

# RISK ASSESSMENT

SAFE SUSTAINABLE SOLUTIONS



## Analytical approach for risk assessment:

Regulation (EC) 1935/2004 of the European Parliament establishes that all materials and articles must be produced in accordance with good manufacturing practices and that they must not in any way transfer to food components capable of posing a danger to human health, significantly altering the composition of food products and leading to the modification of organoleptic characteristics during their habitual or foreseeable use.

EFSA is also required by Article 10 of Regulation (EC) No 1935/2004 to carry out a risk assessment of the migration of substances from materials and articles in contact with food and to provide a scientific opinion on:

- new substances intended for use in food contact materials prior to their authorization and inclusion in a positive list;
- substances that are already authorized under Regulation (EC) No 1935/2004 but need to be re-evaluated.



When you are certain of the possible presence of some substances in the packaging, you need to understand if the substance is listed, and if it has a legal limit.

As a tool to operate this study, Food Contact Center uses continuously updated databases.

If no migration limits have been found in the regulatory study, the Food Contact Center assesses the substances from a toxicological point of view, in accordance with Article 3 of Regulation (EC) No 1935/2004, according to internationally recognized scientific principles of risk assessment.

### Article 3 General requirements

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:
  - (a) endanger human health;
  - or
  - (b) bring about an unacceptable change in the composition of the food;
  - or
  - (c) bring about a deterioration in the organoleptic characteristics thereof.
2. The labelling, advertising and presentation of a material or article shall not mislead the consumers.

**EVENT REPORT**  

APPROVED: 16 February 2016 PUBLISHED: 10 March 2016

**Review of the Threshold of Toxicological Concern (TTC) approach and development of new TTC decision tree**  
European Food Safety Authority and World Health Organization

**2. The Cramer scheme**  
The original Cramer et al. (1978) decision scheme has been computerised in the Toxtree computer program; the software is available at <http://toxtree.sourceforge.net/>. For the present report, v2.6.0 (July 2013) was used which is described as the Cramer tree with extensions. The extensions to the Cramer decision scheme are discussed in Appendix 1. Presently the latest version is v2.6.13 (March 2015).

**6. Conclusions**  
**6.1. General conclusions**  
The TTC approach as currently applied is a valid, science-based screening tool useful for the prioritisation of chemicals and for more general applications in chemical risk assessment.



In order to assess the toxicity of a compound, literature studies are carried out to verify the effect that substance may have in humans.

For many of these substances, however, toxicological data are scarce or absent. Despite this, it is increasingly important to assess the potential health impact of these trace substances.

In this case, it is possible to refer to the EFSA document, which provides the use of decision rules (Cramer's rules) in order to establish the substance's possible toxicity, by using the so-called "threshold of toxicological concern" approach (TTC) that allows to assess, from a qualitative point of view, the risk associated with substances present in the diet in infinitesimal quantities. The approach can be used in the initial assessment of a given substance and also to decide whether a full risk assessment should be carried out or not.

The toxicological limits, as per the Plastic Europe2 guideline, can be transformed into migration limits in the worst case hypothesis that every day an adult consumes 1 kg of 1 dm<sup>3</sup> packaged food.

Table I.1. Commonly used TTC values

Type of threshold	TTC value µg/person per day	TTC value µg/kg bw per day
Structural alert for genotoxicity	0.15	0.0025
Structural alert for AchE inhibition (OPs and carbamates)	18	0.3
Cramer Class III	90	1.5
Cramer Class II	540	9.0
Cramer Class I	1800	30

**PlasticsEurope**  
Produttori di Materiali Plastici

September 2014

**Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under Article 19 of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food**

Step 1: Worst case exposure calculation based on European default assumption

Based on the default assumption in Europe that every day an adult person consumes 1 kg of food packaged in a 1 dm<sup>3</sup> cube, an estimated worst-case daily intake number can be calculated using the following simple formula.

$$EDI_{\text{worst case}} \text{ (mg/person/day)} = 1 \text{ kg food/person/day} \cdot \text{Migration (mg/kg food)}$$

$$\text{TTC value } \mu\text{g/person/day} = \text{migration } \mu\text{g/Kg}$$

## OUR SOLUTION

Once the migration of a certain potentially hazardous substance has been identified with certainty, we characterize the risk and we assess the probability of taking the substance through the criteria set out above, combined with the factors of use of the type of packaging.

THIS IS OUR WAY OF SUPPORTING COMPANIES IN THE RISK ASSESSMENT REQUIRED BY LEGISLATION



$$\text{EXPOSURE}_{\text{from FCMs}} = \text{MIGRATION (Conc. in Food)} \times \text{Food Consumption} \times \text{Packaging Material Usage}$$

1 <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5708>

2 <https://plasticseurope.org/sustainability/plastics-health/safety-of-plastics/food-contact/>