

## EFSA Publishes Guidance on the TTC Approach

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The European Food Safety Authority (EFSA) has published [Guidance on the use of the Threshold of Toxicological Concern \(TTC\) approach in food safety assessment](#). This approach can be used when there is limited chemical-specific toxicity data available but where the chemical structure of the substance is known and where exposure can be estimated. EFSA's guidance provides step-by-step instructions on how to use the TTC approach.

Noting that TTC values are numbers that describe generic human chronic exposure thresholds that have been established by grouping experimental toxicity data from animal bioassays, the guidance provides the values discussed below.

- For substances with the potential to be DNA-reactive mutagens and/or carcinogens, the relevant TTC value is 0.0025 µg/kg body weight (bw) per day.
- For organophosphates or carbamates, the relevant TTC value is 0.3 µg/kg bw per day.
- All other substances are grouped according to the Cramer classification. The TTC values for Cramer Classes I, II and III are 30 µg/kg bw per day, 9 µg/kg bw per day and 1.5 µg/kg bw per day, respectively.

For substances with exposures below the TTC values, the guidance points out that the probability that they would cause adverse health effects is low and, if an estimated exposure to a substance is higher than the relevant TTC value, a non-TTC approach is required to reach a conclusion on potential adverse health effects.

It is also worth noting that the EFSA recalls that the TTC approach should not be used for substances for which sufficient toxicity data is available or for substances falling within one of the exclusion categories (such as inorganic substances, nanomaterials, high potency carcinogens and substances with a potential for bioaccumulation).

EFSA also published the a summary of the comments received during the public consultation on the draft guidance on the use of the TTC approach in food safety assessment (see the PackagingLaw.com article, [EFSA Opens Public Consultation on Draft TTC Guidance](#)). EFSA received 101 comments and three letters during the public consultation.

Both the Guidance on the use of the TTC approach in food safety assessment and the outcome of the public consultation on the draft version of the guidance can be accessed on [EFSA's website](#).

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