

Recent developments for risk assessment of substances to be used in non-harmonised FCM



List of materials and articles



Harmonized regulation

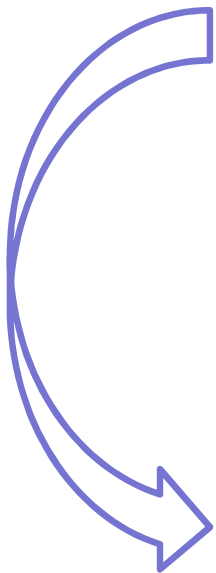
- ☐ Active and intelligent materials and articles
- ☐ Ceramics
- ☐ Plastics
- ☐ Regenerated cellulose

Non-harmonized regulation

- | | |
|--|---|
| <input type="checkbox"/> Printing inks | <input type="checkbox"/> Adhesives |
| <input type="checkbox"/> Cork | <input type="checkbox"/> Silicones |
| <input type="checkbox"/> Rubbers | <input type="checkbox"/> Textiles |
| <input type="checkbox"/> Glass | <input type="checkbox"/> Varnishes and coatings |
| <input type="checkbox"/> Ion-exchange resins | <input type="checkbox"/> Waxes |
| <input type="checkbox"/> Metals and alloys | <input type="checkbox"/> Wood |
| <input type="checkbox"/> Paper and board | |

Risks from FCM

Risk associated to FCM depends on:

- 
- Nature of substances
 - Migration of substances
 - Exposure
- Intentional added substances (IAS)
 - Non intentional added substances (NIAS)
(impurities, degradation products...)

Harmonized FCM

Overview of FCM regulation at EU level



Harmonized FCM

EU guidelines

Technical
dossier

Risk
assessment

IAS

NIAS

Plastic materials
regulation UE
10/2011

New
guidelines ?

Harmonized FCM



Migration	Toxicological test
< 0.05 mg / kg food	3 genotoxic tests
0.05 to 5 mg / kg food	As above + 90 days oral toxicity
5 to 60 mg / kg food	As above + Study on ADME Reproduction and development toxicity Long term toxicity / carcinogenicity

New EU guidelines ?



3 thresholds of human exposure:

1.5 µg / kg bw / day

30 µg / kg bw / day

80 µg / kg bw / day

Harmonized FCM / NIAS



□ : NIAS

Quotation from COMMISSION REGULATION (EU) No 10/2011 (plastic materials)

...reaction and degradation products are non intentionally present in the plastic material (NIAS). As far as they are relevant for the risk assessment, the main reaction and degradation products of the intended application of a substance should be considered and included in the restrictions of the substance.....

Any potential health risk in the final material or article arising from reaction and degradation products should be assessed by the manufacturer in accordance with internationally recognized scientific principles on risk assessment.

 **No specific risk assessment methodologies for NIAS**

Non harmonized FCM

In the absence of specific measures, regulation shall not prevent Member States from maintaining or adopting national provisions provided they comply with the rules of the Treaty.

Non harmonized FCM / IAS



French risk assessment: EU guidelines + **3 specifications**

**Pros and cons
for
environment**

**Substances
technological
functions**

Theoretical exposure level (TEL)

$$\text{TEL } (\mu\text{g/person/day}) = 0,8 \times (\text{MA} + \text{MB} + \text{MC})/3 + 0,2 \times \text{MD}$$

MA = aqueous
MB = alcoholic
MC = acid
MD = fat

Non harmonized FCM / IAS

TEL	Toxicological test
5 to 50 µg/ pers/day	3 genotoxic tests
50 to 5000 µg/ pers/day	As above + 90 days oral toxicity
> 5000 µg/ pers/day	As above + Study on ADME Reproduction and development toxicity Long term toxicity / carcinogenicity

French national regulations/recommendations



REGULATIONS

- ☐ Rubber
- ☐ Silicones
- ☐ Wood
- ☐ Aluminium and alloys
- ☐ Stainless steel
- ☐ Ionized materials
- ☐ Cleaning products

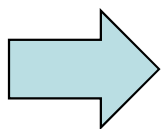
RECOMMENDATIONS

- ☐ Paper and board
- ☐ Common steel
- ☐ Various metals
- ☐ Printing inks
- ☐ Glass, ceramic, enamel
- ☐ Colorants
- ☐ Multilayer materials

ESCO WG: IAS from non-harmonized materials

	Number of substances from WG-ESCO inventory.	Number of assessed substances from WG- ESCO inventory (assessments > 1991)
Paper & board	600	145
Colorants	280	134
Rubber	800	21
Silicones	57	8
Printing ink	987	5
Wood & cork	54	2
Coating	650	10
Total	3428	325

- According to stakeholders: from 8000 to 10 000 used substances without assessment



Need for prioritisation based on:

- ***In silico* tools**
- **Technological interest of substances**
- **Comparison exposition vs TTC**

Non-harmonized FCM / NIAS



☐ : NIAS

➤ Ionizing radiation regulation

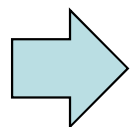
The technical dossier should contain the analytical results of potential degradation substances from monomers and additives.

➤ Rubber regulation

Degradation products should not present any risk for human health

FCM statements

- Many materials and objects are not submitted to harmonized regulation at the EU level.
- National regulation between MS can be different for a given substance.
- French regulation: some materials are not submitted to any risk management (paper and board, printing ink, glass...).



Need of guidelines for non-harmonized FCM



Recent developments:

Non-harmonized FCM note for guidance



Non harmonized FCM note for guidance

Objectives:

- ☐ To Identify the common criteria for non-harmonized FCM.
- ☐ To determine data needed for adequate assessment.
- ☐ To precise the information to be supplied from the petitioners.
- ☐ To establish guidelines for IAS and NIAS.

Non harmonized FCM



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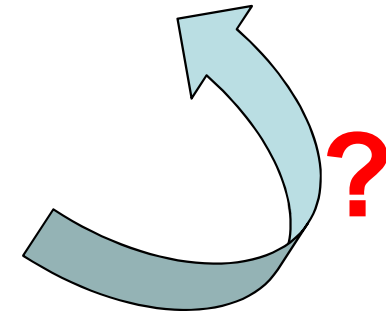
~~Theoretical exposure level (TEL)~~

~~$$\text{TLE } (\mu\text{g/person/day}) = 0,8 \times (\text{MA} + \text{MB} + \text{MC})/3 + 0,2 \times \text{MD}$$~~

~~M = food simulant~~

New EU guidelines
?

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1.5; 30; 80 $\mu\text{g} / \text{kg bw} / \text{day}$



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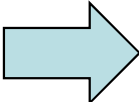
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Conclusions / perspectives

- ☐ Many materials and objects are not submitted to harmonized regulation at the EU level.
- ☐ IAS risk assessment in France is mainly based on the EU guidelines.
- ☐ NIAS risk assessment needs to be well defined.
 -  Decision trees for administrative admissibility of the technical dossier required for substances assessment



THANK YOU