



Committee Product Policy

18 / 09 / 2020

DO'S



ENSURE STRICT PERFORMANCE IN AREAS OF:

- ☒ **Oversight / supervision:**
 - ☒ Have a secretariat representative at each meeting;
 - ☒ Consult with appropriate counsel on all questions related to competition law;
 - ☒ Limit meeting discussions to agenda topics;
 - ☒ Provide each attendee with a copy of this checklist, and have a copy available for reference at all meetings.
- ☒ **Recordkeeping:**
 - ☒ Have an agenda and minutes which accurately reflect the matters which occur;
 - ☒ Ensure the review of agendas, minutes and other important documents by appropriate staff or counsel, in advance of distribution;
 - ☒ Fully describe the purposes, structures and authorities of the groups.
- ☒ **Vigilance:**
 - ☒ Protest any discussion or meeting activities which appear to violate this checklist;
 - ☒ Ask for those activities to be stopped so that appropriate legal check can be made by counsel;
 - ☒ Disassociate yourself from any such discussion or activities and for the attendees, leave any meeting in which they continue (and have it minuted)

DONT'S



DO NOT, IN FACT OR APPEARANCE, DISCUSS OR EXCHANGE INFORMATION NOT IN CONFORMITY WITH COMPETITION LAW, INCLUDING FOR EXAMPLE ON:

Prices including:

- ☒ Individual company / industry prices, price changes, price differentials, discounts, allowances, credit terms, etc.
- ☒ Individual company data on costs, production, capacity (other than nameplates capacities), inventories, sales, etc.

Production, including:

- ☒ Plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers;
- ☒ Changes in industry production capacity (other than nameplates capacities) or inventories, etc.

Transportation rates:

- ☒ Rates or rate policies for individual shipments, including basing point systems, zone prices, freight, etc.

Market procedures, including:

- ☒ Company bids on contracts for particular products; company procedures for responding to bid invitations;
- ☒ Matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them, etc.
- ☒ Blacklist or boycott customers or suppliers

AGENDA

1. Welcome
2. Do's and Dont's
3. Approbation of the minutes of the previous meeting and agenda
4. Priorities of the participants
5. Review Framework Regulation 1935/2007:
Ecorys Report
6. German FCM-legislation
 - a) Mineral Oil Ordinance
 - b) Mineral Oil benchmark Values
 - c) Printing ink Ordinance
7. Reach: Art 33. + SCIP-DB
8. AOB:
 - a) PFAS
 - b) Ceramic & vitreous materials
9. Date NEXT MEETING
10. Tour de Table

Evaluation FCM framework Regulation

HIGHLIGHTS ECORYS REPORT

- 5 main chapters: Effectiveness, Efficiency, Relevance, Coherence, EU Added Value (all interlinked)
- **What exists works:**
 - ✓ Positive list : helps internal market
 - ✓ DoC: positive contribution to the internal market
 - ✓ EC 1935/2004: gives flexibility but no trigger for innovation
 - ✓ Benefits for human health outweigh costs of the legislation to the industry
 - ✓ GMP is crucial
- **But it is incomplete**
 - ✓ NIAS
 - ✓ Cocktail effect
 - ✓ NON-Harmonised are missing and delayed → also problem for the MML
 - ✓ Plastics: delay in publication of the positive advices on the use of recycled material
 - ✓ No obligation for DoC for all materials
 - ✓ No tailored approach for GMP and lack of controls

HIGHLIGHTS ECORYS REPORT – PAPER & BOARD

Paper & Board – one of the priority materials for action

Specific comment:

- DBTL (Dibutyltin dilaurate) - identified in REACH as possibly mutagenic and as toxic for reproduction. DBTL is still authorised in the Dutch regulations on paper and board.
- Sections on specific substances – MO, PFAS, etc.

SME's

- Mutual recognition is badly functioning → more national legislation → extra burden for SME's
- Compliance work most difficult for SME's
 - Different national legislations
 - Position in the market → more difficult to get information

Linking Reach and FCM

- Reach → restriction of all uses → no link with union list (report cites SVHC, NGO want Substs of known concern)
- **Attention: Risk based approach must be maintained!**

Non-harmonised

- National legislation → different interpretations for different materials and products
- many national measures → more difficult to reach Harm. legislation

Harmonised measures necessary for: Printing inks, Paper&Board, Silicones, Varnishes, Coatings, Rubber

NIAS & Cocktail effect are missing

EVALUATION FCM FRAMEWORK REGULATION

- Positions FEFCO, CITPA, CEPI
 - [PIJITF-proposal](#), with transparency matrix
 - Lobby of national governments to gain support of the PIJITF-proposal
-
- [To the matrix](#)

German FCM-legislation

- a) Mineral Oil Ordinance
- b) Mineral Oil benchmark Values
- c) Printing ink Ordinance



GERMAN PRINTING INKS ORDINANCE

- Notified on 17/08/2020 to TRIS → Standstill periode until 18/11/2020
- No prior consultation of the stakeholders

ALWAYS BARRIER UNLESS

- No transfer to the food: low MOAH concentration
- Appropriate measures to prevent migration
- Food producer doesn't need a barrier
- MOAH – Alkylated Aromatic polycyclic C16-C35 one or more ring structure (ex. DIPN)
- MOSH – no limit

LIMITS

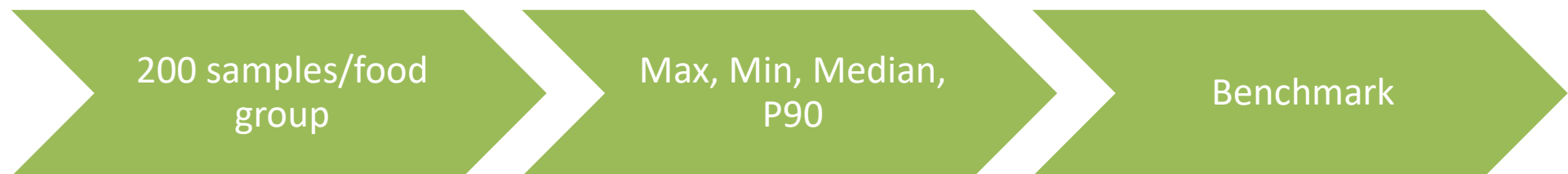




GERMAN BENCHMARK LEVELS

“Orientation, which source independent levels of MOH (MOSH/MOAH) in food of a specific group may be expected **based on statistical data and as a result of GMP** along the production chain.”

If benchmark levels are exceeded this may give an indication for contamination pathways which should be explored and considered. For the final evaluation of a product its composition and packaging, all information about raw materials, processing and FCM along the production chain and intended use and expected consumption should be considered.



- Existing analysis from ind & government

- =P90



GERMAN BENCHMARK LEVELS

Food Category	GER MOSH (mg/kg)	BE (MOSH – mg/kg)	MOAH (mg/kg)
Vegetable oil, plant oils (tropical oils excluded)	13	100	<LOQ
Bread, rolls, biscuits, pastry, grains & grain based products, oats, pasta, rice, breakfast cereals	6	15	<LOQ
Confectionary, chocolate	9	20-30	<LOQ
Nuts, oilseeds, coconut, peanuts and dried fruit and mixtures thereof	4	150	<LOQ

Limits of quantification (LOQ) based on JRC Technical Report:

- For low fat foods < 4% : 0,5 mg/kg.
- For high fat foods > 4% : 1mg/kg food.

German Printing Inks Ordinance

TIMELINE

2016

JRC baseline
study & EU
parlement
Resolutie voor
harmonisatie
van alle FCM

Duitse
Notificatie aan
de EU

3 maanden
Stand Still (ext.
als Detailed
Opinion)

12-18
maanden
Stand Still, als
EU initiatief

2017

pFCM
proposition
par la
commission
(fiasco)

Revision
Framework
Regulation
(EU1935/2004)

2019

Study Ecorys

Impact
Assessment

2020

Re-issu of the
German
Printing inks
Ordinance

RE-ISSUE OF THE GERMAN PRINTING INK ORDINANCE

- Not much difference with the first version
 - Only German version available
 - NO TRIS-notification
-
- Remarks are based on the previous version
-
- After some weeks/months things are surprisingly calm

Proportionality

- Too broad → Interpretation problems

Legislation

- Conflict with other legislations (cfr. Swiss ordinance, BE&NL lacquers)
- Different legislation in different member states

Trade Barriers

- Mutual Recognition → No Clause in the Ordinance
- Free circulation of goods
- Production Cost

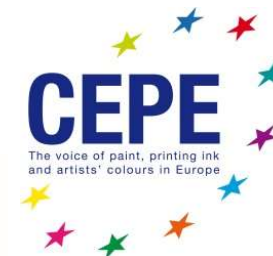
Technical Feasibility

- Complexity of the Value Chain → Where does my product end up (p.e. Varnishes)
- **Key Raw Materials missing from the list** → severe consequences for the printing of FCMs
- Slows innovation

The PIJITF represents the value chain from the manufacturers of ink raw materials to food business operators.



A sector of CEPE aisbl



5. REACH: database complexe producten (SCIP)

SCIP DB – SUBSTANCES OF CONCERN IN PRODUCTS

Waste Framework Directive – article 9

- Member States shall take measures to prevent waste generation. Those measure shall, at least, include:
 - (i): promote the reduction of the content of hazardous substances in materials and products, [...], and ensure that **any supplier of an article** as defined in point 33 of Article 3 of Regulation (EC) No 1907/2006 [...] **provides the information pursuant to Article 33(1) of that Regulation to the European Chemicals Agency as from 5 January 2021.**
- The **European Chemicals Agency shall establish a database** for the data to be submitted to it pursuant to point (i) of paragraph 1 by 5 January 2020 and maintain it. The European Chemicals Agency shall provide **access to that database to waste treatment operators**. It shall also provide access to that database to consumers upon request.

→ KB 23/03/2020
(publ 02/06/2020)

4.1.1 Communication of information on substances in articles

Any supplier of an article containing a substance has to provide to the recipient of the article (Article 33(1)) or to a consumer (Article 33(2)) relevant safety information, available to him, when both the following conditions are met:

- The substance is included in the Candidate List (see section 2), and
- The substance is present in articles produced and/or imported above a concentration of 0.1% (w/w),



Mixture

<0,1w%



>0,1w%



Product

<0,1w%



>0,1w%



Product

<0,1w%



>0,1w%



GOAL SCIP

Decrease the generation of waste containing hazardous substances

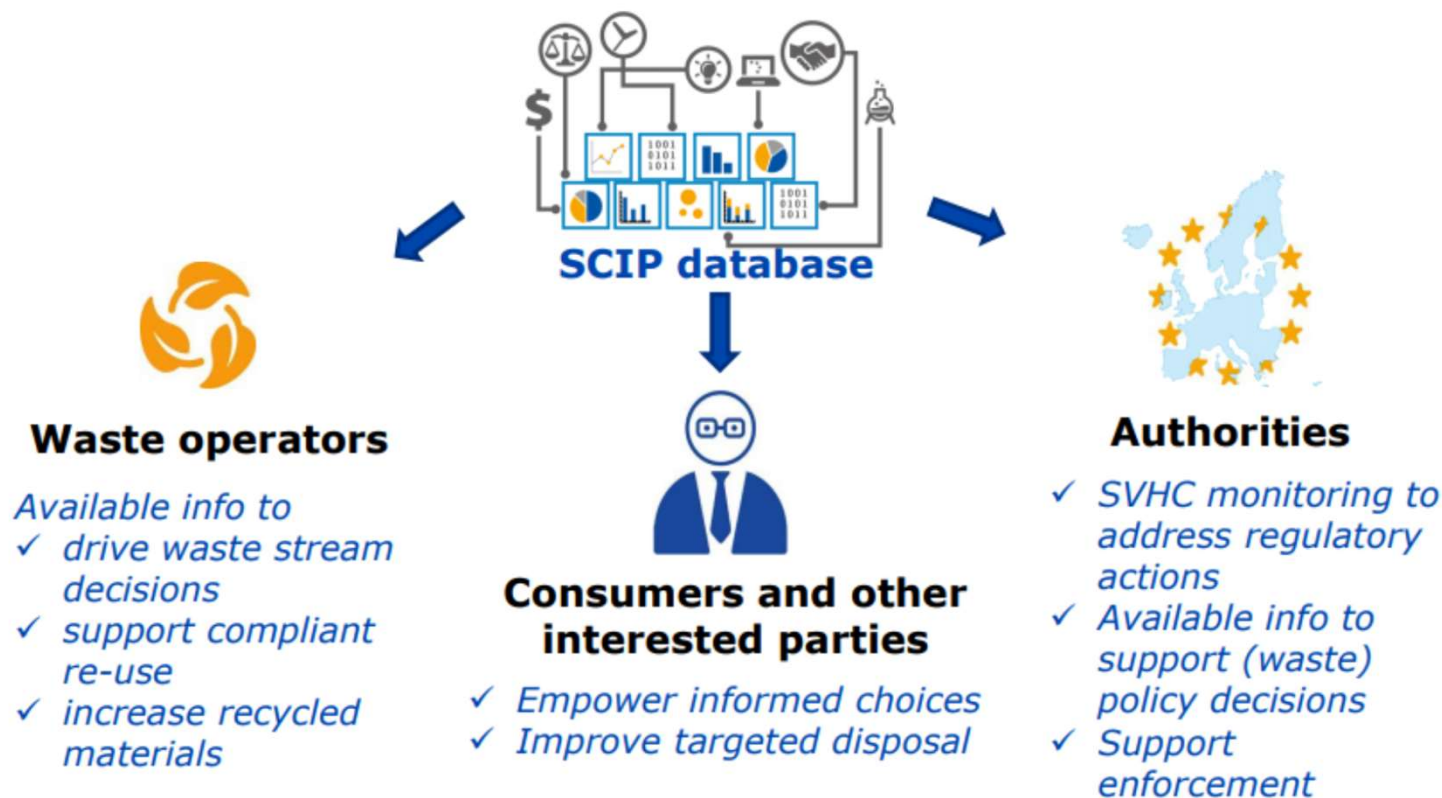
Monitoring by use of substances of concern in articles + actions

Contributing to a more circular economy: information for improvement of waste treatment operations

Push for substitution of substances of concern in articles and the development of safer alternatives

05 January 2021

Dissemination



No confidential business information disclosed

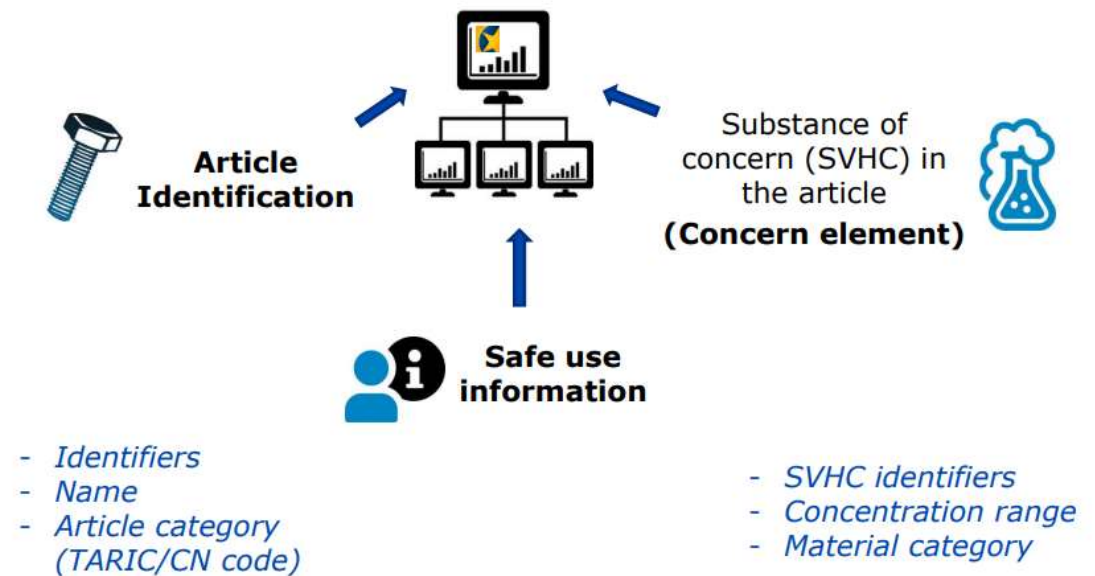
WHAT INFORMATION?

- Company Data
- Data about the article
- Data about the SVHC
- Other information on the safe use of the article

➔ Must lead to the unequivocally identification of the article or product

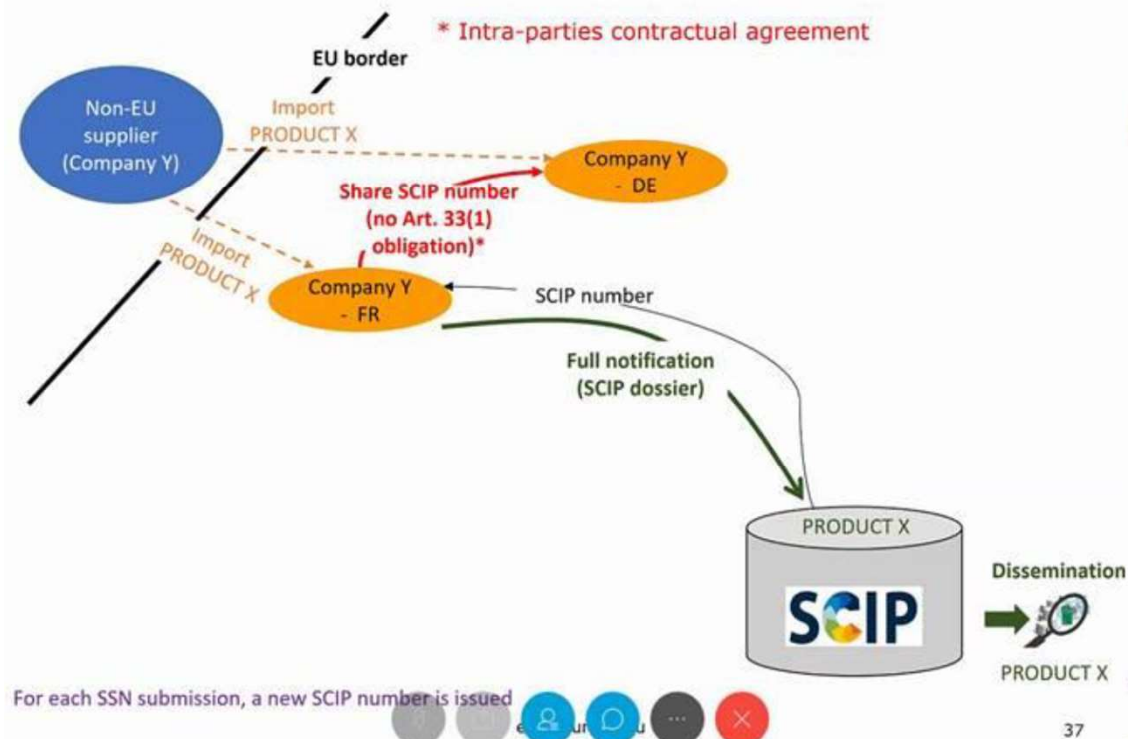


SCIP – Info requirements



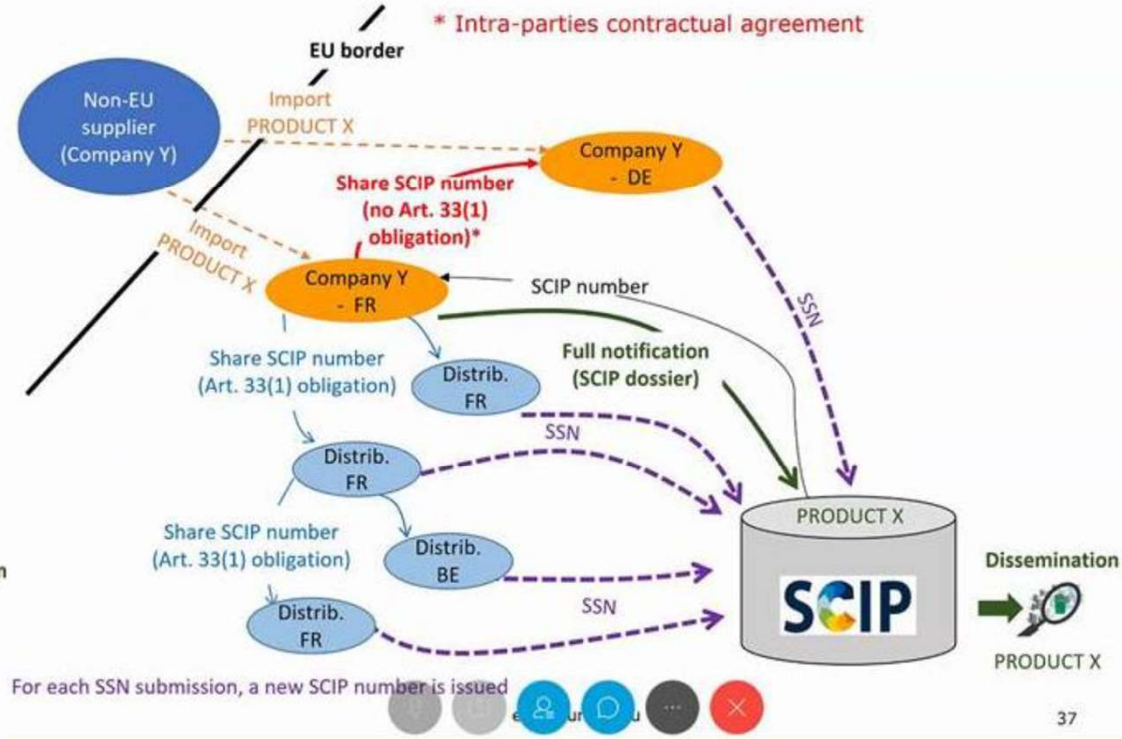
SIMPLYFIED SCIP NOTIFICATION

ECHA Extension of the SSN (2)



37

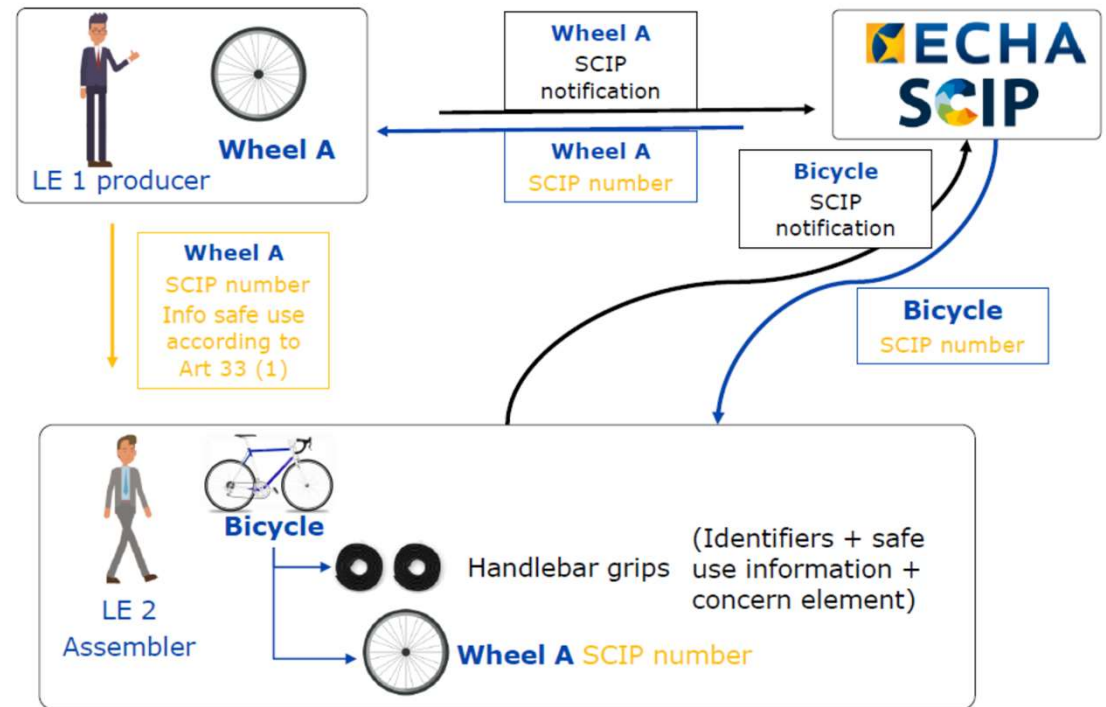
ECHA Extension of the SSN (2)



37

REFERENCING

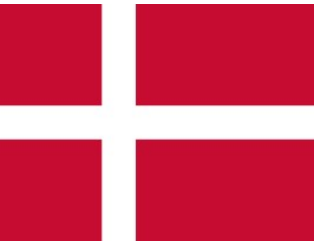
- No change in shape or composition
- Article will be incorporated in a complex product
- Link between downstream user and upstream notification
- Works via the use of **the SCIP-number of the supplier** received after notification



echa.europa.eu

AOB

- a) PFAS
- b) Ceramic and Vitreous materials



PFAS

Danish BAN

PFAS

20 ppm

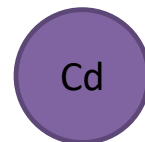
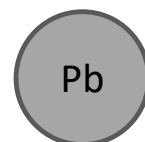
No analytical
tool

Total
Fluorine



- [Directive 84/500/EEC](#)

CERAMIC AND VITREOUS MATERIALS



Release of metals from these materials is of concern



Policy Options

Impact Assessment

Commission Consultation Activity

Inception Impact Assessment - 2017

Preliminary discussions with stakeholders - 2017

JRC Baseline report 2016

CERAMIC AND VITREOUS MATERIALS

COMMISSION CONSULTATION ACTIVITY

Policy option A: Limits

- Lower Limits for Pb and Cd
- New Limits for Al, As, Ba, Co, Cr, Ni

Policy option B: Process options → Less testing + meeting of the new limits

- Support in transition to more modern equipment
- Increasing Quality Control Standards
- Better information flow + traceability on composition of Raw Materials

Policy option C: Exemption

- Exempting the artisanal and traditional products

THANK YOU FOR YOUR ATTENTION

Next meeting

- 09/12
- inDUfed?

Willem van Veen

Willem.van.veen@indufed.be

Emilie Butaye

emilie.butaye@indufed.be

Marc Bailli

marc.bailli@indufed.be

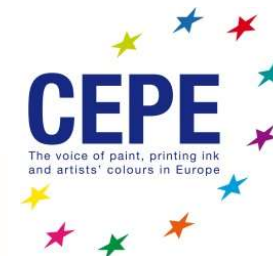
Extra Slides

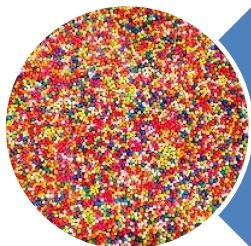
[BACK](#)

The PIJITF represents the value chain from the manufacturers of ink raw materials to food business operators.



A sector of CEPE aisbl





Inks manufacturers need a large number of chemical substances to formulate printing inks



To have EFSA evaluating all of them would take too much time



The main proposal is to have the possibility for industry to carried out industry risk assessment of these substances, according to recognized scientific approach



Then the industry risk assessment needs to be adequately communicated to the next in the chain, to enable him to carried out the compliance work at his level

STORAGE OF SUBSTANCES (IAS + NIAS): TWO REPOSITORIES INDUSTRIAL AND OFFICIAL (CORE)

PART 2

**There shall be a list of chemical substances self-assessed by ink industry, with estimated tolerable daily intake
Shall be available with special rights**

PART 1

**The Core repository shall be a list of chemical substances officially evaluated by authorities, with specific migration limits
Shall be publicly available**

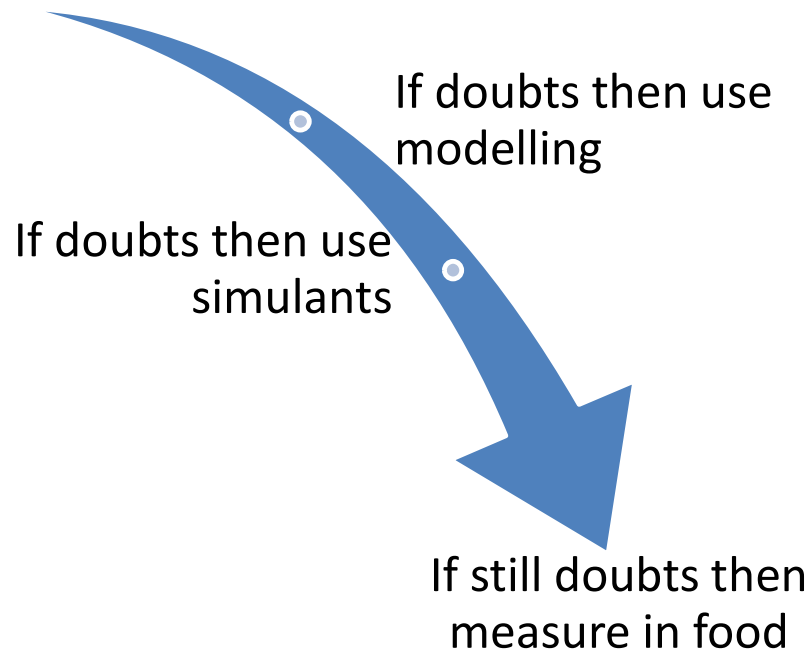
A process of transfer from industrial to official shall be in place

All substances listed should be

- (self) assessed
- safe for use

Demonstrating Compliance – Compliance Testing

First WCC



- General principles could be included in Regulation (Annex)
- Specific details may need to be in Guidance to meet timeline
- Audits: The **processes** used by industry should be audited by accredited third parties
- Checklists: use checklists modelled on those currently used by the food industries to qualify their suppliers.

SUMMARY OF THE PROPOSAL

Capable of swift implementation

Compatible with the existing Framework Regulation

Utilises the existing assessments of substances done by EFSA and other official bodies

Reflects the best known current practices for ensuring the safety of printed FCM

Ensures that limits for the migration of substances are based on toxicological evaluation rather than default limits

Allows for the transparency of industry's assessment and compliance processes

Allows for regular controls by competent authorities