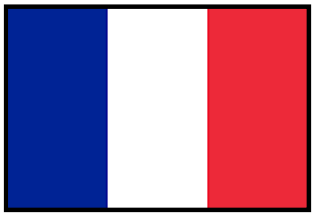
Example of Non Intentional Added Substances (NIAS) evaluation

Assessment of multilayer plastic films treated by ionizing radiations

French national regulations / recommandations



REGULATIONS

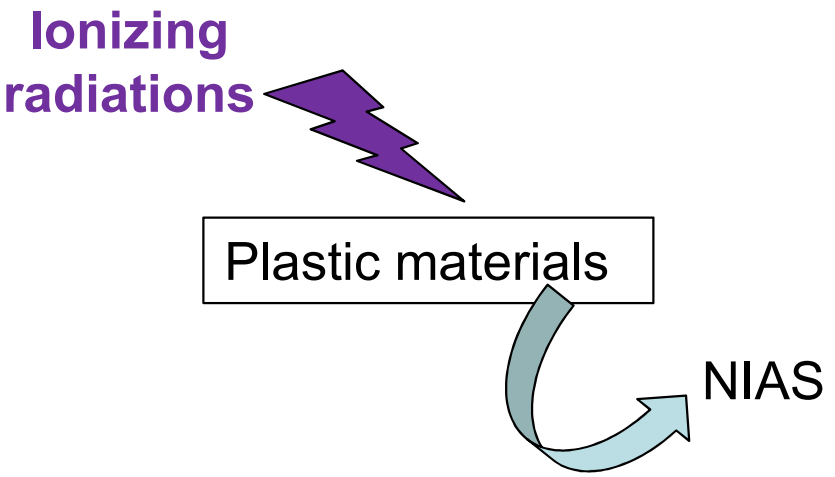
- ❑ Rubber
- ❑ Silicones
- ❑ Wood
- ❑ Aluminium and alloys
- ❑ Stainless steal
- ❑ **Ionized materials**
- ❑ Cleaning products

RECOMMANDATIONS

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

French national regulations / recommandations

Results from concerns based on NIAS formation in plastic after ionizing radiations



Requirements for materials exposed to ionizing radiations (> 10 kGy)

- Technological justification of the procedure.
- Material composition and compliance.
- Experimental conditions (type of radiations, dose rate…).
- Migration before / after radiations.
- Results concerning NIAS screening.

NIAS formation in plastic after ionizing radiations

❑ Parameters / conditions of the process:

- 3 different plastic films (PE) with thin layers (few µm) were treated.
- Each film is a multilayer material.
- Dose of radiations vary from 30 to 50 kGy.

❑ Effects of ionizing radiations on the plastic films:

- Increase polymerisation in the same layer and between different layers.
- Increase mechanical structure of the material.
- Increase thermal resistance.
- Reduction of layers thickness to obtain the same efficiency.

NIAS formation in plastic after ionizing radiations

NIAS risk assessment in 4 steps :

1. Identification / specific migration of IAS
2. Determination of the overall migration before / after radiations
3. Identification / quantification of NIAS before / after radiations
4. Determination of specific migration of NIAS

NIAS formation in plastic after ionizing radiations

❑ 1st step: Identification / specific migration of IAS

- Identification of IAS (monomers and additives) in each multilayer film
  ⇨ Declaration of compliance
- Residual content of each substances was determined
- Specific migration was calculated for each susbtances (worst case)

$$M = Q \times S \times T \times \rho$$

Q = quantity in the final product
S = surface in contact
T = thickness of the material
P = density

NIAS formation in plastic after ionizing radiations

❑ 2nd step : Determination of the overall migration (before / after radiations)

- Based on the COMMISSION REGULATION (EU) No 10/2011
- Simulants: Acetic acid, Ethanol 10%, ~~olive oil~~ → Isooctane

⇨ Overall migration < 10 mg/dm²

NIAS formation in plastic after ionizing radiations

❑ 3rd step : Identification / quantification of NIAS

- Predicted NIAS: targeted analysis of the known substances.

- Unpredicted NIAS: screening analysis of substances with wide range of properties

NIAS formation in plastic after ionizing radiations

❑ 3rd step : Identification / quantification of NIAS

- Predicted NIAS: targeted analysis of the known substance.
- Unpredicted NIAS: screening analysis of substances with wide range of properties
  - → GC/MS

NIAS formation in plastic after ionizing radiations

❑ 3rd step : Identification / quantification of NIAS

- **Analytical optimisation / performances**

Objectives = 0,5 µg / kg food = 0,5 µg / person / d (threshold for no genotox testing)

Full extraction with Dichloromethane

⇨ LOQ = 0,7 mg / kg polymer (determined with alcane as a model).

⇔ 0,84 µg / kg food

NIAS formation in plastic after ionizing radiations

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↳ Objective not met (0,5 µg / kg food)

NIAS formation in plastic after ionizing radiations

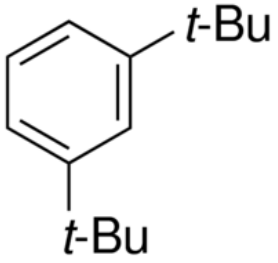
❑ 3rd step : Identification / quantification of NIAS

➢ **The identified substances were compared before and after ionizing radiations**

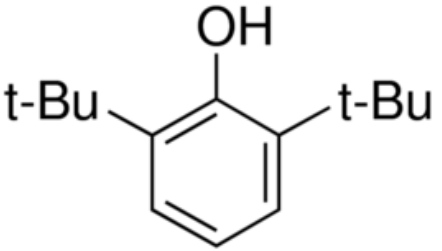
- Main substances: aliphatic alcan, oxydation products and additives (antioxydants)
- After radiations: antioxydants ↘ and their oxidized states ↗

⇨ 2 NIAS identified:

1,3-di-tert-butylbenzene



2,6-di-tert-butylphenol



NIAS formation in plastic after ionizing radiations

❑ 4th step : Migration of NIAS

- Choice of simulants according to the packaging use (all types of food):
  - Isooctane and ethanol 95% (LOQ = 6 µg/kg food)
  - Acetic acid 3% and ethanol 10% (LOQ = 30 µg/kg food)

- Contact conditions:
  - 2 days / 20° C for isooctane
  - 10 days / 60° C for ethanol 10%, ethanol 95% and acetic acid.

NIAS formation in plastic after ionizing radiations

Simulants	Specific migrations (mg/kg food)	
	1,3 di-tert-butylbenzene	2,6 di-tert-butylphenol
Acetic acid	< 0,03	< 0,03
Ethanol 10%	< 0,03	< 0,03
Isooctane	0,012	0,012
Ethanol 95%	0,018	0,018
TEL (mg/person/d)	0,027	0,027

Exposure > 0,5 µg / person / day ⇨ 2 genotoxic assays.

NIAS identification:

Analytical screening (GC-MS)
+
Knowledge of degradation pathways

Statements

- **The lack of scientific knowledge increases NIAS levels of concern**

- **Challenges for NIAS assessment ?**
  - We dont know what to look for ?
  - How to analyse it ? Which analytical method? (NMR or IR efficient to scan but poor LOD)
  - NIAS at industrial level ? At consumer level ?

Conclusion / perspectives

- To acquire database for identification / quantitation of NIAS
- To take into account of their migration into the food
- To establish guidelines for their risk assessment
- To establish good manufacturing practices
- To enhance awareness among manufacturers, risk assessors, risk managers and users concerning NIAS from food contact materials.

THANK YOU