	52720	271	Erucamid	(60)	(60)	-	10	18	
25322-69-4	23651/8080	639	Polypropylenglykol	(60)	(60)	-	< 1	1	
128-37-0	46640	315	2,6-Di-tert.-butyl-p-kresol	3	3	E 321	1	2	

Substance information

Restrictions

Dual Use Information

Amount in dry ink

Max. possible amount in food

**This enables converter to ...**  
 ... make safe use of Siegwirk inks in own products  
 ... pursue a worst case calculation to evaluate potential migration risks  
 ... issue own declaration of conformity for printed package to brand owner

# Example: Worst Case Calculation for small packaging

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**Extra for children (1 year up)**

**Surface ca.  $2 \times 12 \times 7 \text{cm}$  + bottom (ca.  $10 \text{cm}^2$ )**

**Contains 100 g food**

**Surface : Volume = 18 : 1**



# Example: Worst Case Calculation for small packaging

Information provided in Statement of Composition:

Name	Restrictions and specific migration limits (SML) [mg/kg]		Maximum amount in dried ink film [%]	WCC, S/V ratio 6:1 [mg/kg]
	Reg. (EU) No 10/2011	Swiss Ordinance 817.023.21		
Erucamide	(60)	(60)	10	18
Polypropylene glycol	(60)	(60)	< 1	1
BHT	3	3	1	2



# Example: Worst Case Calculation for small packaging

Information provided in Statement of Composition:

Name	Restrictions and specific migration limits (SML) [mg/kg]		Maximum amount in dried ink film [%]	WCC, S/V ratio 6:1 [mg/kg]
	Reg. (EU) No 10/2011	Swiss Ordinance 817.023.21		
Erucamide	(60)	(60)	10	18
Polypropylene glycol	(60)	(60)	< 1	1
BHT	3	3	1	2



**WCC sufficient,  
no migration  
tests are  
necessary!**



# Example: Worst Case Calculation for small packaging

Calculation for different surface to volume ratio:

Name	Restrictions and specific migration limits (SML) [mg/kg]		Maximum amount in dried ink film [%]	WCC, S/V ratio 6:1 [mg/kg]	O/V = 18:1
	Reg. (EU) No 10/2011	Swiss Ordinance 817.023.21			
Erucamide	(60)	(60)	10	18	54
Polypropylene glycol	(60)	(60)	< 1	1	3
BHT	3	3	1	2	6



# Example: Worst Case Calculation for small packaging

Calculation for different surface to volume ratio:

Name	Restrictions and specific migration limits (SML) [mg/kg]		Maximum amount in dried ink film [%]	WCC, S/V ratio 6:1 [mg/kg]	O/V = 18:1
	Reg. (EU) No 10/2011	Swiss Ordinance 817.023.21			
Erucamide	(60)	(60)	10	18	54
Polypropylene glycol	(60)	(60)	< 1	1	3
BHT	3	3	1	2	6



**WCC not sufficient, migration tests are necessary!**



# Example: Worst Case Calculation for small packaging

Calculation for different surface to volume ratio:

Name	Restrictions and specific migration limits (SML) [mg/kg]		Maximum amount in dried ink film [%]	WCC, S/V ratio 6:1 [mg/kg]	O/V = 18:1	6g ink
	Reg. (EU) No 10/2011	Swiss Ordinance 817.023.21				
Erucamide	(60)	(60)	10	18	54	108
Polypropylene glycol	(60)	(60)	< 1	1	3	6
BHT	3	3	1	2	6	12



# Example: Worst Case Calculation for small packaging

Calculation for different surface to volume ratio:

Name	Restrictions and specific migration limits (SML) [mg/kg]		Maximum amount in dried ink film [%]	WCC, S/V ratio 6:1 [mg/kg]	O/V = 18:1	6g ink
	Reg. (EU) No 10/2011	Swiss Ordinance 817.023.21				
Erucamide	(60)	(60)	10	18	54	108
Polypropylene glycol	(60)	(60)	< 1	1	3	6
BHT	3	3	1	2	6	12



**WCC not sufficient, migration tests are necessary!**

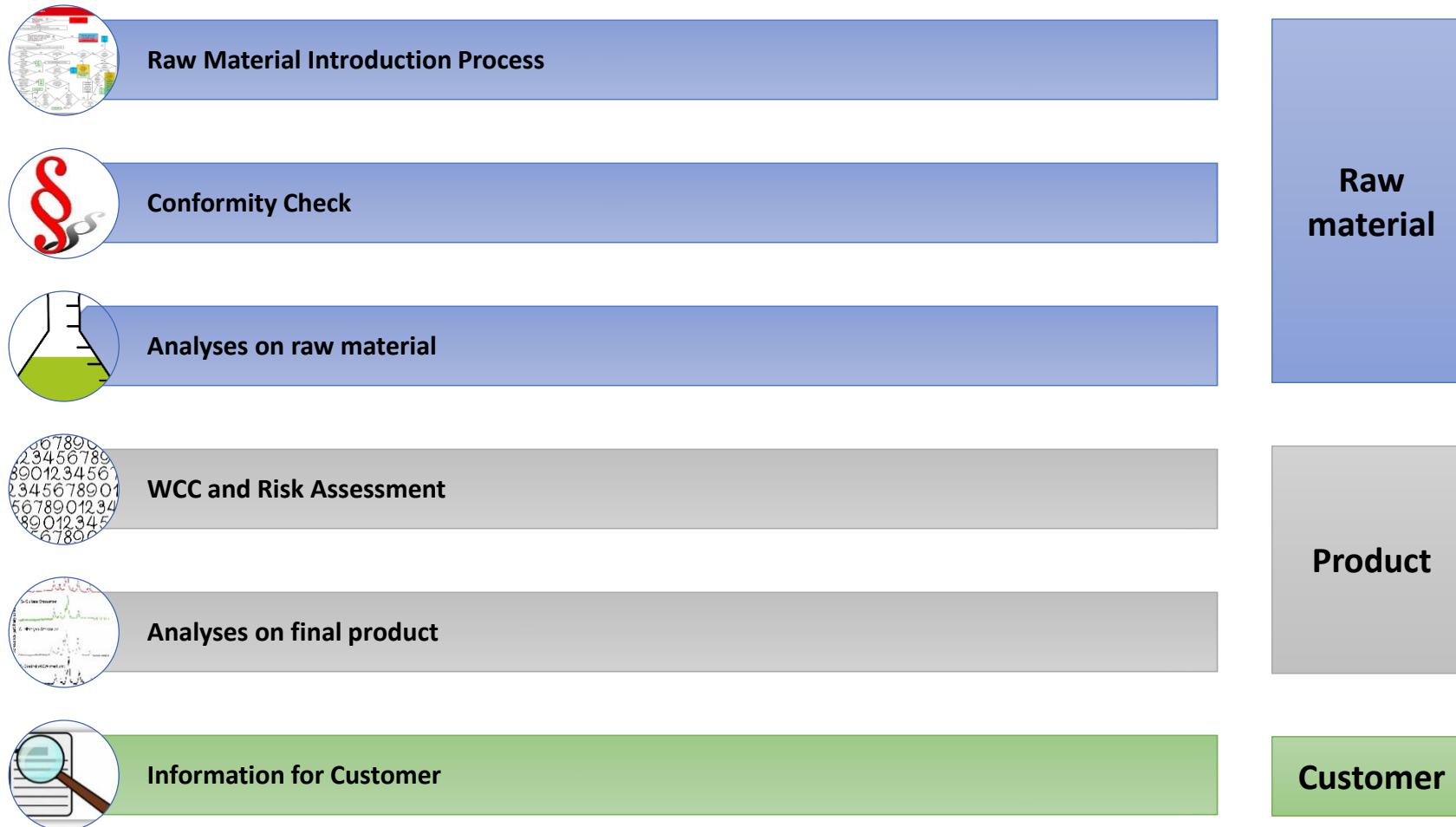
# Compliance Assessment via wcc, modelling or testing

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	Time	Money	Result
Worst case calculation	+	+	Overestimated
Migration modeling	++	++	Slightly overestimated
Migration testing (simulant)	+++	+++	Closest to real value
Migration testing (food)	+++	++++	Correct



# Siegwerk - Safe inks from raw material to packaging





# Further information:



Content of migrant in dried ink layers, applied at 100% area coverage	Typical example of migrant	Max. migration with 6 dm <sup>2</sup> /kg food ("EU cube 10×10×10 cm, 1 kg food")		Max. migration with small package (case 40 g food in pouch 10×3×1.5 cm = 1 dm <sup>2</sup> , 25 dm <sup>2</sup> /kg)		SML (Europe)
		With 3 g/m <sup>2</sup> dry ink	With 5 g/m <sup>2</sup> dry ink	With 3 g/m <sup>2</sup> dry ink	With 5 g/m <sup>2</sup> dry ink	
<b>Evaluated substances</b>						
25%	ATBC (plasticizer, solvent-based inks)	45 mg/kg	75 mg/kg	187 mg/kg	312 mg/kg	60 mg/kg <sup>a</sup>
10%	DEHA (plasticizer, solvent-based inks)	18 mg/kg	30 mg/kg	75 mg/kg	125 mg/kg	18 mg/kg
2%	Erucamide (slip agent, solvent-based inks)	3.6 mg/kg	6 mg/kg	15 mg/kg	25 mg/kg	60 mg/kg
1%	DI-2-ethylhexylsulphosuccinate (surfactant, water-based inks)	1.8 mg/kg	3 mg/kg	7.5 mg/kg	12.5 mg/kg	5 mg/kg
0.02%	Benzothiazolinone (biocide, water-based inks)	0.036 mg/kg	0.06 mg/kg	0.15 mg/kg	0.25 mg/kg	0.5 mg/kg
5%	Benzophenone (photoinitiator in UV inks not intended for food packaging)	9 mg/kg	15 mg/kg	37 mg/kg	62 mg/kg	0.6 mg/kg

<https://ink-safety-portal.siegwerk.com/regulatory-affairs/compliance>

# Thank you!

Dr. Sarah-Lisa Theisen

Department Manager for Product Safety &  
Regulations and Recipe Management EMEA  
Siegwerk Druckfarben AG & Co. KGaA



24 - 27 September • Brussels  
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