

---

# Revision of rubber French decree : methodology

EFSA FCM Network  
November 2019

Gilles RIVIERE  
ANSES

# French decree on rubber FCM (9th november 1994)

Positive list

Povisional list  
(31/12/1998)

Substances cannot  
be used anymore

Substances are essential  
for industrials

Need for regulation revision

# French decree on rubber FCM (9th november 1994)

**Need for regulation revision**

- Impossible to assess all substances
- Plastic and rubber are close in term of composition

**Substances classification**

## Unauthorized substances

**Criteria 1** : substances listed in annex 14 of Reach or absent from french decree and 10/2011 without tox data

**Criteria 2** : substances without tox data but with identical tech. Role than evaluated substances

## Temporary authorized substances

**Criteria 3** : substances present in French decree and absent from 10/2011 without tox data and not meeting criteria 2.

**Criteria 4** : substances with generic term and insufficient characterisation

**Criteria 5** : substances with too old evaluation

restriction n1 : If genotoxicity not evaluated then  $\text{expo} < 0,0025 \mu\text{g}/\text{kgbw}/\text{d}$

restriction n2 : If substances with  $\neq$  restrictions : select the most conservative

## Authorized substances

**Criteria 6** : substances in both 10/2011 and french decree

restriction n2 : If substances with  $\neq$  restriction : select the most conservative

restriction n3 : If no SML : generic SML

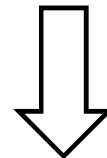
**Unauthorized  
substances**

**These substances are  
excluded from the decree**

**8 substances**

**Temporary  
authorized  
substances**

**New risk assesment  
ASAP**

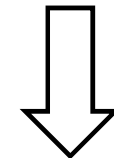


**Povisional list**

**56 substances**

**Authorized  
substances**

**These substances are  
maintained in the decree**



**Positive list**

**125 substances**

# Unauthorized substances

**Synthetic polymer resin**  
(resin)  
(criteria 1)

**Synthetic polymer**  
(processing agent)  
(criteria 1)

**Phenol isobutylated**  
antioxidant  
(criteria 2)

**Octylated diphenylamine**  
(antioxidant)  
(criteria 2)

**Phenol styrenated**  
(antioxidant)  
(criteria 2)

**2-Propanone, reaction products with diphenylamine**  
(antioxidant)  
(criteria 2)

**N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine**  
(antioxidant)  
(criteria 2)

**dinonylphenyl bis(nonylphenyl) phosphite**  
(antioxidant)  
(criteria 2)