**Case study: Risk Assessment using the Matrix Webapp**

Dear participants,

We invite you to prepare an exercise on risk assessment using the Matrix Webapp which will be presented to you in detail during the Seminar.

Exercise:

You are an OPP packaging producer and you supply your customers in the next 5 countries (DE, FR, IT, SP, UK) (the 5 countries where data on food contact packaging have been gathered).

You know OPP packaging can be used for cheese, but not only.

You will have to risk assess this packaging.

How will you proceed, what will your strategy be?

Please try to go as far as possible.

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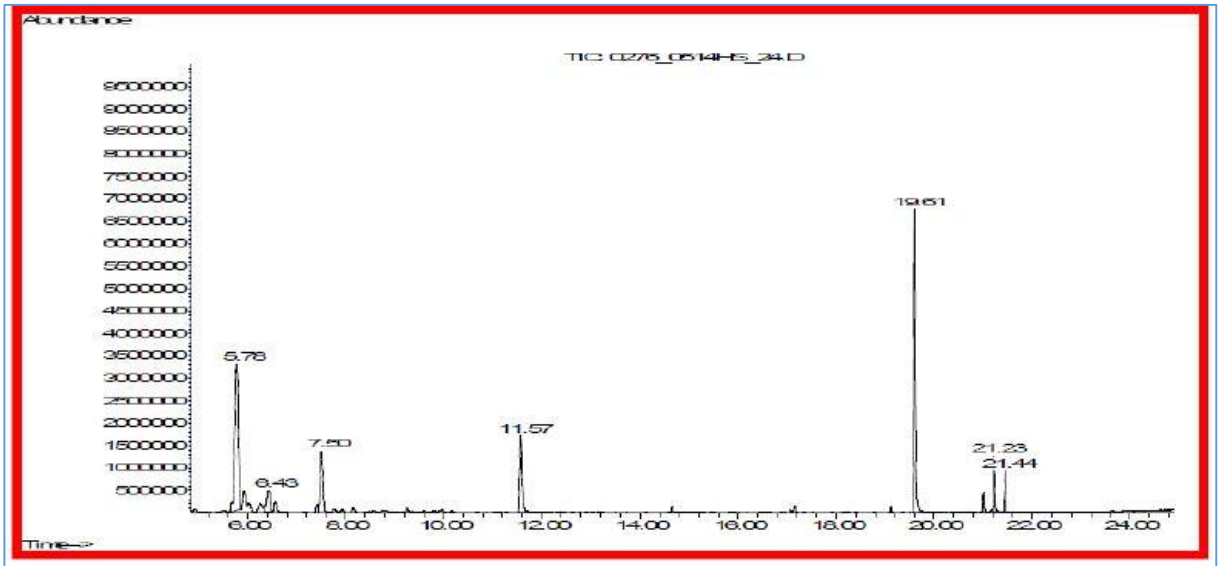
Mterial is to be found hereunder.

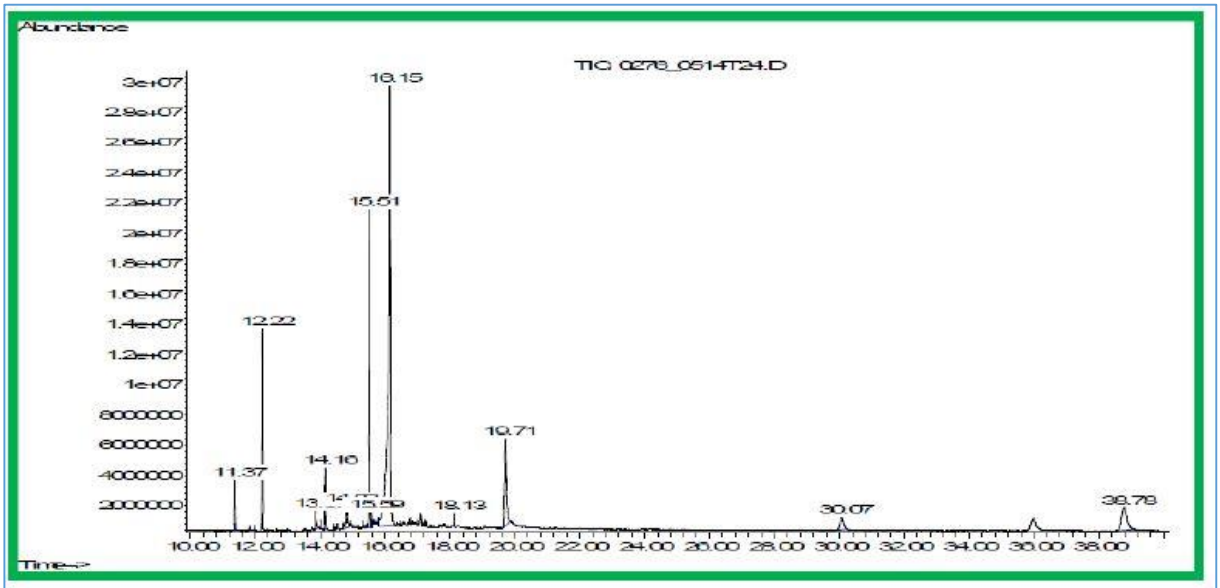
The sample has been analysed and a semi quantitative identification of the composition has been made: volatile and semi-volatile components have been identified. Chromatograms and tables of results are here.

FYI: the headspace : corresponds to the volatile compounds in the packaging;
The internal surface: corresponds to the migration from a packaging of a surface of 1dm². The test conditions are at room T° and for 10 min;
The total extract: determines the substances contained in the packaging. The test conditions are at higher T° and for a longer time.



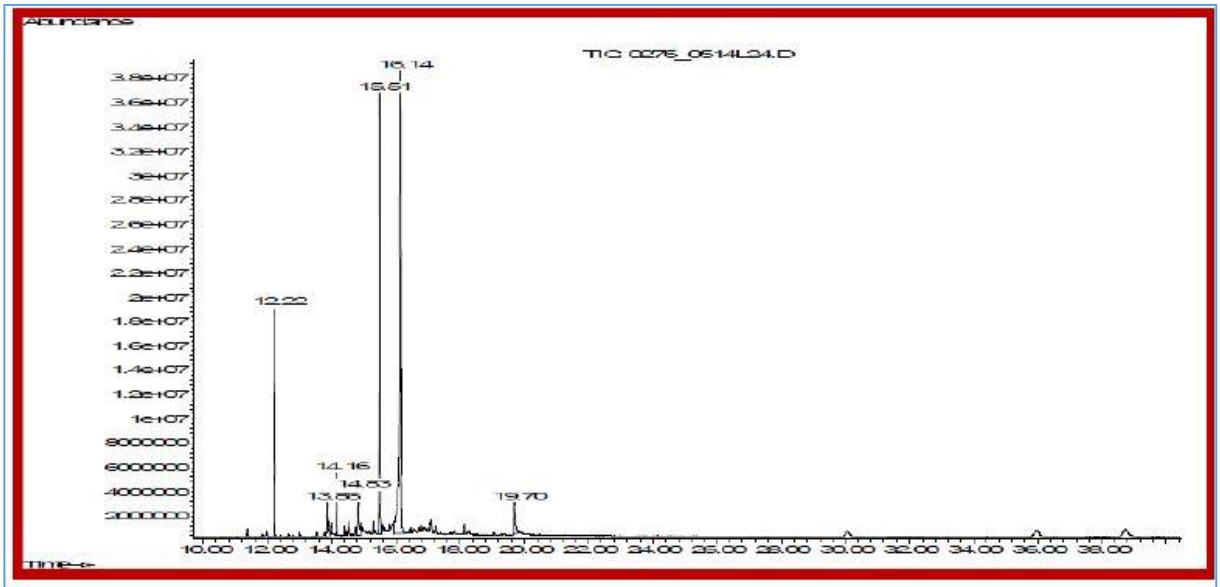

| TR | peak identification | qual | SEMIQUANTITATIVE EVALUATION µg/dm² |
|---|---|---|---|
| 5.78 | Cyclohexane | 91 | 8,3 |
| 7.50 | Cyclohexane, methyl | 94 | 2,9 |
| **11.57** | **Benzene, chloro (internal standard)** | **94** | **2,8** |
| 19.61 | Triacetin | 83 | 5,4 |
| 21.23 | 2,5-CYCLOHEXADIEN-1-ONE, 2,6-BIS(1,1-DIMETHYLETHYL)-4-METHYLENE- | 99 | 1,0 |
| 21.44 | BHT | 98 | 0,7 |

Fig 1: headspace




| TR | peak identification | qual | SEMIQUANTITATIVE EVALUATION µg/dm² |
|---|---|---|---|
| 11.37 | Triacetin | 83 | 24 |
| 12.22 | BHT | 98 | 78 |
| 13.87 | Cyclohexadecane | 91 | 11 |
| **14.16** | **Di propyl phthalate (internal standard)** | **94** | **25** |
| 14.83 | 7,9-Di-tert-butyl-1-oxaspiro(4,5) deca-6,9-diene-2,8-dione | 98 | 19 |
| 15.51 | Sebacic acid, dibutyl ester | 91 | 129 |
| 16.15 | Tributyl acetylcitrate | 91 | 805 |
| 18.13 | Analytical system contaminant | - | - |
| 19.71 | Erucamide | 87 | 83 |
| 30.07 | Antioxidant (m/z = 308,441,646)(Irgafos 168) | - | 30 |
| 38.78 | antioxidant (m/z = 316,647, 662) (Irgafos 168 mono-oxidated) | - | 83 |

Fig 2: total extract




| TR | peak identification | qual | SEMIQUANTITATIVE EVALUATION µg/dm² |
|---|---|---|---|
| 12.22 | BHT | 98 | 45 |
| 13.86 | Cyclohexadecane | 91 | 11 |
| **14.16** | **Di propyl phthalate (internal standard)** | **94** | **12,5** |
| 14.83 | 7,9-Di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione | 98 | 13 |
| 15.51 | Sebacic acid, dibutyl ester | 91 | 84 |
| 16.14 | Tributyl acetylcitrate | 91 | 145 |
| 19.70 | Erucamide | 87 | 15 |

Fig 3: internal surface

The Matrix calculation tool[1] (https://matrixcalculation.eu/*)* will help you to identify which substances need to be further risk assessed. The generic TEL (Tolerable Exposure Level) is 10 µg/dm², you can adapt it manually. Be aware that the Matrix calculation tool is still in beta (test) version.

Short explanation on the use of the Matrix calculation tool (see screenshots at the end of this document):

Step 1: Choose 1 or more countries (the 5 countries are DE, ES, FR, IT, UK)

Step 2: Choose the type of food simulant that is the closest to simulate the food (multi-choice possible).

Step 3: Choose the type of packaging that is the closest to represent the type of packaging to calculate the exposure (multi-choice possible).

Step 4: If migration data or data on residual contents are available, data can be filled in or imported via an excel file and will be taken into account for the exposure calculation.

Step 5: Calculation. The generic TEL (Tolerable Exposure Level) is 10 µg/person.day. TEL can be manually adapted (e.g. 1,5 µg/person.day for CMR substances). The results gives a LOI (Level Of Interest).

Substances present in a concentration above the LOI must be further risk assessed.

Substances present in a concentration below the LOI will lead to an exposure below the TEL and therefore will cause an acceptable risk.

You will need to further assess this substance: “7,9-di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione”. It means you will need a risk characterisation and a risk identification (exposure classification) to calculate the risk assessment of this substance. This substance is identified as a Cramer class III (Substances with chemical structures that permit no strong initial presumption of safety or may even suggest significant toxicity or have reactive functional groups). You might need this information as part of your risk assessment.

[1] *https://matrixcalculation.eu/ , the use is free, you only have to register. What is the Matrix tool ? Matrix is a tool that evaluates the exposure of consumers to migrants from plastic materials. More specifically it relies on exposure factors developed through statistical modelling based on the following information:*

1. *The food consumption habits of consumers in five countries (France, Germany, Italy, Spain and United Kingdom) based on official dietary survey;*
2. *Information on which type of packaging is in contact with different food type based on in depth market survey in the same 5 countries.*

*Those factors do not integrate the migration from packaging materials into food. This last element of exposure needs to come from your own testing on modelling.*

Please use next tables for the risk assessment.

*Table 1. Threshold Classes and corresponding threshold values*

| Classification | TTC(µg/person/d) | Reference |
|---|---|---|
| Cramer class I | 1800 | Munro 1996 [2]* |
| Cramer class II | 540 | Munro 1996 [2]* |
| Cramer class III | 90 | Munro 1996 [2]* |
| Organosphosphates and carbamates | 18 | Kroes 2004 [5]* |
| Carcinogens | 1.5 | TOR rule, Rulis [1]** |
| Genotoxic substances (without aflatoxin-like, azoxy- or N-nitroso compounds) | 0.15 | Kroes 2004[5]** |

Fig 4: Cramer class – TTC (Threshold of Toxicological Concern)

For more information concerning the use of TTC please read following articles:

1) B. Kroes et al. (2004); Structure-Based Thresholds of Toxicological Concern (TTC): Guidance for Application to Substances present at Low Levels in the Diet. *Food and Chemical Toxicology* 42: 65-83. doi:10.1016/j.fct.2003.08.006.
   Available at: http://www.ilsi.org/Europe/Pages/ViewItemDetails.aspx?WebID=84d7fa4a-0fd5-40cd-a49a-2da6fcdfd654&ListID=0348eb34-df85-49dd-9ade-77ed136643f1&ItemID=43
2) S. Koster, A.R. Boobis, R. Cubberley, H.M. Hollnagel, E. Richlinge, T. Wildemann, G. Würtzeng, C.L. Galli (2011); Application of the TTC Concept to Unknown Substances Found in Analysis of Foods. *Food and Chemical Toxicology* 49:1643–1660. doi:10.1016/j.fct.2011.03.049.
   Available at: http://www.ilsi.org/EUROPE/Pages/ViewItemDetails.aspx?ListID=%7b0348eb34-df85-49dd-9ade-77ed136643f1%7d&ItemID=308&URL=http://www.ilsi.org/Europe/Publications/Application%20of%20the%20TTC%20concept%20to%20unknown%20substances%20found%20in%20analysis%20of%20foods.pdf
3) EFSA Scientific Committee; (2012); Scientific Opinion on Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC) (EFSA Journal 2012;10(7):2750); European Food Safety Authority (EFSA), Parma, Italy.
   Available at: http://www.efsa.europa.eu/fr/efsajournal/doc/2750.pdf

Up to you to develop your risk assessment strategy.

Let us share our experiences on the 24th of April 2015.

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**Annex: Matrix Webapp screenshots**

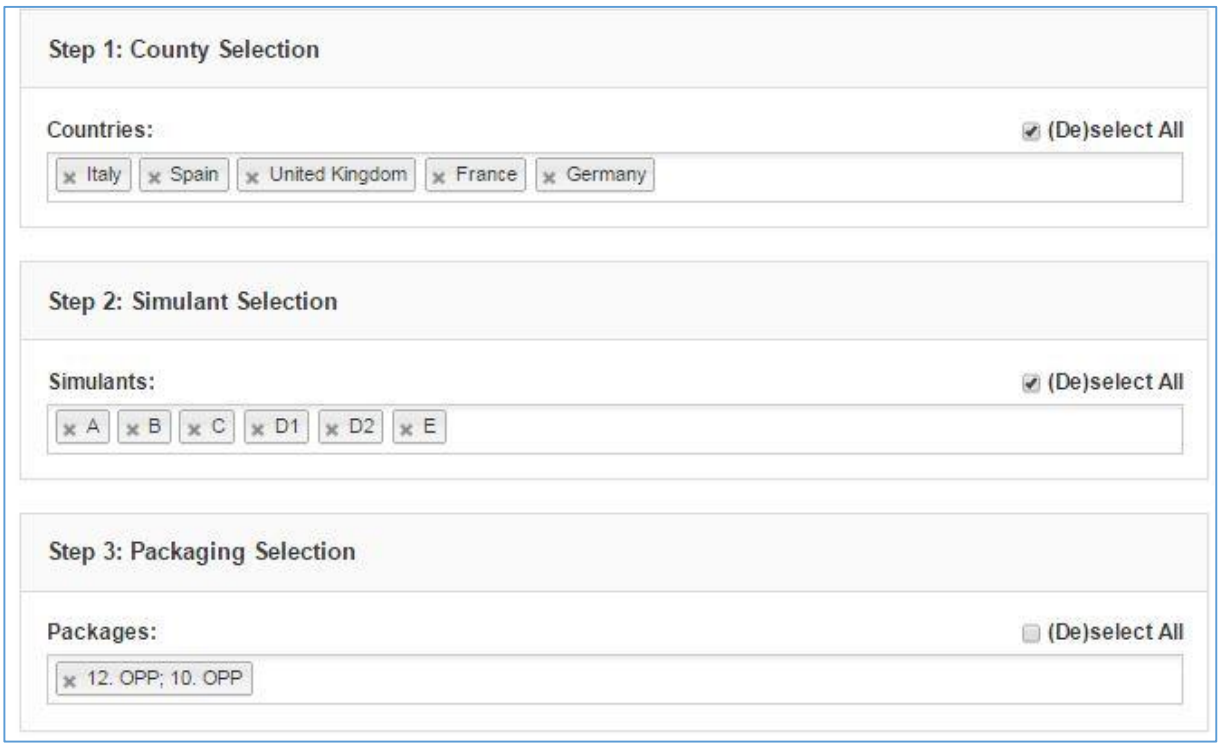


Fig 5: Matrix calculation tool – step 1-3

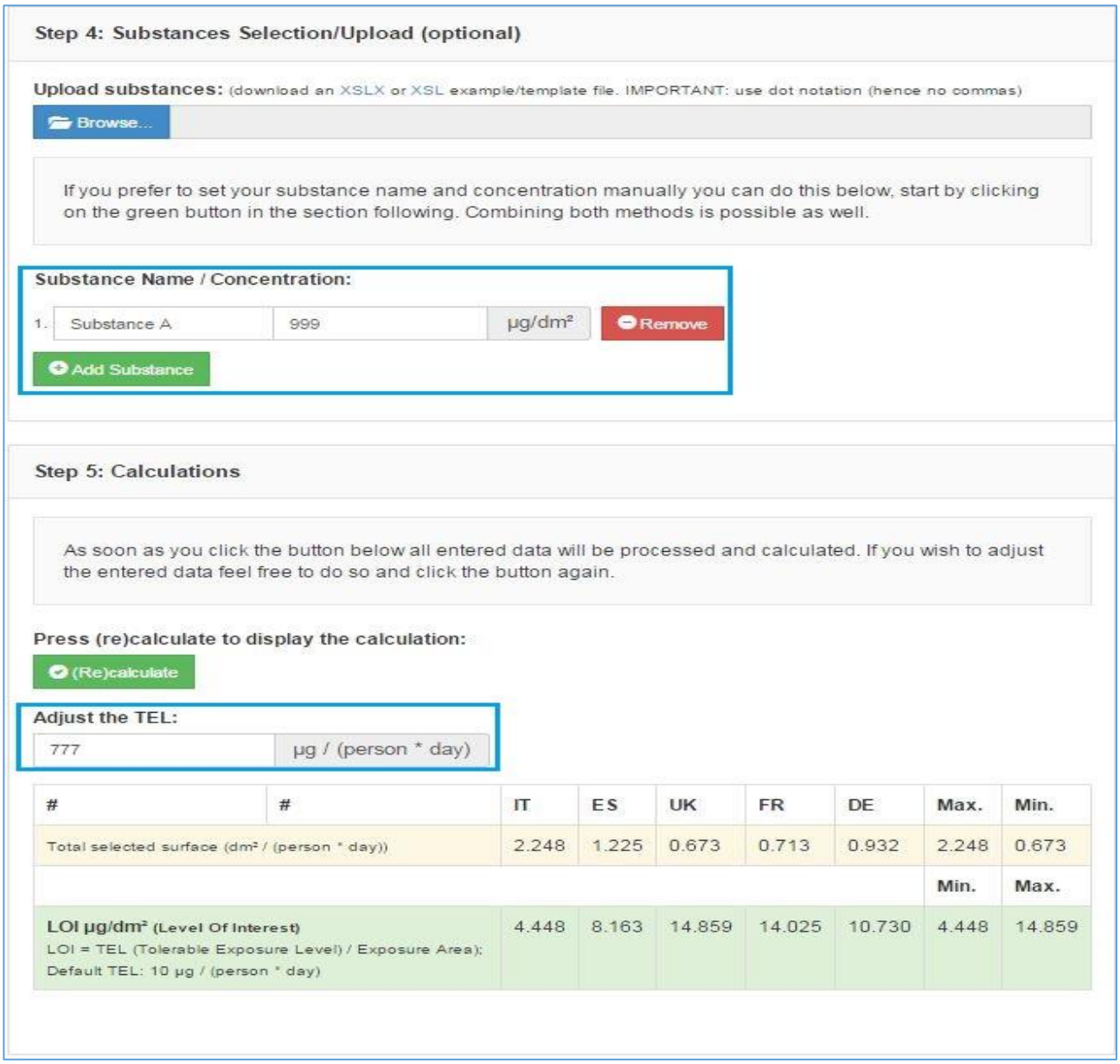


Fig 6: Matrix calculation tool – step 4-5