

The Exposure Matrix Project

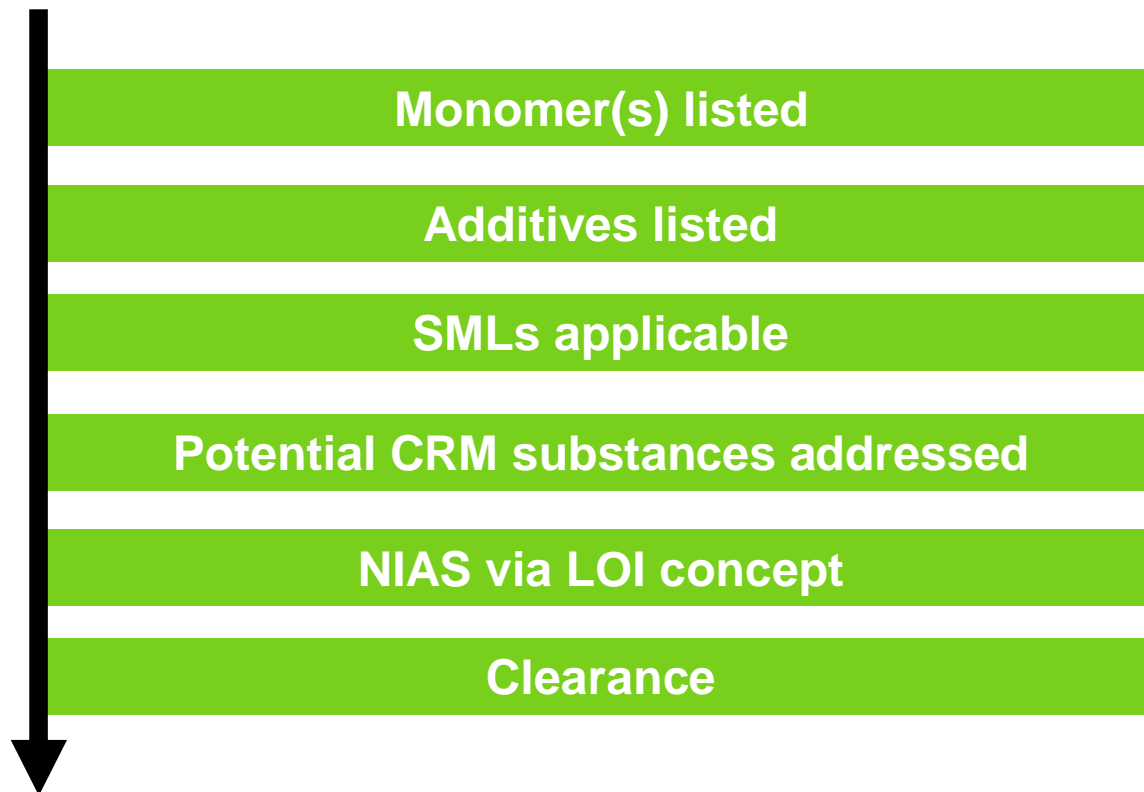
Assessment of NIAS Based on Exposure Data
(Data from Germany only)

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PlasticsEurope
Association of Plastics Manufacturers

Assessment/Evaluation Cascade



Obligation for Producers of Food Contact Materials

- “Declaration of Compliance”- Art. 16 of Reg. 1935/2004/EC, Art. 9 & Annex VII of Dir. 19/2007/EC.
- “Record keeping”- Art. 16 of Reg. 1935/2004/EC- Art. 9.3 of Dir. 19/2007/EC:

*Appropriate documentation to demonstrate that the materials and articles as well as the substances intended for the manufacturing of those materials and articles **comply with the requirements** of this Directive shall be **made available by the business operator to the national competent authorities on request.** That documentation shall contain the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance.’*

4. Amendment of 2002/72/EC

31.3.2007

EN

Official Journal of the European Union

L 91/17

DIRECTIVES

COMMISSION DIRECTIVE 2007/19/EC

of 30 March 2007

amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs

(Text with EEA relevance)

- (13) Compliance with Article 3 of Regulation (EC) No 1935/2004 for substances non-listed in Annexes II and III of Directive 2002/72/EC such as impurities or reaction products referred to in point 3 of Annex II and point 3 of Annex III to Directive 2002/72/EC should be assessed by the relevant business operator in accordance with internationally recognised scientific principles.

The Matrix Project:

Objective:

Developing a tool for risk assessment of NIAS in (plastic) food contact materials and articles, based on exposure.

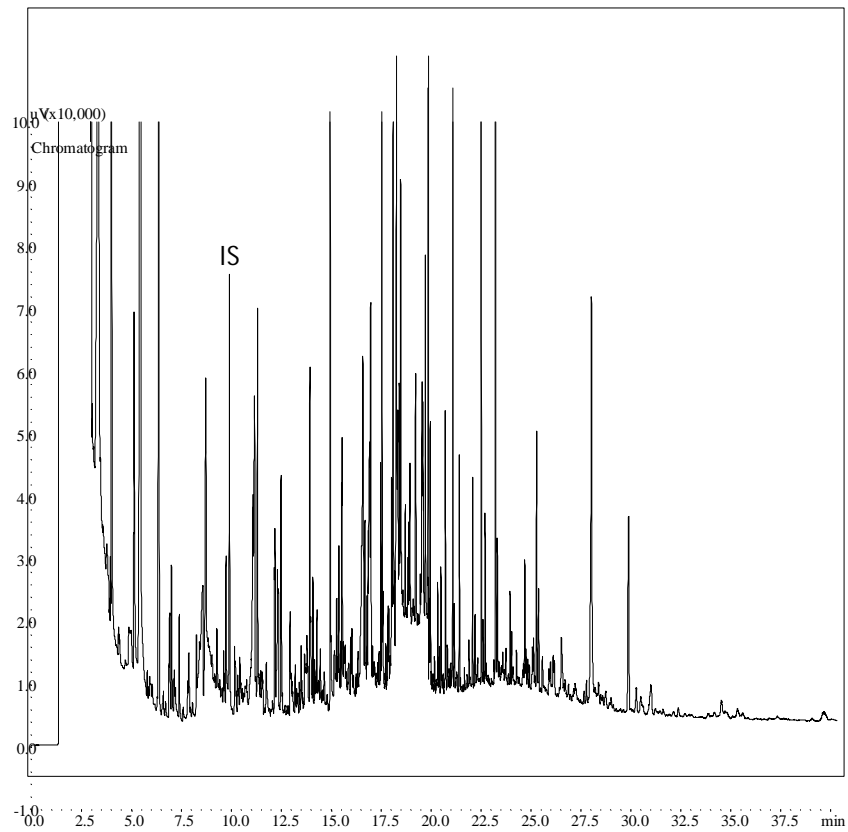
Project Sponsors

- Ø **Plastics Europe**
- Ø **EuPC**
- Ø **FPE**
- Ø **Cefic-FCA**

Costs: 600.000 Euros

Forest of Peaks

The ***Forest of Peaks*** includes both known and unknown substances.



- ∅ **Can we predict all the NIAS: NO!**
Most sophisticated attempts (CSL, TNO) could predict roughly half of them.
- ∅ **Therefore the most comprehensive way is Migrations + concentration + gas chromatography → forest of peaks**

BUT

- Ø Identification of each peak followed by assessment is recognized as impracticable
- Ø The envisaged solution: Fix a level of migration above which every migrant should be known and assessed but under which the corresponding exposure is admitted trivial enough to avoid further assessment
- Ø This level, we call level of interest LOI, linked to each packaging material, will be a function of the exposure of consumers to this material

Defining the LOI

∅ If one knows the surface of a given material to which one consumer is exposed through his daily diet, it is clear that his exposure to any substance migrating from this surface is:

$$\text{Exposure} = \text{Migration} \times \text{Surface}$$

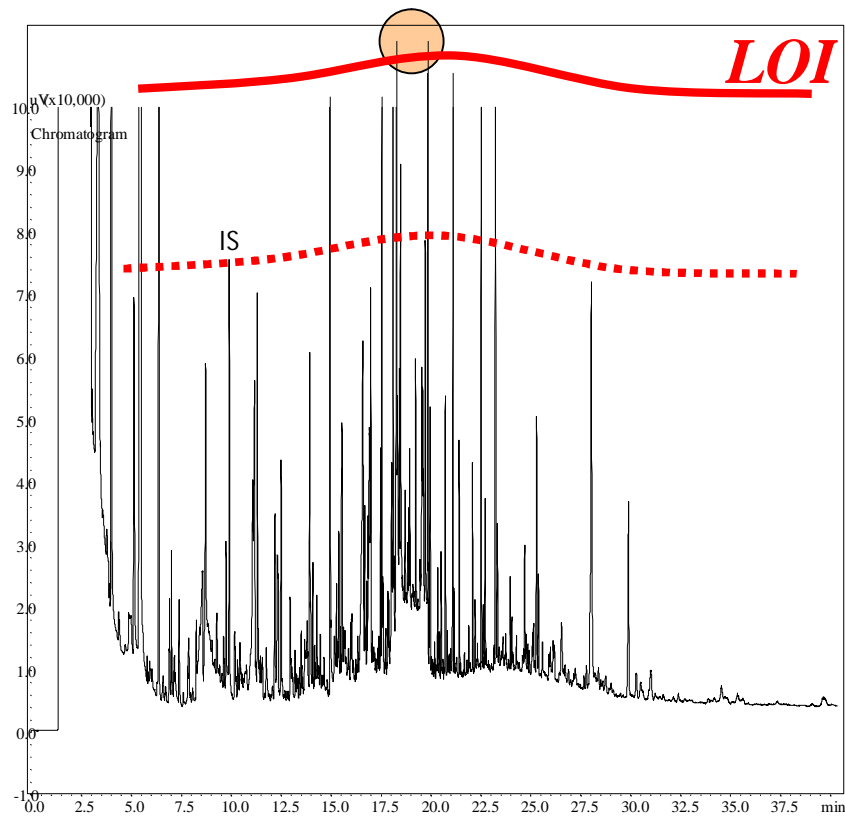
Exposure [$\mu\text{g}/\text{person}/\text{day}$] = Migration [$\mu\text{g}/\text{dm}^2$] x S [$\text{dm}^2/\text{person}/\text{day}$]
If one fixes a tolerable level of exposure TEL for NIAS

$$\frac{\text{TEL (NIAS)}}{S} = \frac{\text{max. migration}}{\text{tolerable for this material and this consumer}} = \text{LOI}$$

∅ This needs of course to be estimated for the whole population.

The surfaces to which the consumers are exposed are obtained by combining through probabilistic modeling the weights of each food ingested by a population with the surfaces of packaging materials in contact with the unit weight of these respective foods

The Level Of Interest (LOI)



**If the *migration* < LOI
risk is considered
negligible**

Data Input & Probabilistic Approach to Obtain the LOIs

Food intake studies

- ∅ National food intake studies provide daily intakes (g) per food item.

Food packaging data

- ∅ Packaging databases deliver packaging surfaces per food item and packaging material (e.g. surface in m² of PET used for packaging of non-alcoholic beverages),

Probabilistic modelling

- ∅ Run a probabilistic combination of data by the Monte-Carlo method which will deliver for each couple food/packaging the areas of material to which the consumers are exposed through their daily diet.

For the Matrix based on data from Germany, we fixed 51 food classes and 54 packaging materials.

Information collected to get the LOIs: an extract from the GVM data base – packaging surfaces

Packaging consumption with direct food contact in Germany - relevant parameter: packaging surface 2003, packaging < = 6,5 kg nominal contents by material types differentiated after main components and side components	packaging surface 1.000 m ²	aluminium foil	other packaging	non-plastic/plastic, plastic >5% mass share without liquid carton	VLDPE or LLDPE and blends with LDPE	LDPE	acid-ester copolymers (EVA, EMA, EAA, EBA)	HDPE	other PE based blends	multilayer PE	OPP	metallized OPP	other PP	PA	PC	PET (OPET and APET)
1. alcoholic beverages including wines, beers and liquors	16.407	0	0	0	0	0	0	0	0	0	0	0	88	0	0	79
main component	16.319	0	0	0	0	0	0	0	0	0	0	0	0	0	0	79
closures or other side components	89	0	0	0	0	0	0	0	0	0	0	0	88	0	0	0
2. non-alcoholic non-dairy beverages including waters, juices and soft drinks	966.830	0	0	2.804	0	274	0	4.123	0	1.003	0	0	2.795	0	0	634.881
main component	957.107	0	0	0	0	274	0	0	0	1.003	0	0	0	0	0	634.881
closures or other side components	9.724	0	0	2.804	0	0	0	4.123	0	0	0	0	2.795	0	0	0
3. concentrates of juices and soft drinks; syrups for dilution	793	0	0	0	0	0	0	4	0	0	0	0	22	0	0	729
main component	769	0	0	0	0	0	0	3	0	0	0	0	0	0	0	729
closures or other side components	24	0	0	0	0	0	0	1	0	0	0	0	22	0	0	0
4. liquid coffee or tea preparations	158	0	0	0	0	0	0	7	0	0	0	0	0	0	0	151
main component	151	0	0	0	0	0	0	0	0	0	0	0	0	0	0	151
closures or other side components	7	0	0	0	0	0	0	7	0	0	0	0	0	0	0	0
5. dry coffee, tea, cocoa powder, dry beverage powders	166.226	0	0	13.964	0	0	0	0	0	0	15.812	0	239	0	0	3.169

Information collected to get the LOIs: an extract from the BfR report – daily intakes (g)

Food items	All population			Consumers only			
	Mean	Median	95-th perc.	% of cons.	Mean	Median	95-th perc.
1. alcoholic beverages including wines, beers and liquors	220	82	917	93%	236	99	943
2. non-alcoholic non-dairy beverages including waters, juices and soft drinks	997	866	2186	100%	997	866	2186
3. concentrates of juices and soft drinks; syrups for dilution	0	0	0	0%	27	27	27
4. liquid coffee or tea preparations	-	-	-	-	-	-	-
5. dry coffee, tea, cocoa powder, dry beverage powders	17	14	40	97%	17	15	40
6. cereals, unprocessed or puffed; cereal flakes or bars; breakfast cereals and muesli	11	0	67	34%	31	17	105

N.B.: These mean values are higher than the median, therefore they cover more than 50% of the population and take into account the extreme consumers.

Probabilistic Approach to Generate the LOIs

Run a probabilistic combination of data by the Monte-Carlo method which will deliver for each couple food/packaging the areas of material to which the consumers are exposed through their daily diet.

Determination of Surfaces to which Consumers are Exposed

- **Dietary intake study for Germany obtained by BfR from Robert Koch Institute (study on German adults)**
- **Probabilistic model run by BfR supposing all consumed foods are packaged and 100% packaging loyalty (over-estimation)**
- **Results given for each “cell” or combination of one food group with one packaging material**
- **As the sum of all surfaces determined for one material in contact with all the foods for which it is used is the critical parameter, only figures corresponding to the mean values are usable**

Determination of Surfaces to which Consumers are Exposed

- **Results are overestimated because any NIAS is supposed to have the same potential migration for any type of food.**
- **In reality migration depends on the fraction of surfaces in contact with aqueous and fatty foods of the daily diet.**
- **We consider simulants as fixed in Directive 85/572/EEC. This leads to attribute the surfaces in each cell to one or several simulants.**
- **We make the sums of surfaces in contact with foods simulated by A or B or C, and the sums of surfaces in contact with D (some double counting occurs).**

Probabilistic Approach to Generate the LOIs: *PlasticsEurope* Surfaces (dm² per person per day)

Association of Plastics Manufacturers

Contact with packaging material, mean of all respondents in dm ² /d	simulant	aluminium foil	other packaging	non-plastic/plastic, plastic >5% mass share without liquid carton	VLDPE or LLDPE and blends with LDPE	LDPE	acid+ester copolymers (EVA, EMA, EAA, EBA)	HDPE	other PE based blends	multilayer PE	OPP	metallized OPP	other PP
45. vinegar, mustard and other condiments	A+B		0.018					0.001		0.004			0.002
46. yeast and raising agents	A+B		0.002	0.001							0.000		
47. prepared meals and meal components, frozen	0			0.000	0.000	0.000	0.000	0.000			0.000		
48. prepared meals and meal components, refrigerated	A+B+D/3			0.000				0.000					0.000
49. prepared meals and meal components, dehydrated	0 + D/5	0.001	0.000	0.059				0.015					0.001
50. prepared meals and meal components, preserves	A+B/D/3		0.000										
sum		0.102	5.408	1.061	0.002	2.427	0.023	0.409	1.680	0.651	0.930	0.057	2.912
sum simulant 0		0.002	0.929	0.394	0.001	2.396	0.021	0.295	1.661	0.536	0.648	0.000	2.097
sum simulant A-B-C		0.016	4.336	0.339	0.000	0.026	0.002	0.093	0.018	0.059	0.009	0.000	0.592
sum D		0.100	0.188	0.712	0.001	0.031	0.000	0.091	0.010	0.106	0.278	0.057	0.798

Probabilistic Approach to Generate the LOIs: **PlasticsEurope** Surfaces (dm² per person per day)

Association of Plastics Manufacturers

Description of approach:

Look separately at sum simulant A/B/C and sum simulant D

**LDPE: sum of columns LDPE+ other PE based blends + liquid cartons +
Half of all multi-substrate multi-layers with PE as food contact**

**LLDPE: Sum of VLDPE or LLDPE and blends with LDPE + Half of all multi-
substrate multi-layers with PE as food contact layer**

**We fixed TEL-NIAS at 10 µg/person/day; this is the exposure
corresponding to the 10 ppb migration when using the present
conventions, and which are tolerated for a non listed additive behind a
functional barrier**

Probabilistic Approach to Generate the LOIs: Surfaces (dm² per person per day) for Polymers

Material	aqueous dm ² /p/day	fat dm ² /p/day	Material	aqueous dm ² /p/day	fat dm ² /p/day
LDPE	2,4	2	PA	0	0
LLDPE	1,25	1,25	PC	0	0,001
HDPE	0.409*	0.409*	PS	0,355	0,498
Ethylene copolym.	0.023*	0.023*	EPS	0,315	0,315
PP (incl. OPP)	0,708	2,042	PET	2,496	0,108
PVC + PVDC	0.182*	0.182*	Ionomers	0,134	0,128

The LOIs values for plastic producers

Material	aqueous µg/dm ²	fat µg/dm ²	Material	aqueous µg/dm ²	fat µg/dm ²
LDPE	4	5	PA	100	100
LLDPE	8	8	PC	100	100
HDPE	25	25	PS	28	20
Ethylene copolym.	100	100	EPS	30	30
PP (incl. OPP)	14	5	PET	4	10
PVC + PVDC	55*	55*	Ionomers	75	75

N.B.:

For the materials to which the exposure is low to negligible ($S < 0.1 \Rightarrow LOI > 100$), it is suggested to apply a conventional LOI of 100

* Figure derived from total surface in contact with foods due to high values corresponding to simulant 0

Run migrations in aqueous and fatty simulant

Run the migrations under appropriate conditions following the Directive 82/711/EEC as amended or use modeling based on residuals

Obtain „forest of peaks“

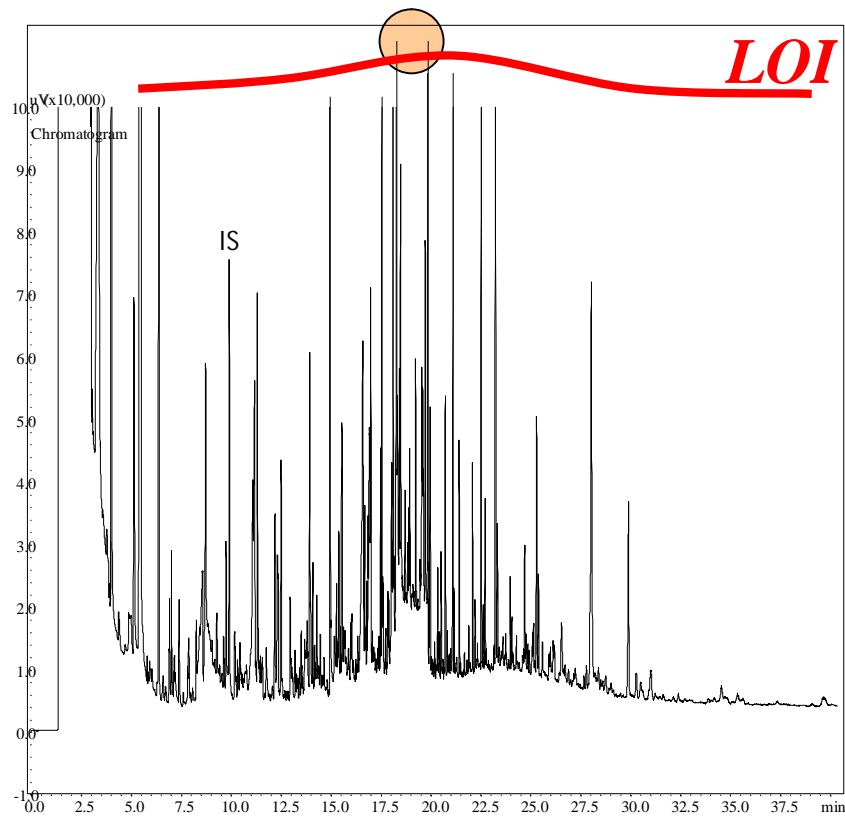
Obtain the “forest of peaks” by e.g. gas chromatography using FID and an internal standard or any other acceptable analytical method - Standard procedures will be developed as guidelines

Trace the LOI

Trace on each “chromatogram” the line corresponding to the LOI

Each company should feel free to use more severe/lower LOIs if desired or less severe/higher LOIs if they are convinced they can justify it

The Level Of Interest (LOI)



**If the *migration* < LOI
risk is considered
negligible**

Practical Use of LOI Values for Plastics Producers

- Any peak above the LOI should be further assessed.
- Peaks below the LOI do not need further assessment.

However this should not replace the standard control of substances with SMLs if any.

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- **Although aiming essentially at the assessment of NIAS the LOI approach is offering also an important information for justification of compliance with the article 3 for the Non Listed Substances (NLS) in EU Directives such as PPAs, solvents, catalysts, ...**
 - **Indeed, we have the indication that for all the NLS below LOI the exposure of the consumers are in the worst cases in the range of 10 µg/p/day and very frequently well below this value which represents a better than ever control and justification of their use**

- **Calculation of LOI includes several approximations that have been always set at the “worst case”, resulting into a systematic *overestimation* of LOI.**
 - **The whole quantity of food in a package is considered to be in contact with both main and side material (e.g. one liter of soft drink in contact with the bottle surface and the same liter in contact with the cap)**
 - **The total quantity of food composing the daily diet is assumed in contact with packaging materials**
 - **100% packaging loyalty figures is assumed.**
 - **Each plastic brand is supposed to take 100% of the market.**

- **For the most widely used plastics (polyethylenes; polypropylenes), the summation of “exposure surfaces” of all materials in which they are present would be a serious overestimation. It would consider the contribution of any layer of a multilayer equal to the same surface of the single material.**

We are then of the opinion that the summation of “exposure surfaces” should be limited to materials where the same plastic is the food contact layer

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- **Addressing all NIAS & NLS individually is practically impossible (costs, analytical capabilities);**
 - **EXPOSURE is the only possible approach, although this is a difficult and expensive exercise;**
 - **Contribution of all packaging chain stakeholders is of utmost importance;**
 - **EXPOSURE is the platform for future regulation**
 - **The exposure concept is being used in the 7th EU framework project FACET**

- **The use of LOIs even with the present values suffering of imperfections, does represent a spectacular progress in the assessment of NIAS and also in the evaluation of the exposure to substances Non Listed in EU Directives and potentially migrating from plastic materials to foodstuffs.**
- **The LOI values will be reviewed as soon as the similar data from the other European countries (E, F, I, UK) will be available.**
- **The Industry will gradually implement the assessment of NIAS by using the LOIs approach, with the values fixed on the basis of the 5 countries explored, as the presently “best practice” possible in this field.**



Plastics

The Material for the 21st Century