

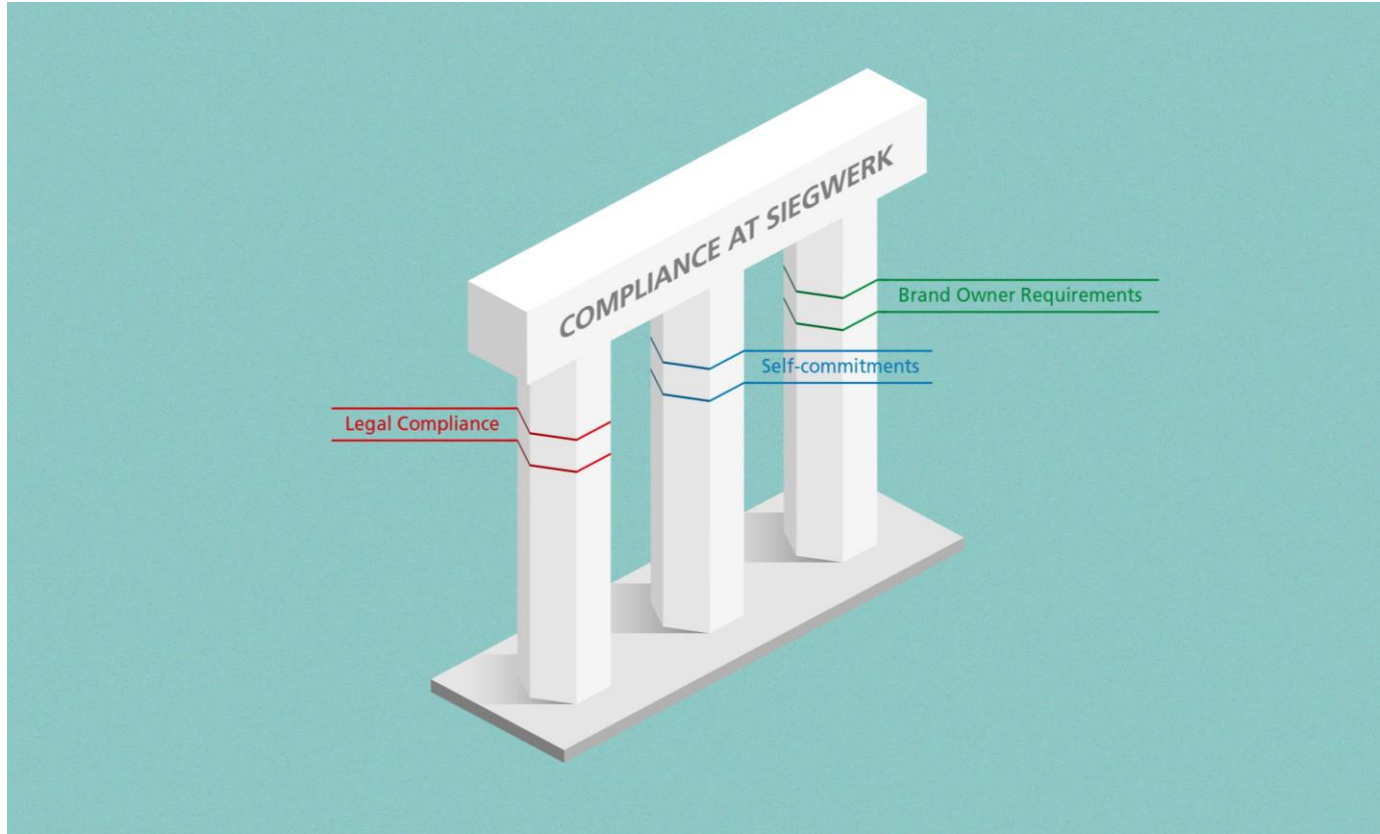


# Safety evaluation of contact sensitive printing inks and future regulatory challenges

Dr. Evert Delbanco / 21.09.2023



# Temple of compliance



# Siegwerk Exclusion Policy

## Globally applicable

- Criteria (hazard categories) for exclusion of a raw material

### **GROUP A**

Acute Toxicity Cat. 1 & 2 [H300, H310, H330]

Acute Toxicity Cat. 3 (inhalation)  
[H331]

Carcinogen or Mutagen Cat. 1A & 1B  
[H350, H340]

Toxic to Reproduction Cat. 1A & 1B [H360]  
(*non-threshold substances*)

STOT Single Exposure Cat. 1 [H370]

### **GROUP B**

Acute Toxicity Cat. 3 (oral, dermal)  
[H301, H311]

Toxic to Reproduction Cat. 1A & 1B [H360]  
(*if threshold exists*)

STOT Repeated Exposure Cat. 1 [H372]

- Substitution principle by default
- If Substitution not possible in the short term, exemption is possible according to the clearly defined and managed procedure for a limited period of time

# Siegwerk – how we support our customers

Systematic processes: Siegwerk beyond EuPIA exclusions

Siegwerk is also committed to foresighted adaptation and even moves beyond the regulations when it comes to ink safety and consumer protection.

Siegwerk has **voluntarily** phased out many chemicals that are out of the scope of the EuPIA exclusion policy considering the toxicological consequences that may arise due to their use in the printing inks.

Examples:

- “Fanal” pigments\* (low fastness and resistance prop.)
- Cobalt driers (reprotoxic)
- Phthalates (endocrine disruptors)
- Mineral oils\* (MOAH carcinogenic)
- PFAS (ecotoxic)
- Toluene\* (ototoxic, reprotoxic)

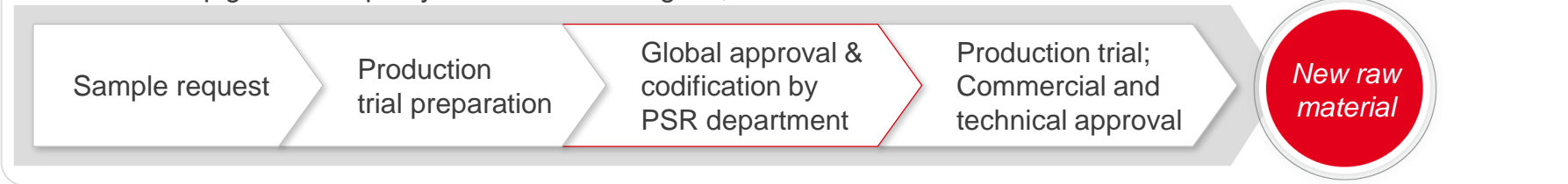


## Siegwerk – how we support our customers

## Systematic processes: raw material approval process

## Siegwerk global approval process checks

- Compliance with exclusion criteria (e.g. carcinogenic, mutagenic, reprotoxic, toxic raw materials)
- Compliance with Siegwirk's stringent purity standards and full understanding on existing impurities in raw materials
- Compliance with chemical registration in each applicable region
- Composition data for NPH ("Nutrition, Pharma, Hygiene") applications (100%)
  - Identify regulated materials in food contact
  - Identify non-regulated but potentially migrating substances
  - Identify all NIAS (non-intentionally added substances)
  - Check pigments for purity & data on carcinogens, PCB's etc.

[illegible]

# Siegwerk – how we support our customers

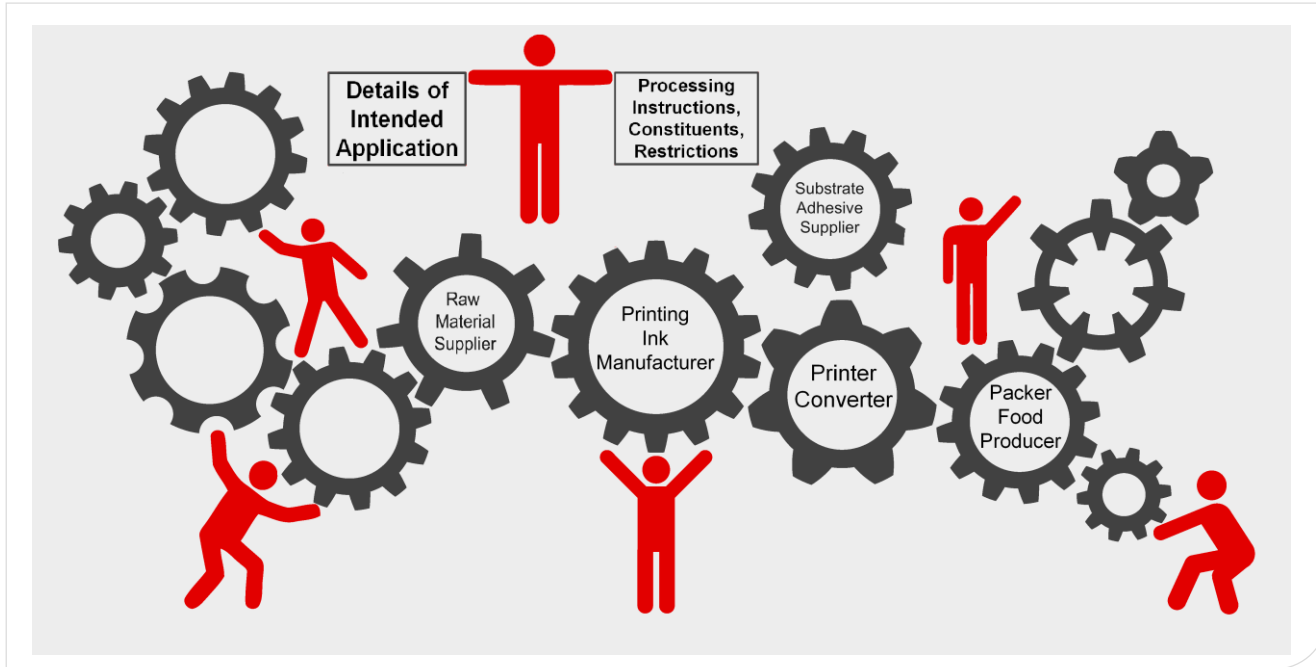
Systematic processes: Siegwerk's Formulation Guideline



- Internal mandatory guideline for Technology and R+D departments
- Covers all raw materials for all regions and applications
- NPH (“Nutrition, Pharma, Hygiene”) evaluations based on regional legislations, e.g. EU “Framework Regulation”, US-FDA, China GB etc.
- Basis for new ink formulations

# Siegwerk – how we support our customers

Co-operation and information sharing among all partners in the food packaging supply chain



Source: VdL.



# Siegwerk – how we support our customers

## Statement of Composition (SoC)

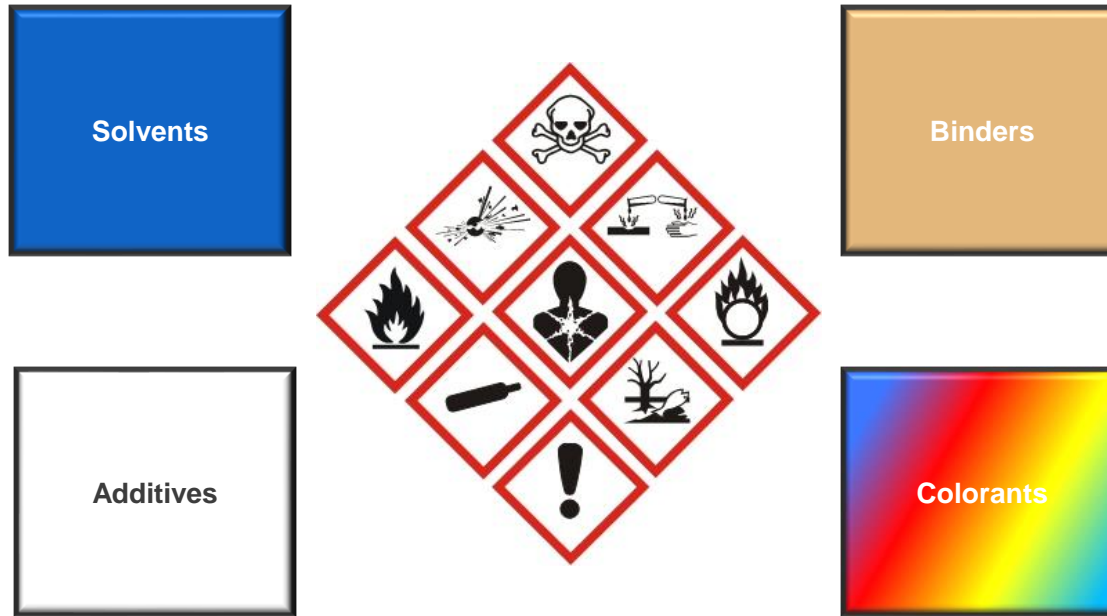
- Information about all potentially migrating substances in the ink / varnish / coating
- Details on identification, concentration and restrictions of the migrant
- Calculation of the maximum possible migration (WCC)
- If applicable: NIAS Risk Assessment
- "Prerequisite": Knowledge of raw materials, definition of migrants

CAS No.	PM/Ref No.	FCM No.	Name	Restrictions and specific migration limits (SML) [mg/kg]		Regulation (EC) No 1333/2008 Regulation (EC) No 1334/2008	For non-volatile/non-reactive substances: Maximum amount in dried ink film [%]	WCC <sup>2</sup> SV ratio	Comment <sup>3</sup>
				Regulation (EU) No 10/2011 Tebilig No 2013/34	Swiss Ordinance 817.023.21				
77-90-7	93760	138	Acetyltributylcitrate	(60)	(60)	FL 09.511	5	10	Possible by-products: Tributyl acrylate (750-68-3), diacetyltributyl citrate (6543-35-4), Tributylcitrate (77-94-1)
126-13-6	91200	308	Sucrose acetate isobutyrate (SAIB)	(60)	(60)	E 444	5	9	
73138-82-6	24070/83 610	741	Resin acids and rosin acids	(60)	(60)	-	1	2	
112-84-5	52720	271	Erucamide	(60)	(60)	-	1	1	
86-92-0			3-Methyl-1-p-tolyl-5-pyrazolone	-	-	-	0.02	0.04	Based on a toxicological risk assessment conducted by Siegwerk a self-derived SML of 0.02 mg/kg can be applied for the migrant if present as NIAS. Details are available on request.



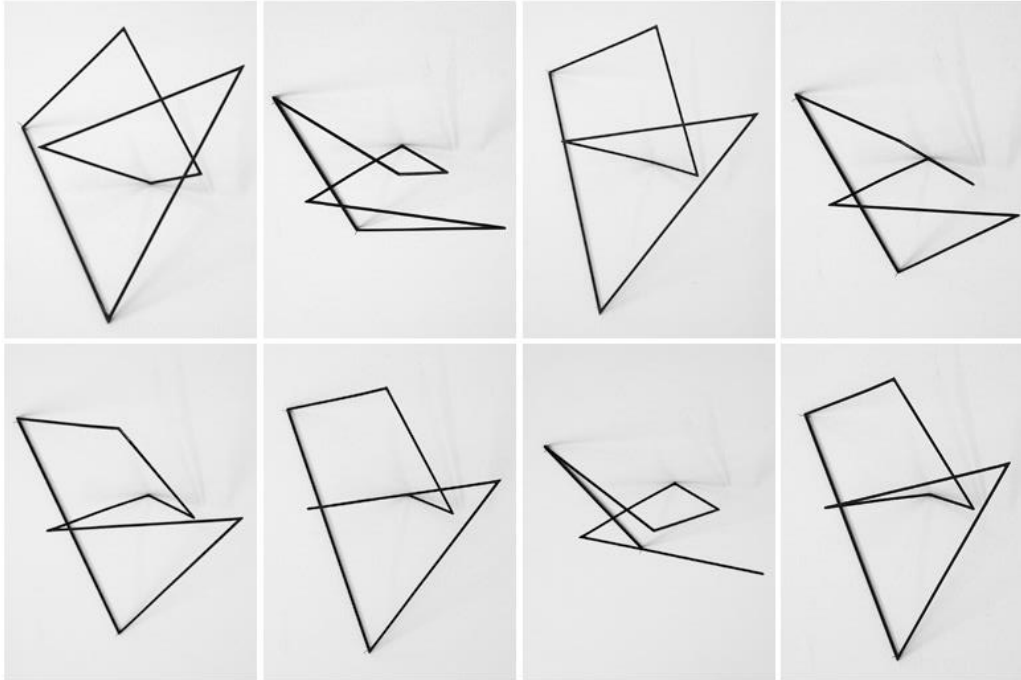
# There are more threats . . .

. . . which need to be considered and assessed



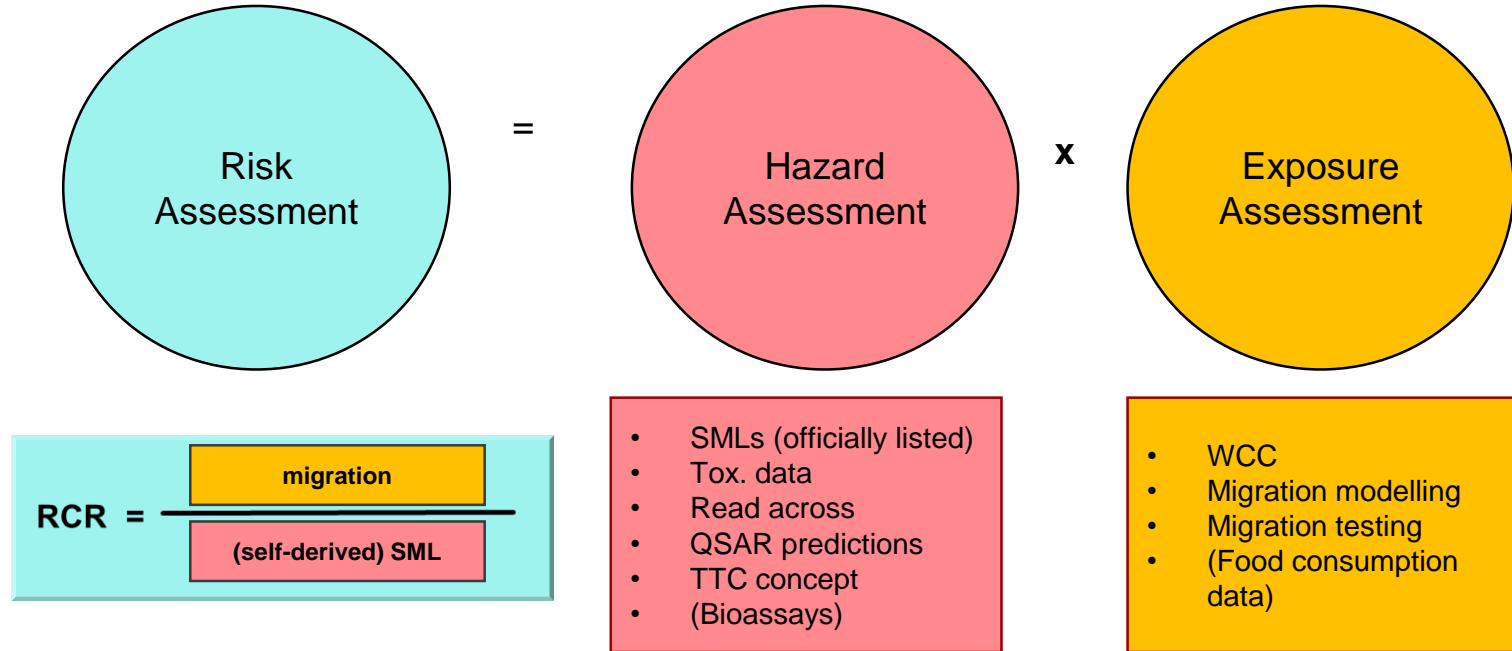
# The perspective defines what you see

IAS or NIAS



Astrid Lincke-Zukunft, Kleine Winkelspitze (2009) – shot from 8 different perspectives

# Risk Assessment Procedure



## Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment

EFSA Scientific Committee

ADOPTED: 24 April 2019

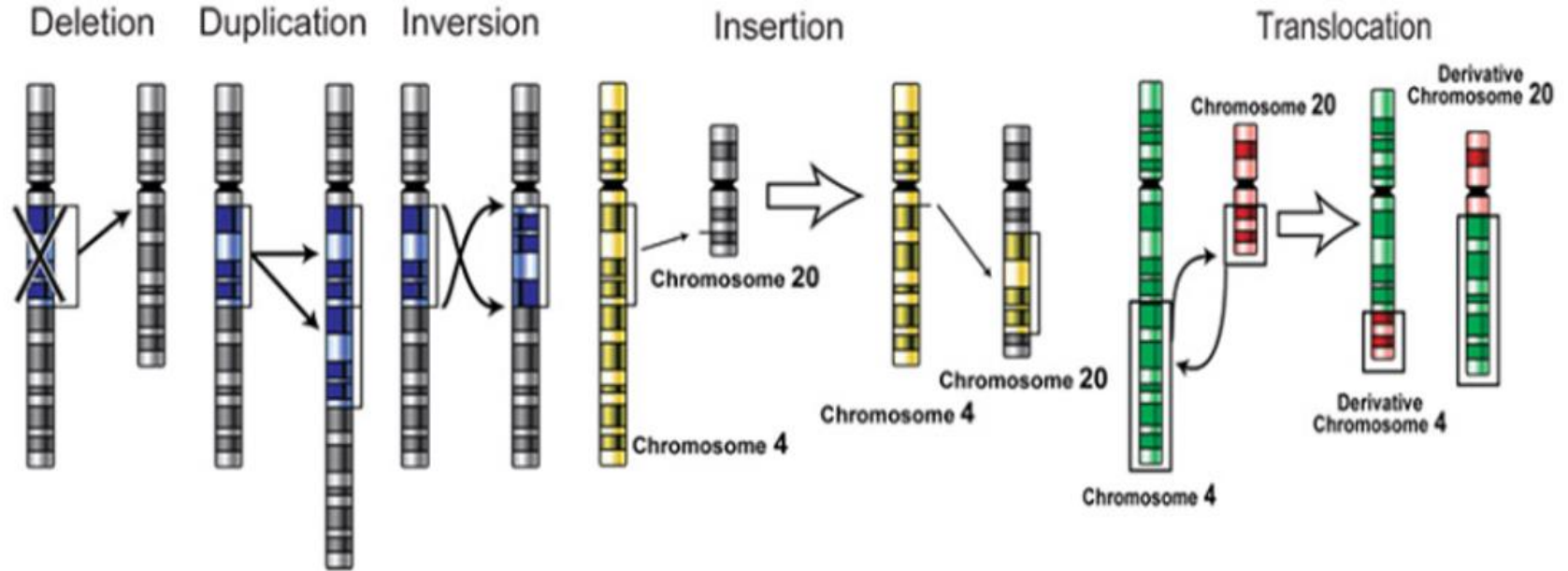
doi: 10.2903/j.efsa.2019.5708

### 3.6. Genotoxicity prediction tools

In applying the TTC approach, it is necessary to assess the potential for DNA-reactive mutagenicity or carcinogenicity often based on few or no experimental data. Evidence may come from read across from structurally similar chemicals, **use of structural alerts or (Q)SAR models**. Modelling of genotoxicity is one of the most extensively developed fields in computational toxicology (Serafimova et al., 2010; Worth et al., 2010, 2013; Mombelli et al., 2016; Patlewicz and Fitzpatrick, 2016). This has been facilitated by our understanding of the underlying biological mechanisms, well established experimental protocols, and availability of a large amount of experimental data in the public domain. Some of the software packages implementing these models are freely available (e.g. Toxtree, T.E.S.T, VEGA, LAZAR).

**Prediction of DNA reactivity should not be based on the use of a single model alone.** In order to optimise sensitivity/specificity when using prediction tools, **it is recommended that at least two independent (Q)SAR models** are applied which are suitable for the structure under consideration to maximise the sensitivity and specificity of the prediction (EFSA PPR Panel, 2016). The independence of the models is based on different training sets or algorithms **(e.g. knowledge-based and statistically based models)** used for developing the models (EFSA PPR Panel, 2016). **Each prediction should be evaluated, based on expert judgement,** for relevance and reliability following internationally agreed standards (ECHA, 2008, 2016; OECD, 2014). Particular caution has to be taken for substances that are 'out of domain' of the model and for which a reliable prediction is not possible. The same applies when the reported confidence score is low.

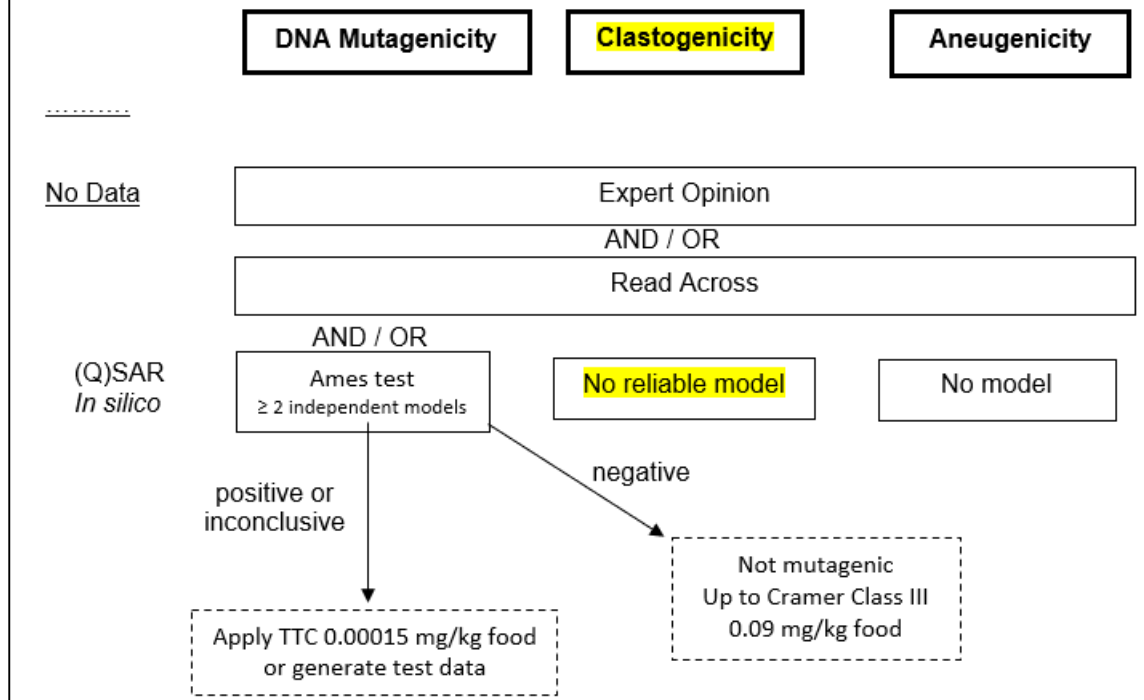
# Clastogenicity – type of mutations



# EuPIA NIAS Guidance








## Attachment 4: Genotoxicity decision tree



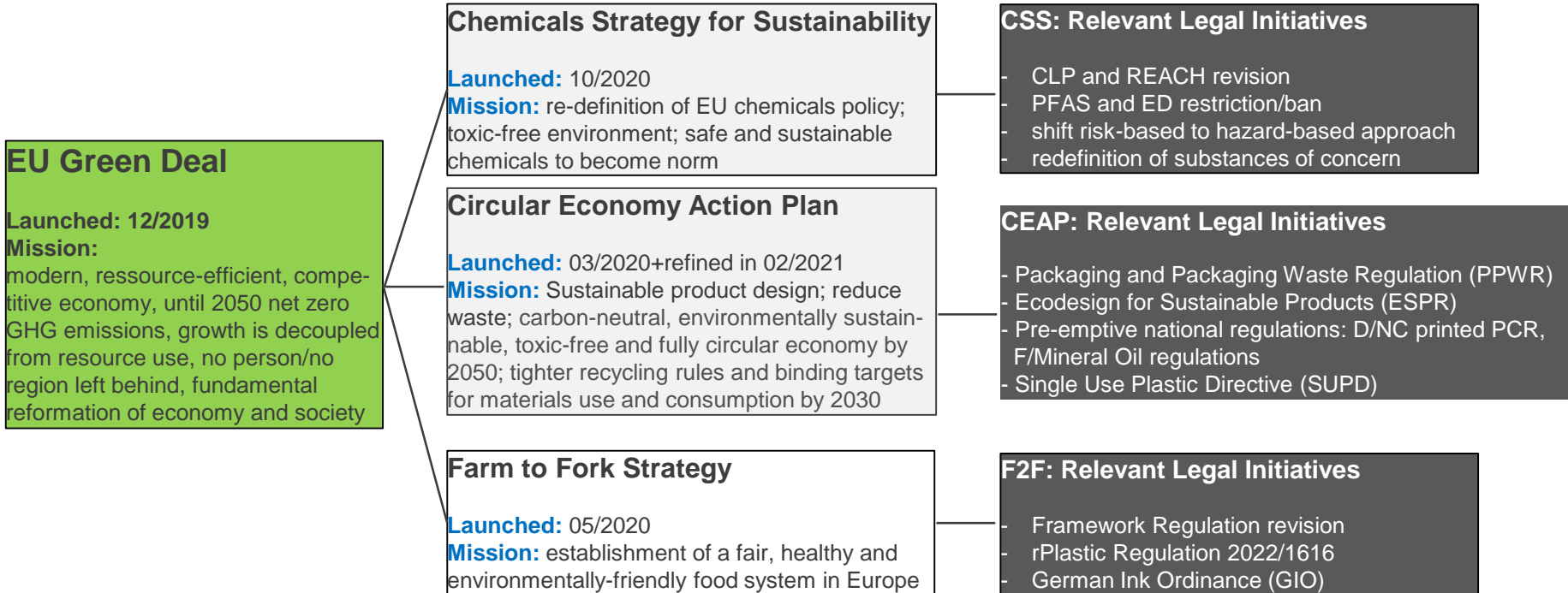
# Siegwerk – how we support our customers

## Siegwerk - Trendsetter for safest inks and coatings

<b>Voluntary Commitment</b>  <b>SIEGWERK</b> based on 	<b>Siegwerk Exclusion Policy</b>	Self commitment based on EuPIA Exclusion Policy and applying the principles on global level
	<b>Foresighted adaptation</b>	Continuous improvement of raw material portfolio regarding consumer, occupational and environmental safety
	<b>PSR Management System</b>	Rigid raw material selection and globally coordinated approval processes to safeguard legal and brand owner compliance result in global benchmark for the composition of inks and coatings
	<b>Transparency</b>	Proactive communication about relevant product related information down the supply chain to support compliance management and sustainability ambitions via product environmental data as well as provision of expert knowledge via the openly accessible Ink Safety Portal



# EU Green Deal: Trying to structure implications and challenges



# Initiatives in detail: German Ink Ordinance

## Comparison to Swiss Regulation 817.021.23



- **Latest version: 01.10.2022**  
(Annex 10; first introduced 2005)
- **Scope printing inks/prints:**  
IAS\*, Indirect Food Contact
- **Positive list principle:**  
> **5.000** substances for manufacture  
(partly with restrictions of use)
- **Major revision** expected in 2024  
deletion of Annex 10, Part B



- **Published: 07.12.2021**  
(Enforcement: **01.01.2026** - 4 years transition)
- **Scope printing inks/prints:**  
IAS\*, Direct **and** Indirect Food Contact
- **Positive list principle:**  
> **1.000** substances for manufacture  
(partly with restrictions of use)
- **Non-listed** substances (NLS):  
allowed if migration < 10ppb + non CMR + not DFC

\*IAS = Intentionally Added Substances

# Initiatives in detail: Framework Regulation

Objective to strengthen Art. 3 (Framework Regulation):

FCMs are to be inert and inherently safe

*migration to be the exemption*

*limits are no longer driving force*

*final material must be effortlessly known as safe*

Main Policy pillars:

A: Shifting focus on the final article

Producers of final FCM become fully accountable (“migratables” must be known)

No difference between IAS and NIAS anymore

B: Prioritization of substances

Generic hazard assessments based on 3-tier approach

Tier 1: prohibition of use (CMRs, EDs, PBTs and vPvBs)

Tier 2: RA by authorities (other substances of concern, e.g. nano-materials)

Tier 3: RA by operators (more benign substances)

# Printed substrates in mechanical recycling processes

Critical steps from ink/coatings perspective

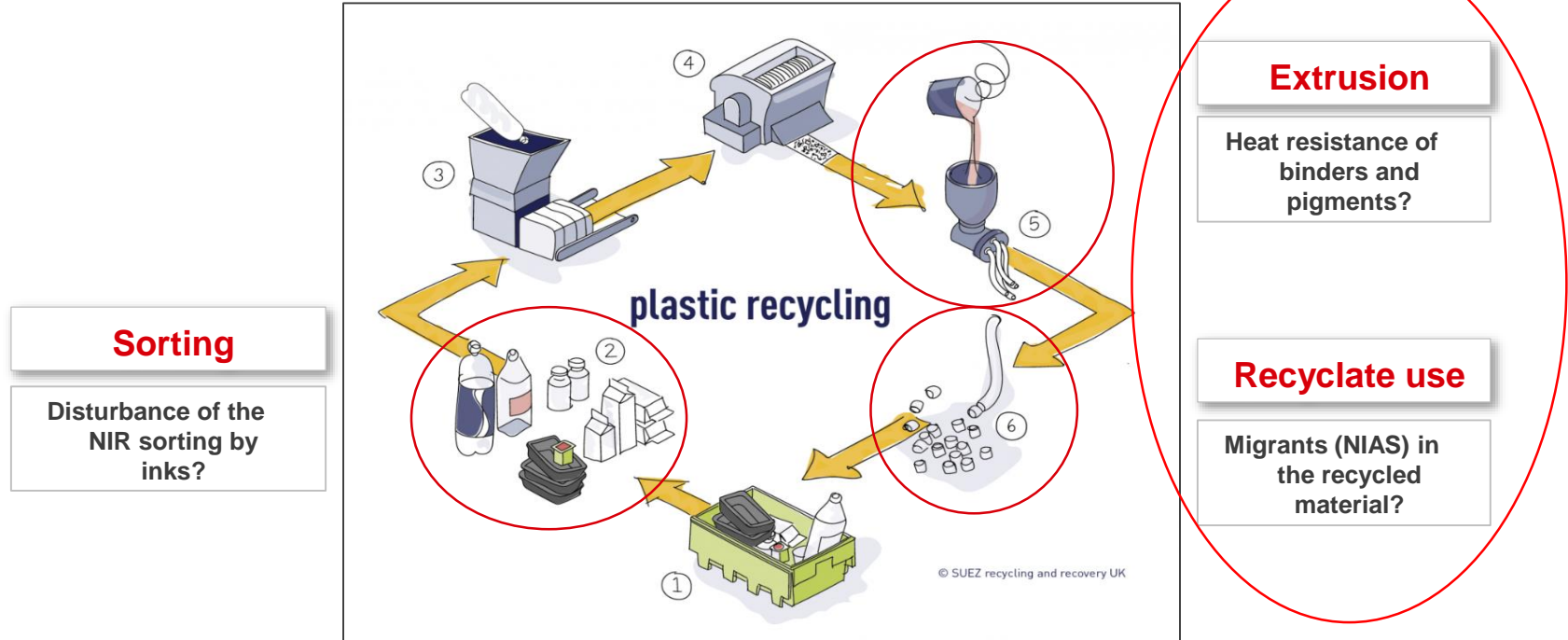


Image Source: Suez

# Ink Safety Portal

INK, HEART & SOUL

We are **responsible.**



**INK SAFETY PORTAL**

Find bundled knowledge on crucial food safety related topics and learn about our claim to provide the safest inks. Let us convince you of our standards: Experience our expertise.



Visit our Ink Safety Portal

Register to gain full access

Benefit from our knowledge

recycled plastics in fcm  
global regulations  
responsibilities  
solution  
performance  
optical illusions  
sustainability  
toxicology  
know how guidance  
nias  
risk assessment  
halal  
migration  
digital ink  
ink safety portal  
eupla  
microplastics  
substances of concern  
collaboration  
compliance  
worst case calculator  
6 steps for safe food pkg  
mineral oils  
guidance support  
transparency



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**SIEGWERK**

**Thank you!**

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